DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 26

[Docket No. 98N–0185]

RIN 0910–ZA11

Mutual Recognition of Pharmaceutical Good Manufacturing Practice Inspection Reports, Medical Device Quality System Audit Reports, and Certain Medical Device Product Evaluation Reports Between the United States and the European Community

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations pursuant to an international agreement between the United States and the European Community (EC). The agreement is entitled ''Agreement on Mutual Recognition Between the United States of America and the European Community'' (MRA). Under the terms of that agreement, the importing country authority may normally endorse good manufacturing practice (GMP) inspection reports for pharmaceuticals provided by the exporting authority determined by the importing authority to have an equivalent regulatory system. Likewise, the importing country authority may normally endorse medical device quality system evaluation reports and certain medical device product evaluation reports provided by conformity assessment bodies (CAB's) determined by the importing country authority to have equivalent assessment procedures. FDA is taking this action to enhance its ability to ensure the safety and effectiveness of pharmaceuticals and medical devices through more efficient and effective utilization of its regulatory resources. The proposed rule which published in the **Federal Register** on April 10, 1998 (63 FR 17744), carried an incorrect docket number in its heading. This final rule carries the correct docket number.

DATES: This regulation is effective on December 7, 1998. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication listed in new § 26.60(b), effective December 7, 1998. Written comments and information relevant to implementation of the MRA and this regulation may be submitted at anytime.

ADDRESSES: Submit written comments and information relevant to implementation of the MRA and this regulation to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Merton V. Smith, Office of International Affairs (HFG–1), Office of External Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0910, or E-mail: ''MSmith@oc.fda.gov''.

SUPPLEMENTARY INFORMATION:

I. Background

On June 20, 1997, the United States and the EC concluded an agreement on the MRA. The MRA includes two sectoral annexes covering products regulated by FDA. The sectoral annex on medical devices covers medical device quality system-related inspection reports and certain product evaluation reports. The sectoral annex for pharmaceutical GMP's covers pharmaceutical GMP inspection reports. The MRA also includes sectoral annexes covering products regulated by other U.S. regulatory agencies, including telecommunication equipment, electromagnetic compatibility, electrical safety, and recreational craft. Finally, the MRA includes a ''framework'' agreement that contains general provisions.

At the conclusion of negotiations, the United States and the EC submitted the text of the MRA to their respective authorities to complete the necessary procedures for approval and implementation. For FDA, these procedures included publishing a proposed rule that was published in the **Federal Register** of April 10, 1998 (63 FR 17744). The proposed rule was based on the provisions contained in the two FDA sectoral annexes and the ''framework'' agreement of the MRA concluded on June 20, 1997. FDA received comments from 14 persons in response to this proposed rule. Many of these comments supported the proposed rule. Some comments raised significant issues but none that, in FDA's view, necessitated any substantive changes to the proposed rule. On May 14, 1998, FDA informed the Office of the U.S. Trade Representative (USTR) that it supported the signing of the MRA. The MRA was signed in London on May 18, 1998. Provisions of the MRA are between the United States and EC, and do not create rights in third parties.

II. Summary of Comments

A. General Comments and Issues

Most comments by industry associations and pharmaceutical and medical device manufacturers generally were supportive of the MRA and the proposed rule. Some comments by others expressed concern about possible diminished public health and safety if certain precautions are not taken.

1. Five comments strongly supported the MRA and the proposed rule, citing its potential to improve patient access to safe and effective technologies, reduce unnecessary regulatory redundancies, enhance the access of United States and EC companies to each other's markets, provide significant savings to both companies and regulators, and set the stage for further regulatory cooperation and harmonization. They indicated that the proposed rule and the MRA allow for incorporation of the best regulatory attributes.

FDA agrees with these comments. FDA takes the view that equivalence of GMP reports and other conformity assessment reports and evaluations between the FDA and EC Member State authorities and CAB's can be relied on to help ensure the safety, quality, and effectiveness of products exported to the United States while also reducing the regulatory burden on manufacturers. For the United States, the MRA and this regulation also permit FDA to redirect some of its inspectional resources from countries whose systems are found equivalent to, or higher to, risk priorities not covered under the MRA. The agency may thus better target its limited foreign inspection and other resources devoted to imports and other regulatory concerns. Thus, FDA will be able to leverage its resources by relying on information from its counterpart regulatory authorities in foreign countries that have demonstrated equivalence. Under the MRA and this regulation, as equivalence is achieved between regulatory systems of EC Member State authorities, or CAB's, and FDA, there will be reduced need for importing countries to engage in resource-intensive foreign inspection, sampling, and examination of products being for entry from countries with equivalent systems. This can assist in speedier approvals of safe and effective products and in more comprehensive and effective surveillance of GMP's and quality systems. In addition, during the transition period, collaborative confidence-building activities between FDA and EC Member State authorities and CAB's can result in harmonization of requirements at a high level of

consumer protection, thus enhancing regulatory controls.

2. One comment described three fundamental principles which underlie the comment's concerns about the MRA and the proposed rule: (1) The paramount goal for FDA implementation of the MRA and the proposed rule must be to safeguard public health of U.S. consumers; (2) equivalence determinations performed by FDA must improve or at least maintain current U.S. public health protections; and (3) the United States' democratically accountable, policy-making process must be maintained.

FDA agrees with these comments. FDA has consistently articulated these same principles in its policies relating to international cooperative agreements over the last decade. In 1988, the FDA and Directorate-General III (Industrial Affairs) of the European Commission began early discussions in consideration of agreements in the areas of pharmaceutical and medical device GMP inspections. The FDA's primary motivation in seeking such agreements was at that time, and still is, a desire to leverage its limited inspectional resources and to enhance public health protection through increased assurance that regulatory counterparts are applying similar controls. FDA described the value of pursuing international cooperative agreements with selected foreign regulatory bodies in its 1992 ''Report of the Task Force on International Harmonization'' (Ref. 1). The Task Force concluded that such international agreements are an effective means of facilitating the safety, effectiveness, and/or quality of products that are offered for import into the United States and of efficiently setting priorities for the agency's inspectional resources. The Task Force concluded that a properly conceived and executed agreement would permit FDA's use of foreign government inspectional information to assist in the agency's regulatory decision-making and could help FDA to set priorities for foreign inspection or import surveillance programs. As a result of specific Task Force recommendations, in 1995 FDA revised its Compliance Policy Guide (Ref. 2) to emphasize that the agency's primary goals for entering into agreements with foreign governments are for the purposes of better utilizing its regulatory resources and furthering its mission of protecting the U.S. consumer.

The significant increase of international commerce in pharmaceuticals and medical devices and the question of how FDA can continue to ensure the safety and effectiveness of these medical products prompted the agency to convene a Foreign Inspection Working Group in 1995 to evaluate the agency's foreign inspection program and related import product monitoring. In 1997, this group issued its ''Summary Report of the Foreign Inspection Working Group'' (Ref. 3) that recognized the need for inspectional approaches that involve cooperative activities such as the development of international agreements between FDA and counterpart regulatory authorities in other countries.

Section 26.21 of this rule provides that the importing country has the right to fulfill its legal responsibilities by taking actions necessary to ensure the protection of human and animal health at the level of protection it deems appropriate. In addition, under § 26.74 nothing in this part limits the authority of FDA to take appropriate and immediate measures that it determines necessary to prevent compromising human health and safety, or to fulfill its legislative, regulatory, or administrative responsibilities.

To ensure a democratic and open process, the FDA will make available in a public docket the complete administrative file that constitutes the basis for FDA's equivalence determinations. In addition, any other related documents the agency receives under the MRA and this regulation will be releasable to the public (or not releasable) according to current Freedom of Information Act (FOIA) provisions. FDA also will assess the degree to which a foreign regulatory system or CAB is accountable to consumers and other interested parties as part of its equivalence determinations. (App. D of subpart A, criteria I.F.). A regulatory system that is not sufficiently transparent to assess accountability may not be found equivalent.

3. One comment stated that the MRA and the proposed rule would replace FDA-conducted inspections of foreign pharmaceutical plants and FDA reviews of foreign medical devices with inspections and evaluations performed by EC Member State authorities and CAB's located in EC Member States.

The implementation of the MRA and this regulation may or may not result in the replacement of some FDA inspections and product evaluations of medical devices produced by manufacturers located in EC Member States. Inspection reports and product evaluations may normally be endorsed under certain conditions only if, after a comprehensive assessment during the 3-year transition period, FDA determines that such reports will provide the information that FDA needs for its regulatory decision making.

4. One comment stated that the MRA negotiation took place primarily for trade facilitation purposes. Evidence of this conclusion was offered by the fact that the negotiations were co-chaired by USTR and the Department of Commerce (DOC) and that press releases and other public statements have characterized the discussions as ''trade negotiations.''

FDA participated in the negotiations leading to the MRA under its own authority to enter agreements with foreign authorities (see, inter alia, sections 519 and 803 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(i), 383)). Furthermore, the agency believes that the MRA and this regulation, properly based on a rigorous determination of equivalence of regulatory systems, can help ensure the safety, quality, and effectiveness of these imports while also reducing the regulatory burden on manufacturers, thereby facilitating availability of these important medical products. The goals of facilitating trade and protection of the public health are not necessarily incompatible. The role of USTR and DOC was one of coordination. FDA's ability to reach decisions on the basis of its public health priorities was upheld, and never compromised, during the negotiations. FDA officials led the negotiations concerning the FDA annexes, and FDA's views were incorporated into the portions of the ''framework'' agreement where FDA's interests were affected. USTR and DOC as well as European trade counterparts undoubtedly desired an MRA for trade reasons. Those agencies, however, supported FDA's position in the negotiations and did not interfere with FDA's desire to maintain health and safety protections. FDA believes that this degree of FDA autonomy will continue as the MRA and this regulation are implemented.

Furthermore, FDA has entered into an interagency Memorandum of Understanding (MOU) with the USTR that ensures that any decisions about the MRA that relate to matters under FDA's jurisdiction will be made only by FDA (see the notice of availability for this MOU published elsewhere in this issue of the **Federal Register**). Specifically, the MOU requires that USTR notify FDA of matters that the Joint Committee will be considering. The MOU states that while USTR would normally speak and vote for the U.S. Government in the Joint Committee, subject to arrangements with other agencies covered by the MRA, FDA will speak for, and vote on behalf of, the U.S.

Government on any matter pertaining to FDA's statutory or regulatory authority raised within the Joint Committee or within any other bodies established under the MRA. In addition, the Sectoral Annex for Pharmaceutical GMP's is specifically exempted from certain provisions of the ''framework'' agreement, in order to avoid any possible confusion about the use of CAB's that are not utilized in the Annex. Finally, throughout the ''framework'' agreement and the FDA product-related annexes there are clear safeguard requirements that stipulate if there are health and safety concerns on the part of the importing authority, the importing authority may take appropriate action.

5. One comment stated that the goal of the MRA and the proposed rule appears to be to harmonize health, safety, and environmental standards to the lowest acceptable levels.

While the process of confidence-building and equivalence determination may lead to harmonization of some standards, FDA disagrees that lowest common denominator standards will result. During the transition period, collaborative activities and joint equivalence determinations by FDA-EC Member State authorities and CAB's may result in harmonization of requirements that will enhance consumer protection. By law, section 803(c)(1) of the act requires the Commissioner of Food and Drugs (by delegation under 21 CFR 5.10) to work to ''harmonize regulatory requirements,'' but conditions these actions on findings by the Commissioner that ''such harmonization continues consumer protections consistent with the purposes of this Act.'' FDA's experience in working as a party to the Global Harmonization Task Force (GHTF), the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, and the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products has demonstrated that regulatory public health authorities do not compromise health and safety as standards are harmonized, because the relevant discussions and and the resulting documents have been thorough, science-based, and protective of public health. (Harmonization can lead to higher standards because in instances where one regulator has a requirement that others lack, the ensuing discussions of why one regulator has such a requirement often leads to understanding, acceptance, and inclusion of a corresponding provision in the harmonized standard.)

6. One comment expressed the belief that the MRA and the proposed rule put U.S. consumer protection at risk of compromise and cited as evidence the fact that the negotiations extended well beyond their original deadlines, and were reportedly near collapse due to concerns about whether EC regulation is as stringent for pharmaceuticals and medical devices as U.S. regulation.

The comment is correct in stating that the MRA negotiations took longer than expected and that FDA had concerns during the early stages of MRA discussions that early MRA drafts would not provide appropriate public health protections for U.S. consumers. For example, the provision for a 3-year confidence-building transition period was not considered during early MRA discussions. Acceptance of the need for a transition period during which time equivalence would be assessed was one of the keys to moving the MRA negotiations ahead. Indeed, Article 2 of the Sectoral Annex for Pharmaceutical GMP's states that the determination of equivalence of the regulatory systems by the parties is the cornerstone of that Annex. FDA believes that the requirement of a comprehensive assessment of equivalence before inspection reports and product evaluations will be normally accepted, and other safeguard clauses such as §§ 26.21 and 26.74, as discussed previously, provide strong public health protections. In the medical device provisions, EC acceptance that FDA must, as a matter of law and policy, maintain final decision making authority over premarket notifications, and that the MRA could cover premarket notifications only for certain devices, enabled conclusion of the MRA.

7. One comment stated that FDA must make a commitment to seek additional resources to accomplish the activities required by the MRA and the proposed rule.

In the preamble to the proposed rule, FDA acknowledged that neither startup costs nor operational costs are being covered by additional FDA funding in FDA's current budget and that startup costs will have to be absorbed by current funding. Certain key activities of the MRA and this regulation, such as joint inspections of manufacturers located in EC Member States, may be accomplished as part of FDA's inspections of these manufacturers that have been scheduled for the next fiscal year as part of FDA's normal budget process. Other activities of the MRA and this regulation will likely result in new costs. These additional costs are difficult to estimate because they depend significantly on the initial findings from FDA's equivalence assessments of EC Member State authorities and CAB's. FDA will likely be better able to estimate these additional costs as experience is gained during the first year of the transition period. After the first year, FDA will reassess its need to seek additional funding for the activities required by the MRA and this regulation.

8. One comment stated that a failure to devote adequate resources to the programs of the MRA and the proposed rule during the implementation stage would endanger their success.

FDA agrees with this comment. FDA will engage in activities during implementation as its resources permit. FDA recognizes the critical need to undertake a number of activities during the transition process as part of its assessment of the equivalence of CAB's located in EC Member States, including participating in seminars, workshops, joint training exercises, and observed inspections, as well as the analysis required for the equivalence determination process. In addition, any significant problem that is identified may require additional activities to address and resolve it. Finally, the parties will need to develop a consensus on what must be present in quality system and product evaluation reports (or, where harmonization cannot be achieved, each side will need to identify what it needs). Further, the parties will develop a notification and alert system for defects, recalls, and similar problems. All of these activities will require resources, and FDA recognizes their completion is critical to the success of the MRA and the implementation of this regulation.

9. One comment stated that the number of repetitive inspections must actually decrease if the potential value of the MRA and the proposed rule is to be realized.

FDA's interest in the MRA is its view that public health protection can be better assured through enhanced regulatory cooperation. Although FDA agrees that cost savings to industry and to government regulatory authorities can be realized by an actual decrease in the number of inspections that are unnecessarily duplicative, there are additional benefits that may be achieved by the activities required under the MRA and this regulation that make the MRA endeavor worthwhile. For example, the cooperative activities between FDA and EC Member State authorities that will of necessity be part of the equivalence determination

process may result in harmonization or congruence of requirements resulting in strengthened consumer protection, more effective regulatory approaches, and reduced regulatory burden on each side of the Atlantic.

10. One comment suggested that FDA must use the inspectional savings anticipated by the MRA and the proposed rule for increased surveillance activities.

Any resource savings resulting from the MRA and this regulation will be used by FDA as necessary and appropriate to enhance the effectiveness of FDA's regulatory programs.

11. One comment stated that FDA should complete confidence building activities as expeditiously as possible and should devote adequate resources to that job.

FDA agrees with this comment and, as stated previously, will devote resources to this program to the best of its ability.

12. One comment noted that the proposed rule did not address FDA guidance documents and asked how guidance documents would be handled under the MRA and this regulation. The comment implied that some FDA guidance documents contain requirements.

FDA will handle guidance documents under this MRA as it handles all guidance documents, according to FDA's Good Guidance Practices (62 FR 8961, February 27, 1997). If FDA determines that there is a need for guidance documents under the MRA, it will publish them or refer to them as appropriate. FDA periodically makes available to the public lists of guidance documents and those that are relevant to the implementation of the MRA or this regulation will be referred to during such implementation. Guidance documents do not themselves contain requirements; they do sometimes refer to or explain requirements that exist in statutes or regulations.

13. One comment expressed concern that the MRA and the proposed rule might result in lower health, safety, and environmental standards in both the United States and the EC. The comment expressed concern that the ''framework'' agreement might allow undue pressure to relax regulation in one sector of commercial activity in order to secure market access in another unrelated sector. Consequently, the comment asked FDA to seek ''the elimination of the umbrella framework agreement'' to ensure that U.S. health and safety standards are not compromised.

FDA declines to take the action requested by the comment. The ''framework'' agreement will not result in lower health or safety standards for FDA-regulated products. The MRA and this regulation expressly preserve the authority of a party to determine, ''through its legislative, regulatory, and administrative measures, the level of protection it considers appropriate for safety; for protection of human, animal, or plant life or health; for the environment; for consumers; and otherwise with regard to risks'' (MRA Article 15, ''Preservation of Regulatory Authority,'' and § 26.74 of this regulation).

Additionally, this regulation expressly recognizes, at several places, that statutory and regulatory requirements applicable to drugs and devices remain in place unchanged (see, e.g., § 26.1(b) (definition of ''equivalence'') see also § 26.32(c) and § 26.62(c) and that each party may take actions necessary to ensure the protection of human and animal health ''at the level of protection it deems appropriate'' (see § 26.21; see also § 26.74(a) and (b) (preservation of regulatory authority)).

This position is consistent with both the statutes FDA administers and international agreements such as the Agreement on Technical Barriers to Trade which expressly recognizes that ''no country should be prevented from taking measures necessary to ensure the quality of its imports, or for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade * * *.'' (See paragraph 6 of the preamble to the Agreement on Technical Barriers to Trade).

FDA further notes that, under an MOU with USTR concerning the MRA (see the notice of availability for this MOU published elsewhere in this **Federal Register**), USTR will notify FDA of matters to be considered by the Joint Committee, which will be established to consider issues relating to the effective functioning of the MRA. While USTR normally will speak and vote for the United States in the Joint Committee, subject to arrangements with other agencies covered by the MRA, FDA will speak for and vote on behalf of the United States on any matter pertaining to FDA's statutory and regulatory authority. FDA will also represent the U.S. Government on such matters in any other committee or bodies with similar functions established under the MRA or its annexes. This MOU will ensure that, insofar as FDA-regulated products and issues are concerned, public health and safety issues are adequately considered and addressed.

14. One comment strongly disagreed with FDA's position that a 30-day comment period for the proposed rule was adequate. The comment was characterized as ''a preliminary identification of key issues involved in the [MRA or the proposed rule] process'' and requested that the comments be viewed as ''the beginning of an ongoing open process in which public comments will be considered at later junctures'' with future opportunities to discuss issues with FDA and other government officials.

As stated in the preamble to the proposed rule (63 FR at 17744 at 17747), FDA provided a 30-day comment period because a longer comment period was unnecessary in light of the numerous opportunities for public input the agency provided during the MRA negotiations. These opportunities included the creation of a public docket for MRA-related issues on May 9, 1996, dissemination of a document concerning the MRA on October 18, 1996 (including an opportunity for public comment on that document), public exchange meetings on March 31, 1995, and October 30, 1996, a Transatlantic Business Dialogue (TABD) meeting on November 8 and 9, 1996, which included a discussion of the MRA, and other public meetings on March 14, 1997, and September 23, 1997. The MRA itself was initialed by governmental representatives on June 20, 1997, and has been available on the World Wide Web (WWW) for over a year. Therefore, the agreement upon which the proposed rule was based had been available for analysis and comment by interested members of the public for some months. In view of these opportunities for public discussion and consideration of the MRA, the 30-day comment period for the proposed rule was adequate.

FDA also stated that it was in the public interest to proceed expeditiously to implement the MRA, and that the 30-day comment period was not contrary to Executive Order 12889 (63 FR 17744 at 17747).

As for the comment's remarks concerning future opportunities for public comment, the agency shares this interest and notes that the public has many avenues for contacting FDA on almost any issue. For example, a person may send a letter to the agency, request a meeting, submit a citizen petition to request issuance or revision of a

regulation or to request agency action or reconsideration on a particular matter, or submit comments on a document published in the **Federal Register** (see, e.g, 21 CFR 10.20, 10.30, 10.33, 10.65).

In sum, FDA agrees that the agency will need to communicate with the public, on a regular basis, as the MRA is being implemented. Interested persons may submit comments on the MRA, or implementation of the MRA, to the agency at any time. In addition, as noted previously FDA's administrative practices and procedures regulations (21 CFR part 10) provide a range of processes for interaction with the agency. Furthermore, the agency contemplates frequent meetings and other communications with the public as MRA implementation progresses.

B. Composition and Operation of the Joint Committees

Several comments encouraged, or would revise the rule to provide for, opportunities for public, industry, or specific agency involvement in various programs or bodies established by the MRA and the proposed rule or by their operation.

1. Four comments said that FDA should ensure industry or public access to and participation in the activities of the MRA and the proposed rule. Three comments advocated industry participation and suggested that FDA and the EC consult the industry during the transitional and operational phases of the confidence building stage. Two of these three comments specifically identified TABD as being critical or essential to implementing the MRA and the proposed rule. Another comment expressed the opposite view, i.e., concern about what the comment described as the TABD's involvement in the MRA negotiations. One comment asked FDA to ensure greater public participation and access for nongovernmental organizations in future mutual recognition agreement negotiations and throughout their implementation.

The agency appreciates and values public and industry input and advice on many matters and intends to employ a variety of means to seek input from the public on the implementation of the MRA and this regulation. However, the MRA and its sectoral annexes represent an agreement between governments that contemplates examination of one another's equivalence in specific areas of regulation. Although FDA believes it would be inappropriate to amend the rule to require industry or consumer participation or the participation of specific industry or consumer representatives on delegations to meetings or to require FDA or the EC to consult industry, FDA plans to consult interested persons—whether they represent the industry, public interest groups, or any other interested person—at appropriate stages of implementation of the MRA and this regulation.

As for the comment requesting greater public participation in future mutual recognition agreement negotiations and implementation, that request is outside the scope of this rule. However, we refer interested persons to ''A Plan that Establishes a Framework for Achieving Mutual Recognition of Good Manufacturing Practices Inspections,'' dated May 20, 1998 (see ''What's New on the FDA Website'') (''www.fda.gov/opacom/newonweb.html'').

2. Four comments discussed representatives to either the Joint Committee or the Joint Sectoral Committee in proposed §§ 26.17 and 26.47 (''Role and Composition of the Joint Sectoral Committee'') and 26.73 (''Joint Committee''). Three comments requested clarification as to which U.S. Government agencies would be represented on the Joint Committee or the Joint Sectoral Committees; two comments advocated including officials of USTR and the Department of Commerce on the Joint Sectoral Committees; and one comment recommended including EC trade offices on the Joint Sectoral Committees. All four comments advocated industry representation, or regular participation, in the Joint Committee and/or the Joint Sectoral Committees.

FDA declines to amend the rule to describe which U.S. or EC governmental bodies will send representatives to meetings of the Joint Committee or Joint Sectoral Committees as requested by the comments. In general, the government representatives to either the Joint Committee or the Joint Sectoral Committees will vary depending upon the issues presented to those committees (see, e.g., § 26.73(a) (stating that the Joint Committee consists of ''representatives'' of both parties) and § 26.73(b) (authorizing the Joint Committee to establish Joint Sectoral Committees ''comprised of appropriate regulatory authorities and others deemed necessary''). Thus, each party has the flexibility to determine which government authorities should be present and to match a particular governmental authority's expertise to the issue or issues before a committee. Amending the rule so that either committee would have to include specific representatives of U.S. Government authorities would unnecessarily impair such flexibility, and it would be especially inappropriate for FDA to amend the rule to specify what representatives the EC would send to the committees.

In any case, as explained in section II of this document, the USTR will normally speak for and vote on behalf of the United States in the Joint Committee, subject to arrangements with other agencies covered by the MRA, and FDA will speak for and vote on behalf of the United States on any matter pertaining to FDA's statutory or regulatory authority. Furthermore, the Joint Committee (when FDA is representing the United States) and the Joint Sectoral Committee likely will be addressing technical issues of the sort that FDA, not USTR or DOC, will be considering. The agency is confident that, in all cases, the composition of the Joint Committee or Joint Sectoral Committees will be appropriate for the topics being discussed.

As for the comments seeking industry representation or participation in the Joint Committee or the Joint Sectoral Committees, FDA declines to revise the rule to require such industry representation or participation. Because the MRA, including its sectoral annexes, is an agreement between governments, it is neither necessary nor appropriate to amend the rule to include or to require nongovernmental entities or organizations on the Joint Committee or the Joint Sectoral Committees.

3. One comment asked for clarification about the composition of the Joint Committee and asked whether U.S. citizenship is required for U.S. members.

U.S. representatives addressing FDA topics will be FDA officials. Except in extremely rare circumstances, U.S. citizenship is a requirement for employment by FDA. European representatives will be European Commission officials, possibly accompanied by officials of member country regulatory authorities.

C. Transparency and Confidentiality Issues

Several comments discussed the need for ensuring public or industry participation in equivalence or other regulatory matters under the rule. Other comments emphasized a need for withholding certain information, such as trade secrets and confidential commercial information, from public disclosure.

1. One comment suggested that the rule contain a mechanism for public participation in the equivalence determination process. The comment would provide the opportunity for public comment or input throughout the 3-year transition period, as soon as FDA

decides which foreign regulatory systems and CAB's it will review to determine whether they are equivalent, and again when FDA makes a preliminary determination of equivalence. The comment also called for public notice in the **Federal Register** and a response to any public comments when FDA issues a final determination.

FDA intends to hold periodic meetings with interested parties. FDA also plans to prepare and to make public summaries of key meetings held with its EC counterparts concerning implementation of the MRA and this regulation. Further, FDA will make available to the public the administrative file that constitutes the basis for any of FDA's equivalence determinations subject to exemptions from disclosure provided in the FOIA and restrictions in related statutory provisions discussed in the response to comment 2 in section II.C of this document. These approaches should give interested persons insight as to the information FDA considered when making an equivalence determination.

FDA also will use the **Federal Register** and its Internet home page to make available information on equivalence determinations under the MRA and this regulation. Interested persons can submit comments on these determinations.

The agency believes it is important that all interested parties have an opportunity to contribute to the equivalence assessment process. To facilitate such contribution, FDA intends to hold public meetings during the 3-year transition period. In addition, FDA invites all interested persons to provide the agency with information that is: (1) Generally relevant to implementation of the MRA and this regulation; and, (2) of particular relevance to equivalence criteria in Appendix D of subpart A of this rule, and their application to the authorities listed in Appendix B of subpart A of this rule. Information should be sent to the Dockets Management Branch (address above), and should be identified with docket number 95N–0185.

2. Three comments would revise the proposed rule to ensure that the public has access to: Draft programs for assessing equivalence of a regulatory system under proposed § 26.6(b); information provided by a foreign government concerning that government's regulatory activities under proposed § 26.6(c); ''audit'' reports by European authorities submitted to FDA; or records of CAB's reviewed by a foreign government to the extent that such records would be publicly available if they were reviewed by FDA. One comment explained that public disclosure would ensure accountability and enable U.S. consumers to maintain confidence in an ''equivalent'' inspection system. One comment would also revise the proposed rule to state expressly that neither party may obstruct public access to information that is publicly available under the laws or regulations of that party.

In contrast, four comments sought clarification concerning disclosure or confidentiality issues and proposed § 26.76, such as whether reports between the parties would be subject to public disclosure under the FOIA; whether information provided to the EC would be subject to EC confidentiality policies; and whether alert or vigilance reports (required by proposed § 26.50) exchanged between the parties as part of an ongoing investigation would be subject to public disclosure.

FDA declines to revise the rule as suggested by the comments. Under § 26.76(a) of this regulation and Article 17 of the MRA, each party agrees to maintain, to the extent required under its laws, the confidentiality of information exchanged under this regulation and the MRA. Trade secrets, confidential commercial or financial information, and information relating to an ongoing investigation are not subject to public disclosure (see § 26.76(b)). Additionally, the parties may designate portions of information that it considers to be exempt from disclosure, and parties are to take all precautions reasonably necessary to protect information exchanged under the MRA and this regulation from public disclosure (see § 26.76(c) and (d)).

Those receiving information under the MRA will treat the information according to their domestic laws and policies. FDA will treat information it receives consistent with the FOIA, Privacy Act, and FDA's regulations and policies. EC Member States will treat information they receive according to the applicable laws in their respective territories. Therefore, information supplied to FDA by a foreign government or CAB and other information or documents discussed by the comments are subject to the rules on public disclosure (or nondisclosure) in the FOIA, the Privacy Act, parts 20 and 21 (21 CFR parts 20 and 21). FDA further notes that other laws, regulations, and agreements may provide additional safeguards against public disclosure of trade secrets and confidential commercial information. For example, section 301(j) of the act (21 U.S.C. 331(j)), in brief, prohibits any person from using to his or her own advantage or revealing trade secret information acquired by FDA under various provisions of the act. Article 39 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (better known as the ''TRIPS'' agreement), to which the United States is a signatory, states that:

> Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

These laws and agreements would also be applicable to information and documents acquired by FDA under the MRA and this regulation. Consequently, given the existence of various agreements, laws, and regulations pertaining to public disclosure and confidentiality, no revision to this rule is necessary.

The public availability of the documents or information identified in the comments would, therefore, depend on whether they contained information that, under U.S. laws, regulations, or other obligations, is exempt from public disclosure. In some instances, portions of a document may be publicly available. For example, alert or vigilance reports under § 26.50, when provided to FDA, would be available for public disclosure under § 20.111 if the investigation of the reported incident has been completed; however, personal identifiers would be redacted, as FDA currently does under § 20.111.

3. Two comments would revise proposed § 26.76 so that a person submitting information to FDA could decide whether all or part of the information is confidential or trade secret and therefore not subject to public disclosure.

FDA declines to revise the rule as suggested by the comments. The agency believes this issue is handled adequately under current FDA regulations and policies. FDA policy is to make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, property rights in trade secrets and confidential commercial or financial information, and FDA's need to promote frank internal policy deliberations and to pursue regulatory activities without disruption (see § 20.20). Under FDA regulations, marking records submitted to FDA as confidential raises no obligation by FDA to regard such records as confidential, to return them

to the person submitting the records, to review the records to determine whether all or part of them are available for public disclosure, or to withhold them from public disclosure (see § 20.27). FDA determines whether data or other information are confidential and not subject to public disclosure, consistent with § 20.28.

4. One comment would revise proposed § 26.76 so that trade secrets, ongoing investigations, and patient records are confidential.

FDA declines to amend the rule as requested by the comment. Such a revision is unnecessary given current statutory and regulatory requirements involving public disclosure and confidentiality, including the prohibition in section 301(j) of the act against disclosure of trade secrets, all of which apply to information FDA receives from the regulatory authorities and CAB's.

5. One comment would revise the rule so that a foreign country receiving documents from FDA would have to make those documents available to the U.S. public, even if the foreign country's laws would not make those documents publicly available. The comment would make information submitted to a foreign country available to the public if that information were publicly available in the United States.

FDA declines to revise the rule as suggested by the comment. Requiring a foreign country to make information available to U.S. citizens when such disclosure would be contrary to the foreign country's own laws and regulations is beyond the scope of this rulemaking and beyond FDA's regulatory authority. In addition, the public availability in the United States of information provided to EC officials is already dealt with in FDA's regulations, particularly § 20.89. (Under § 20.89, disclosure of nonpublic information to foreign officials does not automatically result in that information being available to the public generally.)

6. One comment would revise proposed § 26.20 as it pertains to the application of the alert system against individual companies. The comment expressed concern about lack of transparency and due process before a company is placed in or removed from ''a negative regulatory status'' and suggested that the elements to be considered as part of the alert system be described.

The comment misunderstands the purpose of the alert system provisions of the MRA and this regulation. The agency wishes to clarify that the purpose of the alert system is to implement a timely exchange of product quality information and not information on the regulatory status of inspected firms. The agency is keenly aware of the need to avoid predecisional or otherwise inappropriate regulatory classification of a firm or product. In implementing § 26.20, FDA intends to apply the same standard of fairness and due process it currently affords to manufacturers with respect to regulatory matters. While keeping in mind the need to be fair to manufacturers, however, the agency must keep public health and safety paramount in ensuring that the alert system functions effectively to protect consumers from unsafe or ineffective products. Regarding ''transparency,'' as discussed in section II of this document, FDA will apply to the alert system established by the MRA and this regulation the applicable requirements as to disclosure and nondisclosure.

The proposed rule did set forth the elements to be considered in developing a two-way alert system (see 63 FR 17744 at 17752), and the alert system is designed to serve as a means for notifying each party of crises and emergencies. For example, the documentation element for the two-way alert system refers to elements such as ''definition of crisis/emergency and under what circumstances an alert is required'' and ''mechanism of health hazards evaluation and classification'' (id.). The crisis management system element mentions ''crisis management and communication mechanisms,'' ''establishment of contact points,'' and ''reporting mechanisms.'' In short, the alert system does not place specific firms in a ''negative regulatory status'' or otherwise punish firms as the comment suggests.

7. One comment asked about the confidentiality of submissions under the MRA, particularly submissions to medical device CAB's.

Confidentiality by FDA and EC regulatory authorities is addressed under Article 17 of the MRA. Confidentiality concerns are also addressed in FDA's regulations (e.g., part 20) and guidance materials. FDA urges manufacturers to include clear and definitive language regarding their views on the confidentiality of submissions in contracts developed with CAB's. Just as submitters currently identify information they believe to be confidential commercial or trade secret information in submissions to the agency, they should clearly mark the same types of information in submissions to CAB's. Although FDA needs to make the final decisions as to confidentiality, as discussed previously in comment 3 in section II.C of this document, the contractual agreement between submitters and the CAB's should address the desired handling of information marked in this manner and contractual provisions should specifically address the need to share information with regulatory agencies participating in the MRA, including FDA.

D. Equivalence issues

1. One comment recommended that equivalence determinations and suspensions of equivalence determinations should be made by the importing authority only, rather than jointly by the parties to the MRA and the proposed rule. The exporting country should develop the case for equivalence, while the importing country should have complete control over the final equivalence decision. This would maintain the importing country's sovereign prerogative to protect the health and safety of its citizens.

FDA agrees that the importing authority must have control over the decision as to whether the exporting authority is equivalent, and the agency believes that the decision-making process set up by the MRA and this regulation provides adequately for this. The MRA and this regulation stipulate that equivalence determinations will be made by the Joint Sectoral Committee, which consists of representatives of the parties. This regulation states that decisions of the Joint Sectoral Committee ''will be taken by unanimous consent'' (§§ 26.17(b) and 26.47(b)). Therefore, no equivalence determinations can be reached in the Joint Sectoral Committee without concurrence by both sides. Hence, in all cases, the relevant authority of the importing country (FDA, in the case of imports into the United States) will have definitive decision making authority.

Similarly, the importing party's right to determine that an equivalence determination should be suspended is also protected by the MRA and this regulation. Decisions to suspend equivalence are taken in the Joint Sectoral Committee, and when that Committee cannot reach unanimous consent on the appropriate action, the matter is referred to the Joint Committee. (As discussed earlier, FDA officials will speak for, and vote on behalf of, the U.S. Government on any matter pertaining to FDA's statutory or regulatory authority raised within the Joint Committee or Joint Sectoral Committees.) If unanimous consent is not reached within a set time period in the Joint Committee, the contested authority must be suspended. Thus, if

during these deliberations, the importing authority remains convinced that an exporting authority's equivalence determination should be suspended, the contested authority will be suspended even if the other party disagrees.

Furthermore, the importing country's sovereign prerogative to protect the health and safety of its citizens is further protected for pharmaceuticals by § 26.21 and for medical devices by § 26.67(f). Section 26.21 provides that a party may, if necessary to ensure the protection of human and animal health at the level of protection it deems appropriate, take actions such as suspension of the distribution of the pharmaceutical, product detention at the border of the importing country, withdrawal of the batches and any request for additional information or inspection as provided in § 26.12. Section 26.67(f) provides that a party may, prior to the suspension of a CAB, cease accepting the results of conformity assessment procedures performed by that CAB if the decision for such action is made on the basis of health, safety or environmental considerations, among others. The ''framework'' of the MRA and this regulation also contain a provision (Article 15 and § 26.74, respectively) preserving domestic legislation.

2. One comment stated that equivalence determinations must be based on an exacting review of the foreign regulatory system. This comment emphasized that equivalence should be determined to exist only where a finding can be made that the foreign system meets or exceeds the level of public health protection, enforceability, transparency, and effectiveness of the U.S. system.

FDA agrees with this comment, and intends to carry out a careful, detailed, and complete review of foreign regulatory systems in order to determine whether equivalence does, in fact, exist. FDA's review will examine whether the foreign system, as it is implemented by the exporting authority, provides the same (or a higher) level of public health assurance as the FDA system. The enforcement activities of the foreign regulatory system and the foreign system's effectiveness in assuring public health protection are very important components of the overall equivalence analyses. For pharmaceuticals, they are specifically covered in subpart A of this regulation, Appendix D, Subsection I (Criteria for Assessing Equivalence for Post- and Preapproval). Criterion I. (Ability to enforce requirements and to remove products found in violation of such requirements from the market) and Criterion V. (Execution of regulatory enforcement actions to achieve corrections, designed to prevent future violations, and to remove products found in violation of requirements from the market) focus on the execution of regulatory enforcement actions. All of the criteria taken as a whole cover the public health protection and effectiveness of the foreign system. In addition, Criterion I. F. (Accountability of the regulatory authority) relates to transparency, in that there must be a system through which the regulatory authority is accountable for its actions. Similar criteria will be developed and applied for competent authority oversight of medical devices. FDA expectations as to medical device CABs' reviews of premarket evaluations are set forth in a guidance document announced in the **Federal Register** of July 2, 1998 (63 FR 36240).

3. One comment requested clarification of equivalence assessment (§ 26.6) and asserted that enforcement and regulatory compliance systems between the United States and the EC need to be comparable. The comment explained further that, before assessments can be made, local regulations for pharmaceutical manufacturing should be in place. The comment added that EC countries have not issued and made public such regulatory documents as warning letters, to identify unacceptable manufacturers.

The agency emphasizes that, as stated in the definition of equivalence, to be equivalent to the United States, EC regulatory authorities need to be ''sufficiently comparable to assure that the process of inspection and the ensuing inspection reports will provide adequate information to determine whether respective statutory and regulatory requirements of the authorities have been fulfilled.'' (§ 26.1(c)). However, ''[E]quivalence does not require that the respective regulatory systems have identical procedures.'' Furthermore, among the criteria for assessing equivalence, contained in Appendix D of subpart A, is the ''[A]bility to enforce requirements and to remove products found in violation of such requirements from the market'' and ''[A]ccountability of the regulatory authority.'' The agency expects that these two criteria, in combination with others in Appendix D, should address the comment's concerns.

The agency does not understand the comment's apparent premise that, before assessment can commence, regulatory systems must already be comparable. The agency intends to assess the equivalence of an authority based upon the criteria in Appendix D of subpart B as they exist at the time the agency makes the assessment, and needed steps can be taken to address any shortcoming noted.

4. One comment emphasized the need to assure a level playing field in terms of inspectional activity (i.e., the length and frequency of inspections and the number of auditors). This comment recommended collection of statistics about these activities during the transition period and then steps to ensure a reasonable harmonization in approaches between European and FDA audits.

FDA agrees with this comment. Equivalence must exist not only in the foreign authority's legislation and written procedures (including those concerning audits), but also in the manner in which these policies are actually implemented. Under the MRA and this regulation, the conduct of inspections is one of the criteria (Criteria IV) that must be considered in reaching equivalence determinations for pharmaceuticals.

5. One comment questioned how the MRA and the proposed rule would stop a country from relaxing its standards to create an industry-friendly regulatory environment within its jurisdiction, resulting in movement of industry from countries with strict enforcement to countries of less strict enforcement.

There are limits to what governments can do to influence corporate choices about location or relocation of manufacturing sites; many factors play a part in these corporate choices. In any case, the MRA and this regulation have several mechanisms to help prevent ''a race to the bottom'' with respect to regulatory controls. First, the process for ascertaining equivalence will be rigorous. Second, after an equivalence determination has been made, Article 18 of the Sectoral Annex for Pharmaceutical GMP's (§ 26.18 of this regulation) and Article 19 of the Sectoral Annex for Medical Devices (§ 26.49 of this regulation) provide that the parties and authorities are to inform and consult one another, as permitted by law, on proposals to introduce new controls or to change existing technical regulations or inspection procedures, and to provide the opportunity to comment on such proposals. Furthermore, the parties must notify each other in writing of any changes to relevant legislation, regulations, and procedures. Third, Article 15 of the MRA and § 26.15 of this regulation provide for monitoring activities for the purpose of maintaining equivalence. Fourth, either side may refrain from ''normally endorsing'' audit reports or device evaluation reports if regulation is

insufficiently strict. Fifth, if FDA believes that the foreign authority has made changes to its control system that lessen the equivalence of that system, FDA has the right to contest the equivalence of that regulatory authority.

Although the MRA and this regulation cannot prevent an exporting country from relaxing its standards, the MRA and this regulation ensure that the importing country must be notified, the equivalence determination of the exporting country can be suspended, and importing countries can take needed actions to protect their citizens.

6. One comment offered support for the proposed rule's recognition that an equivalence assessment must include joint training and joint inspections. This comment emphasized that the MRA and the proposed rule should provide for monitoring and verification of on-going equivalence, including on-going training, on-going joint inspections, and periodic on-going visits.

FDA agrees with this comment. This regulation, as currently drafted, provides for such monitoring and verification in § 26.15 for pharmaceuticals and § 26.69 for medical devices. In the case of medical devices, § 26.69 does not specifically mention training, but also does not exclude it. Joint training exercises are listed in § 26.37 as a confidence building activity during the transition period, and FDA considers monitoring and verification of on-going training to be an essential element of verifying that equivalence continues to exist.

7. One comment stated that the MRA and the proposed rule should provide for periodic expiration of an equivalence determination within 3 to 5 years following the initial determination. FDA should then publish a notice in the **Federal Register** for public comment on whether the equivalence determination has worked and should be renewed. Before renewing the equivalence determination, the United States should verify that the foreign country's or CAB's procedure continues to be equivalent.

FDA agrees that periodic reexamination of a foreign system that has been found equivalent is a prudent practice to ensure that equivalence continues to exist. The agency intends to provide for monitoring of continued equivalence in its implementation of equivalence determinations arrived at under the MRA and this regulation. However, the agency does not believe it necessary to require a ''sunset'' provision for periodic reexamination of equivalence in the MRA or this regulation. FDA will consider how to provide for reexamination of equivalence during implementation of the MRA.

E. ''Piggy back'' Agreements

1. One comment suggested that the MRA and the proposed rule should prohibit the development of what the comment called the ''piggy-back dilemma'' because they would set a precedent for these types of arrangements. The comment described an example of such a ''piggy-back'' arrangement as FDA establishing a mutual recognition agreement with country A, country A then establishing a mutual recognition agreement with country B, and then FDA automatically granting a mutual recognition with country B on the basis of its mutual recognition agreement with country A.

FDA disagrees with the comment's conclusion that the MRA and this regulation would set a precedent for entering into such ''piggy-back'' arrangements. The MRA and this regulation require a determination of equivalence be made by FDA of each EC Member State regulatory authority and each device CAB located in EC Member States before any inspectional or evaluation reports would be ''normally endorsed'' by FDA under certain conditions. There are no provisions in the MRA or this regulation for the ''normal endorsement'' of reports from any countries or CAB's that have not been determined to be equivalent by FDA.

2. One comment strongly opposed what the comment called ''piggy back equivalence'' as described in the proposed rule under § 26.11(b) because it would take away FDA's authority to make its own equivalence determinations and otherwise compromise its ability to ensure public health.

The so-called ''piggy-back'' or ''surrogate'' inspections described in § 26.11(b) provide that FDA may ''normally endorse'' inspection reports resulting from joint inspections by an equivalent authority and a nonequivalent authority of manufacturers located in the nonequivalent authority's territory. Under the provisions of the MRA and this regulation, FDA has the option of participating in all ''surrogate'' inspections and expects to exercise this right as necessary. Furthermore, the MRA and this regulation have other safeguards in place for these types of inspections, and more generally as described previously, that ensure public health protections are maintained.

F. Pharmaceutical issues

1. One comment stated that if FDA has confidence that the EC can regulate drug substances, biologics should also be included in the scope of the document.

Many biological products, such as vaccines and therapeutic drug products, are included in the scope of the MRA and this regulation. Other biological products, specifically human blood, plasma, tissues and organs, were excluded from the scope of the MRA. In order for there to be a finding of equivalence, the parties to the MRA and this regulation must have sufficiently comparable regulatory systems for the products. Not all EC Member States have established regulatory systems for human blood, plasma, tissues, and organs at this time, so it would not be possible to have a finding of equivalence during the transition period for these products. Plasma derivatives were excluded from initial consideration because the U.S. regulation of plasma derivative products has recently undergone intense scrutiny and regulatory change; therefore, the FDA did not believe it appropriate at this time to include plasma derivatives within the scope of the MRA and this regulation.

2. One comment suggested that § 26.1 of the proposed rule be amended to include a definition for the term ''normally endorsed.''

The agency believes that a codified definition of ''normally endorsed'' is not needed because the rule (at § 26.12) exemplifies circumstances in which the reports would not be normally endorsed. However, FDA wishes to clarify that normal endorsement generally means that an authority will accept the information contained in the inspection report to evaluate and determine a manufacturer's compliance with that authority's requirements, and FDA expects to endorse the finding in the reports most of the time. FDA is not, however, prevented from reaching different conclusions in appropriate circumstances.

3. One comment suggested revisions to the definition of GMP's (§ 26.1(c)(1)) to explicitly include packaging, labeling, testing, and quality control.

FDA believes the suggested revisions are unnecessary. Labeling, testing, quality control, and packaging are part of manufacturing. FDA believes that the proposed definition meets the needs of part 26 because it is consistent with FDA's statutes and regulations.

4. One comment said that the proposed definition of ''inspection report'' (§ 26.1(e)) was inconsistent with

the definition of ''inspection'' because it lacked reference to report coverage of commitments made as part of the approval to market a product. The comment suggested added wording to include such commitments.

The agency believes it unnecessary to modify the definition of ''inspection report,'' as suggested, because it should be clear from other sections of the rule (such as §§ 26.2, 26.3, and 26.14), that FDA fully expects that reports covering preapproval inspections of drug manufacturers will, as a matter of course, include information relating to commitments made as part of the marketing approval. In addition, as stated in § 26.8, the agency intends to work quickly with counterpart authorities under the MRA to determine inspection report contents and format.

5. One comment suggested that the proposed rule clarify that it would apply only to inspection of firms that are exporting covered pharmaceutical products from either of the two regions to the other.

The agency believes that the current wording in § 26.3 is sufficiently clear to limit the scope of inspections to only those firms located in the two regions. The rule states in relevant part that the ''provisions of this subpart shall apply to pharmaceutical inspections carried out in the United States and Member States of the European Community* * *.'' Furthermore, § 26.12 refers to inspection reports being normally endorsed by the importing (emphasis added) party. Clearly, the importing party is interested in only inspection reports because of products being imported into its territory.

6. One comment suggested changing the word ''both'' to ''either'' in § 26.4(a) on the grounds that a product regulated as a drug by one party but not the other should not be excluded from this regulation because at least one party will apply current GMP standards to the product.

The agency disagrees with the suggestion. If an importing country regulates an article as a drug, but the exporting country does not, the importing country would likely hold the article to a different (higher) set of manufacturing standards. In such a situation, it is unlikely that the importing country would find the exporting country's inspection report of value in assessing the manufacturer's compliance.

7. One comment objected to the provision in § 26.6(c) that equivalence assessments mandate joint inspections. The comment suggested that they be minimized or replaced by ''accompanied inspections'' where the lead authority is clearly designated.

FDA believes that the conduct of joint inspections is an essential part of the equivalence assessment process. Such assessments would be incomplete without first hand observation of how an authority conducts an inspection. The agency wishes to clarify that, as stated in the rule, the conduct of joint inspections is ''for the purpose of assessing regulatory systems and the authorities' capabilities.'' The actual format of the joint inspections has not yet been determined, and may include inspections where one party observes the other party's inspectional conduct or where each party has responsibility for part of the inspection. As part of the preparation for implementation of the MRA and this regulation, FDA expects to jointly develop with the EC a standard operating procedure for joint inspection that embodies this approach.

8. One comment said the second sentence in § 26.6(a) (stating that the EC will provide information pertaining to criteria under EC competence) was problematic because the equivalence criteria in Appendix D should be complete, as is, or else augmented, as needed.

The agency believes the comment may have misinterpreted the proposed rule to mean the EC will be held to different, yet to be specified, equivalence criteria. The agency wishes to clarify that the equivalence criteria in Appendix D apply equally and fully to both parties. The sentence at issue addresses information (e.g., European Commission Directives) that the EC will provide relating to these criteria that applies to all Member State authorities, versus information that is specific to a particular Member State as to how Member State authorities meet these criteria.

9. One comment said § 26.6(b) should address the mechanism by which the parties establish and communicate their draft equivalence assessment programs. The comment called for interested parties to have the opportunity to comment on the draft programs before they become official. The comment also suggested that the phrase ''as deemed necessary'' would for FDA be in conflict with legislative mandates that require certain pre- and postapproval inspections.

The agency does not believe it is necessary to codify the mechanism by which the parties establish and communicate their draft equivalence assessment programs. The parties have yet to establish those logistics. Regarding the opportunity for public input on such programs, as discussed in section II of this document, the agency intends to provide for such input in a manner consistent with current policy development and FOIA requirements. The agency is fully aware of its legislative mandates regarding establishment inspections and does not believe the wording of the MRA or the rule is inconsistent with those responsibilities. FDA intends to carry out all activities that it deems necessary to be consistent with its responsibilities.

10. One comment suggested adding wording to § 26.8 to state that FDA will use its current inspection report format, or some modification thereof, until the parties develop and agree upon an inspection report format.

The agency believes the suggested wording is unnecessary because it is confident that the parties will develop and agree upon a mutually acceptable report format in a timely manner.

11. One comment suggested that § 26.9(a) be revised to explicitly require FDA to use International Organization for Standardization (ISO) 9000 and ISO 10000 standards to determine that an authority has demonstrated a pattern of consistent performance with the criteria in Appendix D.

The agency believes it is unnecessary to apply precise statistical methods in demonstrating a pattern of consistent performance, in the context of complying with Appendix D. The agency intends to apply objective and fair criteria in evaluating whether an authority has demonstrated a pattern of consistent performance but does not believe its already rigorous GMP and inspection requirements need an added ''layer'' of requirements based upon the ISO standards mentioned.

12. One comment suggested that § 26.11(c) be amended to include a manufacturer's certification that the product was manufactured in accordance with applicable GMP's.

FDA's view is that such a certification is unwarranted. The agency expects that, in the context of this agreement, authorities would rely upon inspectional reports to determine a manufacturer's current GMP compliance rather than relying upon the manufacturer's own declaration. The agency therefore declines to adopt the suggestion.

13. One comment suggested adding a new paragraph, to complement § 26.11(c), that would exempt U.S. manufacturers from carrying out all of the quality controls specified in the current GMP regulations, provided that the controls specified in Article 22 paragraph 1(b) of Council Directive 73/319/EEC have been carried out in the EC and each batch or lot is accompanied by

certificates of current GMP and marketing authorization compliance.

FDA does not believe it is in the public interest to exempt manufacturers from performing currently required current GMP quality control measures, or to allow products to be released for distribution without requisite laboratory determination of conformance to established specifications. The suggested changes are not adopted.

14. One comment suggested revisions to § 26.13 to explicitly require that: (1) Requests for postapproval inspections include the product and the requester's areas of special concern; and (2) when new inspections are needed the authority receiving the request should state the reasons why a new inspection is needed along with the estimated completion date.

The agency does not believe it is necessary to make the suggested modifications. The agency anticipates that, as a matter of course, inspection requests and corresponding communication will identify products, areas of concern, and other relevant information, as needed.

15. One comment suggested revising § 26.14(b) to require the notified authority to advise the requesting authority of approximately when the inspection will be completed, and to require the requesting authority at that point to detail what issues need to be addressed during the inspection.

The agency declines to accept the suggestion because it believes such operational logistics will be performed as a matter of course, and need not be codified.

16. One comment suggested revising § 26.15 to specify that review of reports includes evaluation mechanisms such as tracking trends and problems and to state that review studies be used to focus on needed training and program improvements.

The agency agrees that report evaluation and trending, along with coordination among the authorities to ensure program improvements, have merit. The agency does not, however, believe it is necessary to codify details of how equivalence monitoring will be performed.

17. With regard to § 26.18, one comment asked how changes in current GMP regulations and initiation of new programs, such as the First Party Audit Program (FPAP), would affect the implementation of the MRA and the proposed rule.

The agency advises that, under § 26.18, FDA will inform, consult with, and offer the opportunity for comment by, the other party, as permitted by law, regarding changes in current GMP regulations or inspection procedures. The mechanisms for conducting that collaboration have yet to be developed. Regarding the FPAP, the subject of an FDA public meeting held on June 23, 1998 (see 63 FR 27583, May 19, 1998), the agency advises that this initiative is currently in very early stages of development. However, conceptually, FPAP is intended to gather information from selected human use pharmaceutical manufacturers regarding their quality assurance measures; the information would be submitted to FDA by those firms and could substitute, in some measure, for information the agency would otherwise obtain from its direct inspectional activities. The agency cannot predict how these initiatives will affect the nature and volume of current GMP inspections performed under the MRA and this regulation. However, the agency will consult with the other party, in accordance with the provisions of this rule and the MRA itself.

18. One comment suggested revising § 26.18(b) to establish a 30-day timeframe for the United States to notify the EC of any changes to Appendix B, and a 5-day timeframe where such notification can be made electronically.

The agency intends to promptly notify the EC of changes to Appendix B, and to use electronic means of doing so whenever feasible. However, FDA believes it is unnecessary to codify specific timeframes.

19. One comment suggested revising § 26.19 to add reporting timeframes of 15 days for paper correspondence or 3 days for electronic correspondence.

FDA shares the comment's concern regarding the timeliness of exchanging information relating to quality problems, and intends to implement such exchange in a prompt manner to be arranged in concert with the EC. FDA does not, however, believe it is necessary to codify a specific timeframe.

20. One comment suggested revising § 26.20(a) to establish reporting timeframes of 5 days for paper correspondence or 3 days for electronic communications.

As discussed in response to comments on § 26.19, the agency agrees that reporting needs to be done promptly, but does not agree with the suggestion.

21. One comment asked if, and how, the MRA and the proposed rule will accommodate the collection of regulatory samples during pharmaceutical inspections.

The agency advises that the MRA and this regulation do not specify how regulatory samples collected during establishment inspections will be handled. However, FDA anticipates that both parties will handle such samples as they currently do, and that information about such samples would be contained in the inspection report or related documents. The agency is prepared to work with the regulatory authorities should it become necessary to develop procedures relating to sample collection.

22. One comment noted that a recent U.S. General Accounting Office (GAO) report on FDA's foreign inspection program included recommendations intended to improve management of the agency's overseas inspection program. The comment asked if FDA's consideration of the report would affect the MRA or the proposed rule.

The agency has, in response to the GAO report, already initiated several modifications in the management of its overseas inspection program. The agency does not at this point anticipate that implementation of those changes will have a significant effect on the MRA or this regulation.

23. One comment suggested adding a new paragraph to subpart C, § 26.76 that would explicitly prohibit the parties from obstructing public access to information which, by U.S. law, is disclosable to the public.

The agency does not agree that this section is needed because part 26 does not conflict with U.S. laws regarding public access to information. The agency is fully aware of its legal obligations to abide by those applicable statutes, as discussed in section II of this document.

24. One comment suggested numerous editorial changes to add clarity throughout the rule.

The agency has carefully considered the suggested revisions and believes that although some have merit, on balance, the need to retain wording in part 26 that is as close as possible to the MRA itself outweighs the advantages that the changes might afford.

G. Medical Device Issues

The Food and Drug Administration Modernization Act of 1997 (FDAMA), Pub. L. 105–115, 111 Stat. 2296 (1997), included a number of amendments to the act relevant to the MRA's Sectoral Annex on Medical Devices (Medical Devices Annex). First, an FDA pilot program for third-party review of medical devices (see 61 FR 14789, April 3, 1996) was codified in the act as new section 523 (21 U.S.C. 360m), entitled ''Accredited Persons.'' In the **Federal Register** of May 22, 1998 (63 FR 28392), FDA published a notice of availability of a draft guidance on its third-party

accredited persons program under this new section of the act.

Interested persons should also refer to a related notice of availability published in the **Federal Register** of July 2, 1998 (63 FR 36240), entitled ''Draft Guidance for Staff, Industry and Third Parties, Third Party Programs under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community; Availability'' (MRA). This guidance document is also available in FDA's Home Page on the WWW (''www.fda.gov'').

Second, due to amendments made by FDAMA, FDA has exempted a number of devices from premarket notifications under section 510(k) of the act (21 U.S.C. 360(k)) (see 63 FR 3142, January 21, 1998 (Class II devices), and 63 FR 5387, February 2, 1998 (Class I devices)). On May 20, 1998, FDA made available a list of devices which are eligible for third party review under new section 523 of the act. FDA plans to propose to the European Commission that the tables attached to the Medical Devices Annex to the MRA, listing devices eligible for review during the transitional period of the MRA, be revised to reflect the changes in U.S. requirements made by FDAMA and the FDA implementing actions described previously. The EC may also suggest changes concerning devices eligible for the MRA. These adjustments will be made during the transitional period under the MRA.

Third, as discussed in comment 9 of section II.F of this document, FDA now has explicit authority to recognized voluntary consensus standards for devices due to a FDAMA amendment to section 514 (c) of the act (21 U.S.C. 360d(c)).

1. One comment identified a typographical error in Table 1 of the Sectoral Annex on Medical Devices (Annex) of the proposed rule concerning radiographic screens § 892.1960 (21 CFR 892.1960).

FDA agrees with the comment and in the final rule has corrected this typographical error. Also, several minor typographical errors in the device lists were identified by the European Commission and FDA just prior to the signing of the MRA on May 18, 1998. These corrections are also being made in corresponding provisions in this rule.

2. One comment from a manufacturer questioned whether condoms are covered by the MRA.

The list of devices that FDA made available on May 20, 1998, for eligibility in the accredited persons program under section 523 of the act includes condoms, with and without spermicidal lubricant. Therefore, FDA is willing to consider condoms with or without spermicidal lubricant as eligible for participation in the premarket assessment component of the device MRA, if the EC agrees. Condoms without spermicidal lubricant are listed in Table 3 of the Annex for possible inclusion in the scope of product coverage during the Operational Period. However, condoms with spermicidal lubricants may be regulated by the EC, or certain EC Member States, as pharmaceuticals and hence may be outside the scope of the Medical Devices Annex.

3. One comment asked whether clearance of a 510(k) will be equivalent to CE marking.

Clearance of a 510(k) will not be considered equivalent to the CE marking, nor will CE marking be considered equivalent to a 510(k). Under the MRA and this regulation, the exporting country's CAB's perform specified conformity assessments in accordance with the importing country's requirements. The MRA and this regulation are intended to enable determinations: (1) Whether CAB's in the EC are capable of conducting certain premarket and quality system evaluations in accordance with U.S. regulatory requirements in a manner equivalent to how those evaluations are conducted by FDA (with FDA making the final decision, but with an expectation that FDA would ''normally endorse'' a CAB's assessment), and (2) whether CAB's in the United States are capable of conducting certain premarket and quality system evaluations in accordance with EC regulatory requirements in a manner equivalent to those conducted by European CAB's, also referred to as ''notified bodies.''

4. One comment requested implementation of a system by which U.S. manufacturers can obtain government documents for presentation to the EC.

Appendix A of subpart B contains addresses the relevant legislation, regulations, and procedures for the EC and the United States. In addition, the European Commission has a site on the WWW for direct access to EC documents (''http://Europa.eu.int/eur-lex''). Also, just as European notified bodies are frequently a manufacturer's first point of contact regarding the process for meeting the European requirements, it is expected that, under the MRA and this regulation, U.S.-based CAB's will be able to provide manufacturers with information on EC requirements and copies of necessary European documents needed to meet European requirements.

5. One comment stated that industry would like to encourage observed audits. The comment explained that, in an observed audit, a U.S. manufacturer would allow an EC Notified Body representative to accompany an FDA inspector during an inspection of its plant.

FDA agrees that joint industry audits are necessary to demonstrate that CAB's are competent to assess medical devices to each country's requirements and level of public health protection. FDA encourages manufacturers to support observed audits.

6. One comment suggested that, to further strengthen confidence in CAB's, training on auditing should be conducted by the United States and EC, and industry should be encouraged to participate in FDA's third party system, i.e., the accredited persons program.

FDA agrees with the suggestions. Training on premarket and quality system evaluations is planned for CAB's participating in the MRA and in FDA's third-party accredited persons program. FDA has made tentative plans to conduct training for EC CAB's on October 14 to 16, 1998, in the Washington, DC area. Representatives of EC CAB's interested in participating in the MRA should begin making plans to attend this training, which is also being provided to participants in the accredited persons program. This training is intended to address the scope, content, and expectations of the evaluations sufficient to determine the equivalence of the assessments.

7. One comment requested that FDA consider IV catheters, under 21 CFR 880.5200, for inclusion in Table 2, ''Class II Medical Devices Included in Scope of Product Coverage at Beginning of Transition Period.''

During the negotiation of the Annex, there were no expressions of interest in adding IV catheters to any of the tables of eligible medical devices. FDA is willing to consider that issue in the future, but at this time does not intend to include IV catheters in Table 2 at this time.

8. Several comments suggested that the MRA be expanded to include more devices, including class II devices.

As discussed previously, FDA plans to propose expansion of the list of eligible devices to include all devices eligible for third party review under FDAMA, except those medical devices regulated as in vitro diagnostics. (The EC does not yet have legislation in place on in vitro diagnostics.) The agency is considering specific suggestions by industry comments for inclusion of specific devices. These suggestions are extremely useful for future decisions,

although neither the FDA nor the European Commission can, at this time, respond to these industry suggestions by including additional devices under the MRA. Revision of the list will, however, be a step taken early during the transition stage. The pace at which devices can be added to the device premarket assessment aspect of the MRA depends on the availability of guidance documents or FDA-recognized standards, as discussed in comment 8 of section II.G of this document.

9. Several comments urged FDA to accept international standards, instead of developing FDA guidance documents, for the third party review of class II devices. One comment proposed use of 81 international and regional standards to support premarket evaluations and quality system evaluations.

FDA, under FDAMA, has begun to recognize consensus standards for use in its various medical device activities (see 63 FR 9561, February 25, 1998). FDA very much appreciates the submission identifying potentially useful standards. Communications such as this that relate to the use of standards in MRA implementation and other device activities are being considered in regard to FDA's consensus standards initiative announced on February 25, 1998. FDA plans to update the guidance for the recognition and use of consensus standards, as described in the February 25, 1998, document, and in doing so the agency will take into account the suggestions received and the information and experience to be gained during the implementation of the MRA.

FDA's views on the appropriateness of including a device under the premarket evaluation component of the MRA will depend, in part, on whether FDA-recognized standards or review guidance documents exist to provide a basis for product evaluation. Recognized standards or review guidance do not currently exist for many of the additional devices suggested for inclusion in the MRA by certain industry comments. FDA plans to develop guidance documents only where recognized consensus standards fail to address sufficiently the requirements for demonstrating substantial equivalence or other U.S. requirements.

10. One comment suggested that FDA take aggressive steps to identify and designate third party review organizations.

FDA is proceeding in a timely and transparent manner to describe processes and expectations for third parties to participate in both the accredited persons program and the MRA. For example, the agency, in the **Federal Register** of July 2, 1998 (63 FR 36240), issued a comprehensive guidance document entitled ''Draft Guidance for Staff, Industry and Third Parties, Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA),'' to assist interested parties to understand the designation process for CAB's and to prepare their applications. This document has been made available on the CDRH Home Page on the WWW. FDA officials also have discussed the third party programs under FDAMA and the MRA at trade shows and public meetings.

11. Two comments suggested that both quality system evaluation reports and premarket evaluation reports should be harmonized between the United States and EC. Another comment stated that one of the issues to be resolved is determining what duration of an audit is satisfactory to the designating authorities as well as the scope, content, and degree of rigor expected from such audits. One comment further suggested incorporating efforts by an international harmonization group known as the GHTF and its Study Groups I and IV in developing the format for reports. FDA officials, European government officials, and industry representatives are among those active in the GHTF, which is comprised of government and industry representatives from North America, Europe, Asia, and Australia, as well as observers from other countries and international organizations (see International Harmonization, Policy on Standards, in the **Federal Register** of October 11, 1995 (60 FR 53081)).

The comment also suggested that, in the interest of efficiency and to minimize translation costs, such reports should be in an abbreviated form in most circumstances. It further suggested that the reporting forms be limited to certification by the CAB that applicable requirements of the other party's regulations are met and that this certification may reference those documents which were examined to demonstrate compliance. The comment also recommended use of FDA's initiative known as the ''510(k) Paradigm'' that offers other ways of streamlining decisions on 510(k)'s.

FDA expects to use relevant GHTF documents, as appropriate, in implementing the MRA. Study Group I of GHTF is developing a universal format which provides guidance on technical documentation with a view to first identifying similarities and divergences among various regulatory systems and then striving to achieve, to the extent possible, harmonization of requirements. At this time, this study group has reviewed requirements of existing systems and is now developing the essential principles which could facilitate harmonization of requirements, particularly as to premarket submissions. FDA is hopeful that it will be able to use guidance developed by Study Group I as guidance to MRA participants on the development of premarket evaluation reports.

Study Group IV of GHTF is preparing guidelines for auditing quality systems of medical device manufacturers. These GHTF guidelines are now being made available for comments by principal participants in GHTF, e.g., by the EC United Kingdoms' Medical Devices Agency's Home Page and the United States through a future publication as a guidance in the **Federal Register** and in the FDA Home Page. FDA anticipates using audit guidance developed by Study Group IV in the implementation of the MRA.

It is too soon to say precisely what formats will be used for premarket evaluation reports and quality system evaluation reports under the MRA. FDA intends to take into account the concerns expressed in the comment about minimizing the required documentation to that which is necessary. The formats for such reports will be developed during the MRA transition period, and FDA expects guidance from the GHTF study groups to be extremely helpful in this respect. During format development, FDA will work to develop formats that will not be unduly burdensome, so that forms and reports will include information sufficient for the parties to determine if normal endorsement is warranted. FDA will consider the use by third parties of FDA streamlining initiatives such as the 510(k) Paradigm in review of applications under the accredited persons program and the MRA. Information on the 510(k) paradigm can be accessed on the CDRH Home Page under ''Re-engineering Efforts'' (www.fda.gov/cdrh).

12. Two comments raised the concern that the exchange of post market vigilance reports might create an administrative burden for industry if reports are not kept simple. One of the comments noted that industry has wanted to avoid multiple reporting and wishes to report only when there is a real and imminent danger to public health.

FDA believes that adverse event reports need to be clear, concise, and

addressed to public health needs. FDA, through its participation in the GHTF Study Group II, is working toward a streamlined and harmonized system of reporting adverse events that are required by EC and U.S. laws and regulations. This effort is initially focused on harmonizing the guidelines for the types of adverse events that medical device manufacturers need to report. This guidance will make it easier for a manufacturer to decide which events need to be reported to the appropriate bodies in the EC and in the United States. The guidance developed by Study Group II will also be used to institute a mechanism for sharing adverse event data between the EC and United States under the MRA.

13. Two comments expressed support for § 26.48, ''Harmonization,'' and one suggested that FDA should continue to participate in the efforts of the GHTF.

FDA agrees with this comment and intends to continue to participate in these efforts, as resources allow.

14. One comment suggested that the FDA consider provisions by which U.S. CAB's would perform domestic inspections under the act.

This comment addresses issues outside of the scope of the MRA and of this rulemaking. Under the MRA and this regulation, U.S. CAB's will be designated only to conduct product type-examination and verification and/or quality system evaluations for products produced for export to the EC.

15. One comment asked if the ''post market vigilance reports'' addressed under § 26.33(a)(3) were the same as Medical Device Reports (MDR's).

Post market vigilance reports and MDR's are similar mechanisms for reporting adverse incidents in the EC and the United States respectively. A system will be set up during the transition period and maintained thereafter by which the parties will notify each other when there is an immediate danger to public health. (See § 26.50.) As part of the alert system, each party shall notify the other party of any confirmed problem reports, corrective actions, or recalls. The United States and EC plan to develop the data elements of such reports during the transition period, making use of draft documents already being prepared by the GHTF's Study Group II.

16. One comment asked if the regulatory authorities mentioned in § 26.34 and the designating authorities mentioned in § 26.65 are the same.

''Regulatory Authority'' is defined in § 26.60(a)(3) and ''Designating Authority'' is defined in § 26.60(a)(1) of the final rule. It is possible for these authorities to be different, or they may be the same. For the purpose of the Sectoral Annex on Medical Devices, regulatory authorities have the responsibility to implement the provisions of the Annex, including the designation and monitoring of CAB's.

17. One comment asked if the criteria to be used by FDA to determine technical competence for product reviews is identical to that which is to be used in the U.S. third party program for accredited persons.

The technical competence, qualifications, and freedom from conflict of interest for the product review (510(k)) part of the MRA are essentially the same as those being applied in FDA's third-party program for accredited persons. However, the MRA also includes quality systems audits, and CAB's performing quality systems audits under the MRA will need to have the additional training, expertise, and experience to perform quality systems audits. In this respect, the MRA is broader than the FDA third party accredited persons program.

18. One comment supported § 26.31, which states that the Sectoral Annex on Medical Devices should evolve and that the parties will periodically review the program to assess progress and identify enhancements. This comment also requested that timeframes be established for specific actions during the transition period. The comment also recommended that the regulatory authorities establish a schedule for the execution of the specified confidence building activities, under § 26.35, that can serve to ''benchmark'' progress.

FDA finds these comments extremely useful. Specific confidence building activities will depend on the nature of product evaluation and the extent of CAB utilization, and available resources. A process for scheduling confidence building activities and the schedule for accomplishing them will be developed by the United States and EC.

19. One comment stressed the importance of defining the supporting evidence necessary to demonstrate the technical competence and independence of CAB's. This comment also requested that FDA make known to the general public the date and process by which the CAB's will be designated.

FDA issued a **Federal Register** of July 2, 1998 (63 FR 36240) announcing the availability of a draft guidance entitled ''Draft Guidance for Staff, Industry, and Third Parties, Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition between the United States of America and the European Community (MRA).'' This draft guidance addresses the criteria and qualifications expected to demonstrate technical competence and independence of CAB's. In addition, the draft guidance outlines the process for designation of CAB's under the Medical Devices Annex to the MRA. FDA will keep the public informed through the home page on the WWW of events under the MRA, such as designation of CAB's.

20. One comment expressed concern that FDA stated that the operational period will start at the end of the transition period, and that FDA did not state that the transition period will be for a period of 3 years. The comment sought clarification.

FDA disagrees that further clarification is needed. The duration of the Transition Period is 3 years. This is clearly stated in § 26.35 and in the Annex, Article 5.

21. One comment supported the process of the importing party's regulatory authority routinely accepting or ''normally endorsing'' reports.

FDA observes that this was the criterion agreed to in the Annex and stated in the regulation (§ 26.41(d), Exchange and endorsement of quality system reports, and § 26.42(c), Exchange and endorsement of product evaluation reports).

22. One comment sought clarification of the term ''normally endorse'' and expected that the importing party will endorse the vast majority of quality system evaluation and premarket evaluation reports.

FDA anticipates that, once CAB's are designated, the importing party (FDA, in the case of devices to be imported into the United States) it is likely to endorse most reports. Sections 26.41(d) and 26.42(c) describe the expectation that reports will normally be endorsed by the authority of the importing party, except under circumstances delineated in those provisions.

23. One comment supported the need to continue to accept the results of conformity assessment procedures performed by a CAB prior to its suspension as a listed body, except in specified situations as identified in § 26.67(f).

FDA agrees with the comment's description of the Annex and the regulation but would also point out the provisions in the framework agreement and in § 26.74 of this regulation allowing authorities on either side to take appropriate and immediate measures to protect public health.

24. One comment expressed concern that the conformity assessment procedures performed by a CAB prior to

withdrawal remain valid subsequent to withdrawal.

FDA notes that § 26.68, ''Withdrawal of Listed Conformity Assessment Bodies,'' clearly delineates the circumstances under which a party is no longer required to accept or recognize results of conformity assessment procedures performed by CAB's (or, in the case of this Annex, to no long normally endorse reports provided by CAB's). As noted in the response in the preceding comment, however, nothing in the MRA or this regulation supersedes a participating country's ability to preclude shipments of products that present a concern under its laws. Whether there will be ''normal endorsement'' of assessments done by a CAB before its suspension or withdrawal would be determined, on the merits, based on the facts in the particular case (see, also, the discussion in comment 13 in section II.A of this document under the heading ''General Comments and Issues'')

25. One comment suggested a definition section for subpart B.

FDA does not believe that it is necessary to change the regulation to add a definition section. Guidance may be provided in the future, if necessary.

26. One comment expected the list of CAB's would be published along with the final rule, or that the final rule would state when the list will be published.

At this time, FDA is not certain of the date when the designation of CAB's will be made under the MRA. Once this occurs, however, the list will be made public on the FDA Home Page on the WWW.

27. One comment requested availability of a description of the information which must be presented in quality system and premarket evaluation reports to be produced by CAB's. The comment suggested that this information is needed in order to judge the adequacy of the work of various CAB's.

FDA agrees. The information that FDA expects to be present in quality system and product evaluation reports will be made public through the FDA Home Page on the WWW during the transition period. Comment 4 of the section II.F of this document describes how to obtain EC documents.

28. One comment commented on the 90-day period provided for obtaining an inspection and requested provision for extension of this period for good cause.

FDA realizes that the CAB's may not be able to accommodate all inspection requests within 60 or 90 days. Time extensions may be needed, for good cause, but FDA believes procedures for such a request need not be codified in this section.

29. One comment strongly recommended that FDA conduct an on-going verification of the evaluation reports produced by the CAB's because they are vital to ensuring the safety and effectiveness of medical devices. This comment also raised concerns about the potential for conflicts of interest in a system of private review. (Some EC CAB's are private sector bodies.)

FDA is sensitive to the concerns raised in this comment and recognizes the importance of adequate reports from CAB's regarding product evaluations and quality system evaluations as well as FDA's verifications. It is anticipated that FDA will rigorously evaluate both the reports and the CAB's that produce them. In addition, FDA has issued a notice announcing the availability of a draft guidance entitled ''Draft Guidance for Staff, Industry, and Third Parties, Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition between the United States of America and the European Community (MRA),'' published in the **Federal Register** of July 2, 1998 (63 FR 36240). This document addresses conflict of interest concerns as well as technical competence criteria.

Also, it should be kept in mind that final decisions on 510(k)'s will be made by FDA, ''normally endorsing'' submissions by CAB's, during both the transitional stage and the operational stage of the Medical Devices Annex.

33. One comment suggested that the wording of §§ 26.39(b) and 26.46(b) be clarified. These sections address equivalence and listing of CAB's.

FDA believes the wording of these sections is sufficiently clear. Further clarification, if necessary, could be considered in the future after experience is gained under these provisions.

34. One comment stated that CAB's should be designated within the first 2 years of the transition period because sufficient accumulation of evidence supporting equivalence would be unlikely if designation occurred in the last year of the transition period.

FDA points out that Article 6 of the Annex and § 26.36 of this regulation states that ''each Party shall designate [CAB's] to participate in confidence-building activities by transmitting to the other Party a list of CAB's* * *.'' This transmission will be done at the start of the transition period. However, determinations of equivalence will be made following this exchange of lists and, indeed, will be a continuous feature of MRA implementation.

35. One comment suggested that § 26.37 be revised to include the frequency of workshops and seminars throughout the transitional and operational phases.

FDA agrees that workshops and seminars are important. However, provisions for the frequency of workshops and seminars are not appropriate for inclusion in a rule. Furthermore, available resources will determine the frequency of joint training and seminars. FDA will continue to explore cost effective means, such as audio/video conferences and videotape training, to enhance the expertise of the CAB representatives. As stated earlier, an FDA training program for EC CAB's has been tentatively scheduled for October 14 to 16, 1998, in the Washington, DC area.

36. One comment said that § 26.46(c) implies that the designation of additional CAB's in the operational phase will occur only once each year. This comment went on to suggest that, if expansion of the CAB list is expected to be an annual event, then § 26.66(b) should so state.

FDA believes the language in § 26.46(b) is sufficiently clear, and that there is no need for change in the regulatory provisions cited.

37. One comment suggested that § 26.65 be revised to state that, ''Designating authorities shall only designate CAB's where the primary place of business is in the territory of the designating authority.''

FDA disagrees with the suggestion, as it would introduce an unwarranted restriction into FDA's implementation of the MRA and this regulation. In any case, even if FDA were to adopt the comment's suggestion, the intended purpose of the suggested change could easily be overcome if a U.S. division of a foreign CAB simply formed a new corporation, under the law of a U.S. State, with the United States as the principal place of business.

38. One comment noted that medical devices principally regulated by FDA's Center for Biologics Evaluation and Research (CBER) appear to have been excluded from the MRA.

The comment is correct in noting that no CBER-regulated devices are included in the lists appended to the Sectoral Annex on Medical Devices. CBER has the lead responsibility for 510(k) review for 23 medical device classifications. Adding some of these devices to the list of devices that FDA wishes to make eligible for review under the Annex, at this time, would require establishment of special handling procedures, training, and monitoring within CBER without the expectation of a meaningful number

of third party reviews. However, devices regulated by CBER under the device premarket notification provisions of the act (21 CFR 360(k)) might be considered for eligibility in the MRA program as experience and confidence develops.

39. A comment addressed issues of grammar and format and did not deal with substantive matters relevant to the MRA that would have any bearing on its content, issues, or outcome.

FDA declines to alter the text of the proposed rule in response to this comment. Throughout this rulemaking process FDA has attempted to adhere to the language contained in the MRA unless serious substantive matters were identified having bearing on the content, issues, or outcome of the MRA or this regulation. The nonsubstantive issues raised by this comment do not justify any amendments to this regulation.

III. Summary of Changes

1. In response to a comment, the title of the proposed regulation has been changed to the following: ''Part 26—Mutual Recognition of Pharmaceutical Good Manufacturing Practice Reports, Medical Device Quality System Audit Reports, and Certain Medical Device Product Evaluation Reports: the United States and the European Community.''

2. On its own initiative, FDA has determined that the language of proposed § 26.0 should be amended to provide additional and more precise explanation about the applicability of this regulation with regard to other U.S. agencies and the EC. Therefore, proposed § 26.0 has been amended to read as follows:

Section 26.0 General.

This part substantially reflects relevant provisions of the framework agreement and its sectoral annexes on pharmaceutical good manufacturing practices (GMP's) and medical devices entitled ''Agreement on Mutual Recognition Between the United States of America and the European Community'' (the MRA), signed in London on May 18, 1998. For codification purposes, certain provisions of the MRA have been modified for use in this part. This modification is done for purposes of clarity only and shall not affect the text of the MRA concluded between the United States and the European Community (EC), or the rights and obligations of the United States or the EC under that agreement. Whereas the parties to the MRA are the United States and the European Community (EC), this part is relevant only to the Food and Drug Administration's (FDA's) implementation of the MRA, including the sectoral annexes reflected in subparts A and B of this part. This part does not govern implementation of the MRA by the EC, which will implement the MRA in accordance with its internal procedures, nor does this part address implementation of the MRA by other concerned U.S. Federal agencies. For purposes of this part, the terms ''party'' or ''parties,'' where relevant to FDA's implementation of the MRA, should be considered as referring to FDA only. If the parties to the MRA subsequently amend or terminate the MRA, FDA will modify this part accordingly, using appropriate administrative procedures.

3. On its own initiative FDA has amended several sections of the proposed rule to more accurately describe the relationship between the provisions of this part and the provisions of the MRA. Specifically, §§ 26.6(d), 26.61, 26.73, 26.78, 26.79, and 26.81(d) have been appropriately changed to accomplish this purpose.

4. In response to one comment, Table 1 of the proposed rule concerning the product code for radiographic screens, § 892.1960, is amended in the final rule to reflect the correction of a typographical error: ''WAM'' is changed to read ''EAM.''

5. Other typographical errors and nonsubstantive changes in the MRA have been identified by FDA and the EC since the FDA proposed rule was published on April 10, 1998. Because FDA has endeavored to have this regulation reflect the text of the MRA as accurately as possible, the final rule has been amended to reflect all of these nonsubstantive changes. For example, in § 26.4, the reference is now ''European Community (EC), rather than ''European Union'' or ''EU,'' in accordance with the preference of the EC. The EC is the correct entity, as the EU is not a juridical entity.

6. The agency has amended the authority citation to refer to U.S. statutes on confidentiality (5 U.S.C. 552, 18 U.S.C. 1905, and 21 U.S.C. 331) as well as the new accredited persons provisions of the act (section 523, 21 U.S.C. 360m) added by FDAMA.

7. Under Appendix E of Subpart A (Elements to be Considered in Developing a Two-Way Alert System), for administrative reasons the contact points for FDA are changed from ''FDA's Division of Emergency and Investigational Operations'' to the following:

Biologics: Director, Office of Compliance and Biologics Quality (HFM–600), 1401 Rockville Pike, Rockville, MD 20852, phone: 301–827–6190, fax: 301–594–1944.

Human Drugs: Director, Office of Compliance (HFD–300), MPN I, 7520 Standish Pl., Rockville, MD 20855–2737, phone: 301–594–0054, fax: 301–594–2114.

Veterinary Drugs: Director, Office of Surveillance and Compliance (HFV–200), MPN II, 7500 Standish Pl., Rockville, MD 20855–2773, phone: 301–827–6644, fax: 301–594–1807.

8. Under § 26.1(c), the definition of Good Manufacturing Practices (GMP's) has been changed from the following:

(c) *Good Manufacturing Practices* (GMP's): [These GMP conceptual definitions are to be merged by the parties at a future date.]

(1) GMP's mean the requirements found in the respective legislations, regulations, and administrative provisions for methods to be used in, and the facilities or controls to be used for, the manufacturing, processing, packing, and/or holding of a drug to assure that such drug meets the requirements as to safety, and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

(2) GMP's are that part of quality assurance which ensures that products are consistently produced and controlled to quality standards. For the purpose of this subpart, GMP's include, therefore, the system whereby the manufacturer receives the specifications of the product and/or process from the marketing authorization/product authorization or license holder or applicant and ensures the product is made in compliance with its specifications (qualified person certification in the European Community (EC)).

to the following:

(c) *Good Manufacturing Practices* (GMP's): [The United States has clarified its interpretation that under the MRA, that only paragraph (c)(1) of this section has to be understood as the U.S. definition and paragraph (c)(2) as the EC definition.]

(1) GMP's mean the requirements found in the legislations, regulations, and administrative provisions for methods to be used in, and the facilities or controls to be used for, the manufacturing, processing, packing, and/or holding of a drug to assure that such drug meets the requirements as to safety, and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

(2) GMP's are that part of quality assurance which ensures that products are consistently produced and controlled to quality standards. For the purpose of this subpart, GMP's include, therefore, the system whereby the manufacturer receives the specifications of the product and/or process from the marketing authorization/product authorization or license holder or applicant and ensures the product is made in compliance with its specifications (qualified person certification in the EC).

The previous changes reflect discussions between FDA and European Commission officials. As a result of those discussions, the United States has clarified its interpretation that the first paragraph of Article 1(3) of the Sectoral Annex for Pharmaceutical GMP's, has to be understood as the U.S. definition and the second as the EC definition. The agency believes that these changes are appropriate because they clarify that the applicable definition under the MRA

will be consistent with the act and regulations (see, e.g., section 501(a)(2)(B) of the act; 21 U.S.C. 351(a)(2)(B)). Furthermore, the Sectoral Annex on Pharmaceutical GMP's, including its core concept of ''equivalence,'' does not require either party to change its definition or application of GMP's.

9. Changes have been made to the list of regulatory authorities contained in Appendix B of Subpart A (List of Authorities) as a result of the legal review carried out in the EC prior to finalizing the MRA. The European Commission amended its list of regulatory authorities contained in Appendix 2 of the Pharmaceutical GMP Annex of the MRA because the changes more correctly reflect the allocation of administrative competencies in the EC and its Member States and do not alter the activities to be carried out under the MRA.

10. Changes have been made to Table 2. of Appendix B of Subpart B of the rule. That table listed 42 class II medical devices to be included within the scope of product coverage at the beginning of the transition period. Four of the devices that were on the list cannot be reviewed by conformity assessment bodies under the MRA and this rule, because of a statutory prohibition in the act. Accordingly, the agreement will be brought into force without application to those four devices. Section 523 of the act prohibits ''accredited persons'' from performing review of a class II device that is intended to be permanently implantable, life sustaining, or life supporting, and review of such devices must be performed by FDA. This provision was recently added to the act by FDAMA. The agency recently determined that the following four devices are within the scope of the prohibition and have been removed from Table 2: AN 868.5925, powered emergency ventilator; OR 888.3020, intramedullary fixation rod; OR 888.3030, single/multiple component metallic bone fixation appliances and accessories; and OR 888.3040, smooth or threaded metallic bone fixation fastener. The United States has informed the EC of this situation and of the need to make appropriate amendments to the MRA promptly after its entry into force.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, under the Regulatory Flexibility Act (Pub. L. 96–354, as amended by Pub. L. 104–121), and under the Unfunded Mandates Reform Act (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on a substantial number of small entities. The Unfunded Mandates Reform Act requires agencies to prepare an assessment of anticipated costs and benefits before enacting any rule that may result in an expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) in any 1 year.

The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order and in these two statutes. Through this regulation, the agency sets out requirements through which it may normally endorse certain conformity assessment procedure reports. Such reports would be provided by equivalent EC Member State regulatory authorities for manufacturing site inspections to ascertain conformity with pharmaceutical GMP's and by equivalent CAB's for quality system audits and certain medical device premarket evaluations. Obtaining conformity assessment information in the manner described in the final rule is more efficient and cost-effective than the existing approach, where additional inspection efforts by FDA in foreign countries are necessary because foreign regulatory systems have not been found equivalent. The primary benefit of the final rule is to provide credible assurance that the increasing volume of EC Member States' imports into the United States meet pharmaceutical GMP requirements, and medical device quality system evaluation and certain premarket evaluation requirements, as specified in U.S. statutes and regulations. In the future, this credible assurance must be achievable with FDA resource expenditures that rise less than proportionately to the volume of trade.

In recent years, the credibility of the current approach has been strained as FDA's essentially constant foreign inspection capacity has been stretched over an expanding volume of imports from the EC. In the 3-year interval between 1994 and 1997, the value of EC pharmaceutical and medical device imports into the United States has nearly doubled from $5.5 billion to more than $10.7 billion. Growth has been greatest in pharmaceuticals, where annual EC exports have increased by more than $2 billion in each of the last 2 years. In 1997, FDA conducted one inspection in the EC for every $60 million in pharmaceutical exports to the United States, which is less than half the coverage intensity of 1994. In addition, the majority of these inspections have been preapproval in nature. Continuation of the current trend would further decrease FDA's coverage intensity to less than one inspection per $100 million in EC pharmaceutical exports by the year 2000. Equivalence with EC Member State regulatory systems would leverage FDA's regulatory resources so that necessary conformity assessments can be ensured despite higher volumes of future trade.

In addition to helping FDA cope with higher trade volumes, mutual recognition or equivalence-based agreements with exporting nations may permit FDA to redirect some of its inspectional resources to risk priorities not covered by such agreements. This flexibility would provide a more responsive level of U.S. consumer protection in the face of a changing global marketplace with inherently variable risk management priorities.

Another important benefit of the final rule would be the cost savings realized by the regulated industry, largely as a result of the sharing of inspection reports among equivalent regulatory authorities. This exchange, in turn, will minimize the need for duplicative inspections and permit individual firms to undergo fewer inspections of manufacturing sites. FDA does not have data on the average administrative cost incurred by manufacturers of pharmaceuticals (including biologicals) or medical devices as they participate in regulatory inspections, but it is likely that the avoidance of redundant inspections would generate cost savings. The final rule also may shorten product review times for regulated products as a result of the increased efficiency of premarket approval inspection activities and the third-party evaluation of certain medical devices. Quantification of these savings will be highly dependent on the specific countries that achieve equivalence and on the number of medical device audits and evaluations performed by CAB's under the MRA.

The costs of this regulation will have a greater impact on governmental regulatory agencies than on the regulated industry. These governmental costs involve both startup and operational components. FDA has not received additional government funding earmarked for achieving mutual

recognition agreements and, therefore, must proceed to implement these agreements as a concurrent function within normal day-to-day regulatory activities. The 3-year transition period reflects the necessity to absorb these startup costs within existing regulatory budgets. Some activities such as joint inspections may be reasonably easy to absorb as concurrent functions that do not require additional funding, while others such as developing and maintaining systems for routine information exchange may involve new activities. These absorbed governmental costs will fall heavily on FDA, as it must assess equivalence of multiple EC Member States and notified bodies.

For FDA, the absorption of these startup costs will be easier with respect to those EC Member States with which the United States already has a large volume of trade in the products in question, where FDA already conducts enough inspections to have gathered a general understanding of the requirements and regulatory practices of the exporting country. From this perspective, the pace and priorities for mutual recognition agreements during the transition period will be affected by FDA's ability to conduct these processes as concurrent functions within current activities.

In the longer run, an operational system of mutual recognition agreements could pose additional costs or problems for regulatory authorities of exporting countries if equivalence requires a frequency, focus or content of inspections not presently included in regulatory requirements of the exporting nation. For example, Country A may not be able to provide the frequency of medical device inspections desired by Country B without conducting inspections beyond those required for Country A's domestic inspection strategy. Conversely, Country B may not be able to provide to Country A adequate details of the quality of pharmaceutical source materials, because Country B does not have inspectional authority over pharmaceutical starting materials. To the extent that such costs or problems are insignificant or offset by other savings, they will not be obstacles to reaching agreement on equivalence.

This rule is not expected to involve any new incremental costs to the affected industries. Although joint inspections during the transition period may create the appearance of more regulatory effort, they would not impose additional costs on the firms inspected. FDA does not anticipate an increase in the total number of EC inspections, and in fact, the coverage intensity of FDA inspections in the EC would be expected to continue to fall during the transition period, as it has for the past several years. Other activities related to equivalence determinations, such as the procedures for exchanging information and reports, focus on the interface and coordination among regulatory agencies and, as such, will not affect industry in a cost context.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities unless the rule is not expected to have a significant economic impact on a substantial number of small entities. As this final regulation is not expected to impose costs on the regulated industry, and FDA has received no comments that would indicate otherwise, the agency certifies that this rule will not have a significant impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The Unfunded Mandates Act of 1995 requires that agencies prepare an assessment of the anticipated costs and benefits before issuing any final rule that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any 1 year. This rule does not impose any mandates on State, local or tribal governments, or the private sector that would result in an annual expenditure of $100 million or more. Therefore, no further analysis is appropriate for this requirement.

V. Paperwork Reduction Act of 1995

This final rule does not contain any information collection provisions that would be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

VI. References

1. The 1992 ''Report of the Task Force on International Harmonization'' is available from the National Technical Information Service, Vienna, VA; Order # PB93128155.

2. FDA's Compliance Policy Guides ''Sec. 100.900, International Memoranda of Understanding (CPG 7150.19)'' is available from the National Technical Information Service, Vienna, VA 22161 (Order # PB 96–915499INZ) or can be found on FDA's website at the following location: ''www.fda.gov/ora/compliance_ref/cpg/cpgch1.htm#sec.100.900''.

3. The 1997 ''Summary Report of the Foreign Inspection Working Group'' is available from the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

VII. Comparison Table

The following table shows the relationship of the MRA Articles and the sections of the Code of Federal Regulations (CFR) under this rule:

TABLE 1.— RELATIONSHIP OF THE MRA ARTICLES TO SECTIONS IN THE CFR

MRA Article	CFR Section
Sectoral Annex for Pharmaceutical GMP's	Subpart A
Article 1	26.1
Article 2	26.2
Article 3	26.3
Article 4	26.4
Article 5	26.5
Article 6	26.6
Article 7	26.7
Article 8	26.8
Article 9	26.9
Article 10	26.10
Article 11	26.11
Article 12	26.12
Article 13	26.13
Article 14	26.14
Article 15	26.15

TABLE 1.— RELATIONSHIP OF THE MRA ARTICLES TO SECTIONS IN THE CFR—Continued

MRA Article	CFR Section
Sectoral Annex for Pharmaceutical GMP's	Subpart A
Article 16	26.16
Article 17	26.17
Article 18	26.18
Article 19	26.19
Article 20	26.20
Article 21	26.21
Appendix 1	Appendix A
Appendix 2	Appendix B
Appendix 3	Appendix C
Appendix 4	Appendix D
Appendix 5	Appendix E

MRA Article	CFR Section
Sectoral Annex on Medical Devices	Subpart B
Article 1	26.31
Article 2	26.32
Article 3	26.33
Article 4	26.34
Article 5	26.35
Article 6	26.36
Article 7	26.37
Article 8	26.38
Article 9	26.39
Article 10	26.40
Article 11	26.41
Article 12	26.42
Article 13	26.43
Article 14	26.44
Article 15	26.45
Article 16	26.46
Article 17	26.47
Article 18	26.48
Article 19	26.49
Article 20	26.50
Appendix 1	Appendix A
Appendix 2 and Tables 1–3	Appendix B and Tables 1–3
Appendix 3 [Reserved]	Appendix C [Reserved]
Appendix 4 [Reserved]	Appendix D [Reserved]
Appendix 5 [Reserved]	Appendix E [Reserved]
Appendix 6 [Reserved]	Appendix F [Reserved]

MRA Article	CFR Section
Framework Agreement	Subpart C
Article 1	26.60
Article 2	26.61
Article 3	26.62
Article 4	26.63
Article 5	26.64
Article 6	26.65
Article 7	26.66
Article 8	26.67
Article 9	26.68
Article 10	26.69
Article 11	26.70
Article 12	26.71
Article 13	26.72
Article 14	26.73
Article 15	26.74
Article 16	26.75
Article 17	26.76
Article 18	26.77

MRA Article	CFR Section
Framework Agreement	Subpart C
Article 19	26.78
Article 20	26.79
Article 21	26.80
Article 22	26.81

List of Subjects in 21 CFR Part 26

Animal and human drugs, Biologicals, Devices, Exports, Imports, Incorporation by reference, and Inspections.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended by adding part 26 to read as follows:

PART 26—MUTUAL RECOGNITION OF PHARMACEUTICAL GOOD MANUFACTURING PRACTICE REPORTS, MEDICAL DEVICE QUALITY SYSTEM AUDIT REPORTS, AND CERTAIN MEDICAL DEVICE PRODUCT EVALUATION REPORTS: UNITED STATES AND THE EUROPEAN COMMUNITY

Sec.

26.0 General.

Subpart A—Specific Sector Provisions for Pharmaceutical Good Manufacturing Practices

26.1 Definitions.
26.2 Purpose.
26.3 Scope.
26.4 Product coverage.
26.5 Length of transition period.
26.6 Equivalence assessment.
26.7 Participation in the equivalence assessment and determination.
26.8 Other transition activities.
26.9 Equivalence determination.
26.10 Regulatory authorities not listed as currently equivalent.
26.11 Start of operational period.
26.12 Nature of recognition of inspection reports.
26.13 Transmission of postapproval inspection reports.
26.14 Transmission of preapproval inspection reports.
26.15 Monitoring continued equivalence.
26.16 Suspension.
26.17 Role and composition of the Joint Sectoral Committee.
26.18 Regulatory collaboration.
26.19 Information relating to quality aspects.
26.20 Alert system.
26.21 Safeguard clause.
Appendix A of Subpart A—List of Applicable Laws, Regulations, and Administrative Provisions.
Appendix B of Subpart A—List of Authorities.
Appendix C of Subpart A—Indicative List of Products Covered by Subpart A.
Appendix D of Subpart A—Criteria for Assessing Equivalence for Post- and Preapproval.
Appendix E of Subpart A—Elements to be Considered in Developing a Two-Way Alert System.

Subpart B—Specific Sector Provisions for Medical Devices

26.31 Purpose.
26.32 Scope.
26.33 Product coverage.
26.34 Regulatory authorities.
26.35 Length and purpose of transition period.
26.36 Listing of CAB's.
26.37 Confidence building activities.
26.38 Other transition period activities.
26.39 Equivalence assessment.
26.40 Start of the operational period.
26.41 Exchange and endorsement of quality system evaluation reports.
26.42 Exchange and endorsement of product evaluation reports.
26.43 Transmission of quality system evaluation reports.
26.44 Transmission of product evaluation reports.
26.45 Monitoring continued equivalence.
26.46 Listing of additional CAB's.
26.47 Role and composition of the Joint Sectoral Committee.
26.48 Harmonization.
26.49 Regulatory cooperation.
26.50 Alert system and exchange of postmarket vigilance reports.
Appendix A of Subpart B—Relevant Legislation, Regulations, and Procedures.
Appendix B of Subpart B—Scope of Product Coverage.
Appendix C of Subpart B [Reserved].
Appendix D of Subpart B [Reserved].
Appendix E of Subpart B [Reserved].
Appendix F of Subpart B [Reserved].

Subpart C—''Framework'' Provisions

26.60 Definitions.
26.61 Purpose of this part.
26.62 General obligations.
26.63 General coverage of this part.
26.64 Transitional arrangements.
26.65 Designating authorities.
26.66 Designation and listing procedures.
26.67 Suspension of listed conformity assessment bodies.
26.68 Withdrawal of listed conformity assessment bodies.
26.69 Monitoring of conformity assessment bodies.
26.70 Conformity assessment bodies.
26.71 Exchange of information.
26.72 Sectoral contact points.
26.73 Joint Committee.
26.74 Preservation of regulatory authority.
26.75 Suspension of recognition obligations.
26.76 Confidentiality.
26.77 Fees.
26.78 Agreements with other countries.
26.79 Territorial application.
26.80 Entry into force, amendment, and termination.
26.81 Final provisions.

Authority: 5 U.S.C. 552; 15 U.S.C. 1453, 1454, 1455; 18 U.S.C. 1905; 21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 360c, 360d, 360e, 360f, 360g, 360h, 360i, 360j, 360l, 360m, 371, 374, 381, 382, 383, 393; 42 U.S.C. 216, 241, 242l, 262, 264, 265.

§ 26.0 General.

This part substantially reflects relevant provisions of the framework agreement and its sectoral annexes on pharmaceutical good manufacturing practices (GMP's) and medical devices of the ''Agreement on Mutual Recognition Between the United States of America and the European Community'' (the MRA), signed at London May 18, 1998. For codification purposes, certain provisions of the MRA have been modified for use in this part. This modification is done for purposes of clarity only and shall not affect the text of the MRA concluded between the United States and the European Community (EC), or the rights and obligations of the United States or the EC under that agreement. Whereas the parties to the MRA are the United States and EC, this part is relevant only to the Food and Drug Administration's (FDA's) implementation of the MRA, including the sectoral annexes reflected in subparts A and B of this part. This part does not govern implementation of the MRA by the EC, which will implement the MRA in accordance with its internal procedures, nor does this part address implementation of the MRA by other concerned U.S. Federal agencies. For purposes of this part, the terms ''party'' or ''parties,'' where relevant to FDA's implementation of the MRA, should be considered as referring to FDA only. If the parties to the MRA subsequently amend or terminate the MRA, FDA will modify this part accordingly, using appropriate administrative procedures.

Subpart A—Specific Sector Provisions for Pharmaceutical Good Manufacturing Practices

§ 26.1 Definitions.

(a) *Enforcement* means action taken by an authority to protect the public from products of suspect quality, safety, and effectiveness or to assure that products are manufactured in compliance with appropriate laws, regulations, standards, and commitments made as part of the approval to market a product.

(b) *Equivalence* of the regulatory systems means that the systems are sufficiently comparable to assure that the process of inspection and the ensuing inspection reports will provide adequate information to determine whether respective statutory and regulatory requirements of the authorities have been fulfilled. Equivalence does not require that the respective regulatory systems have identical procedures.

(c) *Good Manufacturing Practices* (GMP's). [The United States has clarified its interpretation that under the MRA, that only paragraph (c)(1) of this section has to be understood as the U.S. definition and paragraph (c)(2) as the EC definition.]

(1) GMP's mean the requirements found in the legislations, regulations, and administrative provisions for methods to be used in, and the facilities or controls to be used for, the manufacturing, processing, packing, and/or holding of a drug to assure that such drug meets the requirements as to safety, and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

(2) GMP's are that part of quality assurance which ensures that products are consistently produced and controlled to quality standards. For the purpose of this subpart, GMP's include, therefore, the system whereby the manufacturer receives the specifications of the product and/or process from the marketing authorization/product authorization or license holder or applicant and ensures the product is made in compliance with its specifications (qualified person certification in the EC).

(d) *Inspection* means an onsite evaluation of a manufacturing facility to determine whether such manufacturing facility is operating in compliance with GMP's and/or commitments made as part of the approval to market a product.

(e) *Inspection report* means the written observations and GMP's compliance assessment completed by an authority listed in Appendix B of this subpart.

(f) *Regulatory system* means the body of legal requirements for GMP's, inspections, and enforcements that ensure public health protection and legal authority to assure adherence to these requirements.

§ 26.2 Purpose.

The provisions of this subpart govern the exchange between the parties and normal endorsement by the receiving regulatory authority of official good manufacturing practices (GMP's) inspection reports after a transitional period aimed at determination of the equivalence of the regulatory systems of the parties, which is the cornerstone of this subpart.

§ 26.3 Scope.

(a) The provisions of this subpart shall apply to pharmaceutical inspections carried out in the United States and Member States of the European Community (EC) before products are marketed (hereafter referred to as ''preapproval inspections'') as well as during their marketing (hereafter referred to as ''postapproval inspections'').

(b) Appendix A of this subpart names the laws, regulations, and administrative provisions governing these inspections and the good manufacturing practices (GMP's) requirements.

(c) Appendix B of this subpart lists the authorities participating in activities under this subpart.

(d) Sections 26.65, 26.66, 26.67, 26.68, 26.69, and 26.70 of subpart C of this part do not apply to this subpart.

§ 26.4 Product coverage.

(a) The provisions of this subpart will apply to medicinal products for human or animal use, intermediates and starting materials (as referred to in the European Community (EC)) and to drugs for human or animal use, biological products for human use, and active pharmaceutical ingredients (as referred to in the United States), only to the extent they are regulated by the authorities of both parties as listed in Appendix B of this subpart.

(b) Human blood, human plasma, human tissues and organs, and veterinary immunologicals (under 9 CFR 101.2, ''veterinary immunologicals'' are referred to as ''veterinary biologicals'') are excluded from the scope of this subpart. Human plasma derivatives (such as immunoglobulins and albumin), investigational medicinal products/new drugs, human radiopharmaceuticals, and medicinal gases are also excluded during the transition phase; their situation will be reconsidered at the end of the transition period. Products regulated by the Food and Drug Administration's Center for Biologics Evaluation and Research as devices are not covered under this subpart.

(c) Appendix C of this subpart contains an indicative list of products covered by this subpart.

§ 26.5 Length of transition period.

A 3-year transition period will start immediately after the effective date described in § 26.80(a).

§ 26.6 Equivalence assessment.

(a) The criteria to be used by the parties to assess equivalence are listed in Appendix D of this subpart. Information pertaining to the criteria under European Community (EC) competence will be provided by the EC.

(b) The authorities of the parties will establish and communicate to each other their draft programs for assessing the equivalence of the respective regulatory systems in terms of quality assurance of the products and consumer protection. These programs will be carried out, as deemed necessary by the regulatory authorities, for post- and preapproval inspections and for various product classes or processes.

(c) The equivalence assessment shall include information exchanges (including inspection reports), joint training, and joint inspections for the purpose of assessing regulatory systems and the authorities' capabilities. In conducting the equivalence assessment, the parties will ensure that efforts are made to save resources.

(d) Equivalence assessment for authorities added to Appendix B of this subpart after the effective date described in § 26.80(a) will be conducted as described in this subpart, as soon as practicable.

§ 26.7 Participation in the equivalence assessment and determination.

The authorities listed in Appendix B of this subpart will actively participate in these programs to build a sufficient body of evidence for their equivalence determination. Both parties will exercise good faith efforts to complete equivalence assessment as expeditiously as possible to the extent the resources of the authorities allow.

§ 26.8 Other transition activities.

As soon as possible, the authorities will jointly determine the essential information which must be present in inspection reports and will cooperate to develop mutually agreed inspection report format(s).

§ 26.9 Equivalence determination.

(a) Equivalence is established by having in place regulatory systems covering the criteria referred to in Appendix D of this subpart, and a demonstrated pattern of consistent performance in accordance with these criteria. A list of authorities determined as equivalent shall be agreed to by the Joint Sectoral Committee at the end of the transition period, with reference to any limitation in terms of inspection type (e.g., postapproval or preapproval) or product classes or processes.

(b) The parties will document insufficient evidence of equivalence, lack of opportunity to assess equivalence or a determination of nonequivalence, in sufficient detail to allow the authority being assessed to know how to attain equivalence.

§ 26.10 Regulatory authorities not listed as currently equivalent.

Authorities not currently listed as equivalent, or not equivalent for certain types of inspections, product classes or processes may apply for reconsideration of their status once the necessary corrective measures have been taken or additional experience is gained.

§ 26.11 Start of operational period.

(a) The operational period shall start at the end of the transition period and its provisions apply to inspection reports generated by authorities listed as equivalent for the inspections performed in their territory.

(b) In addition, when an authority is not listed as equivalent based on adequate experience gained during the transition period, the Food and Drug Administration (FDA) will accept for normal endorsement (as provided in § 26.12) inspection reports generated as a result of inspections conducted jointly by that authority on its territory and another authority listed as equivalent, provided that the authority of the Member State in which the inspection is performed can guarantee enforcement of the findings of the inspection report and require that corrective measures be taken when necessary. FDA has the option to participate in these inspections, and based on experience gained during the transition period, the parties will agree on procedures for exercising this option.

(c) In the European Community (EC), the qualified person will be relieved of responsibility for carrying the controls laid down in Article 22 paragraph 1(b) of Council Directive 75/319/EEC (see Appendix A of this subpart) provided that these controls have been carried out in the United States and that each batch/lot is accompanied by a batch certificate (in accordance with the World Health Organization Certification Scheme on the Quality of Medicinal Products) issued by the manufacturer certifying that the product complies with requirements of the marketing authorization and signed by the person responsible for releasing the batch/lot.

§ 26.12 Nature of recognition of inspection reports.

(a) Inspection reports (containing information as established under § 26.8), including a good manufacturing practice (GMP) compliance assessment, prepared by authorities listed as equivalent, will be provided to the authority of the importing party. Based on the determination of equivalence in light of the experience gained, these inspection reports will normally be endorsed by the authority of the importing party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies or inadequacies in an inspection report, quality defects identified in the postmarket surveillance or other specific evidence of serious concern in relation to product quality or consumer safety. In such cases, the authority of the importing party may request clarification from the authority of the exporting party which may lead to a request for reinspection. The authorities will endeavor to respond to requests for clarification in a timely manner.

(b) Where divergence is not clarified in this process, an authority of the importing country may carry out an inspection of the production facility.

§ 26.13 Transmission of postapproval inspection reports.

Postapproval good manufacturing practice (GMP) inspection reports concerning products covered by this subpart will be transmitted to the authority of the importing country within 60-calendar days of the request. Should a new inspection be needed, the inspection report will be transmitted within 90-calendar days of the request.

§ 26.14 Transmission of preapproval inspection reports.

(a) A preliminary notification that an inspection may have to take place will be made as soon as possible.

(b) Within 15-calendar days, the relevant authority will acknowledge receipt of the request and confirm its ability to carry out the inspection. In the European Community (EC), requests will be sent directly to the relevant authority, with a copy to the European Agency for the Evaluation of Medicinal Products (EMEA). If the authority receiving the request cannot carry out the inspection as requested, the requesting authority shall have the right to conduct the inspection.

(c) Reports of preapproval inspections will be sent within 45-calendar days of the request that transmitted the appropriate information and detailed the precise issues to be addressed during the inspection. A shorter time may be necessary in exceptional cases and these will be described in the request.

§ 26.15 Monitoring continued equivalence.

Monitoring activities for the purpose of maintaining equivalence shall include review of the exchange of inspection reports and their quality and timeliness; performance of a limited number of joint inspections; and the conduct of common training sessions.

§ 26.16 Suspension.

(a) Each party has the right to contest the equivalence of a regulatory authority. This right will be exercised in an objective and reasoned manner in writing to the other party.

(b) The issue shall be discussed in the Joint Sectoral Committee promptly upon such notification. Where the Joint Sectoral Committee determines that verification of equivalence is required, it may be carried out jointly by the parties in a timely manner, under § 26.6.

(c) Efforts will be made by the Joint Sectoral Committee to reach unanimous consent on the appropriate action. If agreement to suspend is reached in the Joint Sectoral Committee, an authority may be suspended immediately thereafter. If no agreement is reached in the Joint Sectoral Committee, the matter is referred to the Joint Committee as described in § 26.73. If no unanimous consent is reached within 30 days after such notification, the contested authority will be suspended.

(d) Upon the suspension of authority previously listed as equivalent, a party is no longer obligated to normally endorse the inspection reports of the suspended authority. A party shall continue to normally endorse the inspection reports of that authority prior to suspension, unless the authority of the receiving party decides otherwise based on health or safety considerations. The suspension will remain in effect until unanimous consent has been reached by the parties on the future status of that authority.

§ 26.17 Role and composition of the Joint Sectoral Committee.

(a) A Joint Sectoral Committee is set up to monitor the activities under both the transitional and operational phases of this subpart.

(b) The Joint Sectoral Committee will be cochaired by a representative of the Food and Drug Administration (FDA) for the United States and a representative of the European Community (EC) who each will have one vote. Decisions will be taken by unanimous consent.

(c) The Joint Sectoral Committee's functions will include:

(1) Making a joint assessment, which must be agreed by both parties, of the equivalence of the respective authorities;

(2) Developing and maintaining the list of equivalent authorities, including any limitation in terms of inspecting type or products, and communicating the list to all authorities and the Joint Committee;

(3) Providing a forum to discuss issues relating to this subpart, including concerns that an authority may be no longer equivalent and opportunity to review product coverage; and

(4) Consideration of the issue of suspension.

(d) The Joint Sectoral Committee shall meet at the request of either party and, unless the cochairs otherwise agree, at least once each year. The Joint Committee will be kept informed of the agenda and conclusions of meetings of the Joint Sectoral Committee.

§ 26.18 Regulatory collaboration.

(a) The parties and authorities shall inform and consult one another, as permitted by law, on proposals to introduce new controls or to change existing technical regulations or inspection procedures and to provide the opportunity to comment on such proposals.

(b) The parties shall notify each other in writing of any changes to Appendix B of this subpart.

§ 26.19 Information relating to quality aspects.

The authorities will establish an appropriate means of exchanging information on any confirmed problem reports, corrective actions, recalls, rejected import consignments, and other regulatory and enforcement problems for products subject to this subpart.

§ 26.20 Alert system.

(a) The details of an alert system will be developed during the transitional period. The system will be maintained in place at all times. Elements to be considered in developing such a system are described in Appendix E of this subpart.

(b) Contact points will be agreed between both parties to permit authorities to be made aware with the appropriate speed in case of quality defect, recalls, counterfeiting, and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the product.

§ 26.21 Safeguard clause.

Each party recognizes that the importing country has a right to fulfill its legal responsibilities by taking actions necessary to ensure the protection of human and animal health at the level of protection it deems appropriate. This includes the suspension of the distribution, product detention at the border of the importing country, withdrawal of the batches and any request for additional information or inspection as provided in § 26.12.

Appendix A of Subpart A—List of Applicable Laws, Regulations, and Administrative Provisions.

1. For the European Community (EC):

[Copies of EC documents may be obtained from the European Document Research, 1100 17th St. NW., suite 301, Washington, DC 20036. EC documents may be viewed on the European Commission Pharmaceuticals Units web site at ''http://dg3.eudra.org''.]

Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation, or administrative action relating to proprietary medicinal products as extended, widened, and amended.

Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products as extended, widened and amended.

Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products, as widened and amended.

Commission Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use.

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products.

Council Regulation EEC No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.

Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use.

Guide to Good Distribution Practice (94/C 63/03).

Current version of the Guide to Good Manufacturing Practice, Rules Governing Medicinal Products in the European Community, Volume IV.

2. For the United States:

[Copies of FDA documents may be obtained from the Government Printing Office, 1510 H St. NW., Washington, DC 20005. FDA documents, except the FDA Compliance Program Guidance Manual, may be viewed on FDA's Internet web site at ''http://www.FDA.gov''.]

Relevant sections of the United States Federal Food, Drug, and Cosmetic Act and the United States Public Health Service Act.

Relevant sections of Title 21, United States Code of Federal Regulations (CFR) Parts 1–99, Parts 200–299, Parts 500–599, and Parts 600–799.

Relevant sections of the FDA Investigations Operations Manual, the FDA Regulatory Procedures Manual, the FDA Compliance Policy Guidance Manual, the FDA Compliance Program Guidance Manual, and other FDA guidances.

Appendix B of Subpart A—List of Authorities.

1. For the United States: In the United States, the regulatory authority is the Food and Drug Administration.

2. For the European Community: In the European Community, the regulatory authorities are the following:

Belgium: Inspection générale de la Pharmacie, Algemene Farmaceutische Inspectie.

Denmark: Laegemiddelstyrelsen.

Germany: Bundesministerium für Gesundheit for immunologicals: Paul-Ehrlich-Institut, Federal Agency for Sera and Vaccines.

Greece: Εθνικος Οργανισμος Φαρμακου, Ministry of Health and Welfare, National Drug Organization (E.O.F).

Spain: For medicinal products for human use: Ministerio de Sanidad y Consumo, Subdirección General de Control Farmacéutico. For medicinal products for veterinary use: Ministerio de Agricultura, Pesca y Alimentación (MAPA), Dirección General de la Producción Agraria.

France: For medicinal products for human use: Agence du Médicament. For veterinary medicinal products: Agence Nationale du Médicament Vétérinaire.

Ireland: Irish Medicines Board.

Italy: For medicinal products for human use: Ministero della Sanità, Dipartimento Farmaci e Farmacovigilanza. For medicinal products for veterinary use: Ministero della Sanità, Dipartimento alimenti e nutrizione e sanità pubblica veterinaria–Div. IX.

Luxembourg: Division de la Pharmacie et des Médicaments.

Netherlands: Staat der Nederlanden.

Austria: Bundesministerium für Arbeit, Gesundheit und Soziales.

Portugal: Instituto da Farmácia e do Medicamento (INFARMED).

Finland: Lääkelaitos/Läkemedelsverket (National Agency for Medicines).

Sweden: Läkemedelsverket–Medical Products Agency.

United Kingdom: For human use and veterinary (non-immunologicals): Medicines Control Agency. For veterinary immunologicals: Veterinary Medicines Directorate.

European Community: Commission of the European Communities. European Agency

for the Evaluation of Medicinal Products (EMEA).

Appendix C of Subpart A—Indicative List of Products Covered by Subpart A.

Recognizing that precise definition of medicinal products and drugs are to be found in the legislation referred to above, an indicative list of products covered by this arrangement is given below:

- human medicinal products including prescription and nonprescription drugs;
- human biologicals including vaccines, and immunologicals;
- veterinary pharmaceuticals, including prescription and nonprescription drugs, with the exclusion of veterinary immunologicals (Under 9 CFR 101.2 ''veterinary immunologicals'' are referred to as ''veterinary biologicals'');
- premixes for the preparation of veterinary medicated feeds (EC), Type A medicated articles for the preparation of veterinary medicated feeds (United States);
- intermediate products and active pharmaceutical ingredients or bulk pharmaceuticals (United States)/starting materials (EC).

Appendix D of Subpart A—Criteria for Assessing Equivalence for Post- and Preapproval.

I. Legal/Regulatory authority and structures and procedures providing for post- and preapproval:

A. Appropriate statutory mandate and jurisdiction.
B. Ability to issue and update binding requirements on GMP's and guidance documents.
C. Authority to make inspections, review and copy documents, and to take samples and collect other evidence.
D. Ability to enforce requirements and to remove products found in violation of such requirements from the market.
E. Substantive current good manufacturing requirements.
F. Accountability of the regulatory authority.
G. Inventory of current products and manufacturers.
H. System for maintaining or accessing inspection reports, samples and other analytical data, and other firm/product information relating to matters covered by subpart A of this part.

II. Mechanisms in place to assure appropriate professional standards and avoidance of conflicts of interest.

III. Administration of the regulatory authority:

A. Standards of education/qualification and training.
B. Effective quality assurance systems measures to ensure adequate job performance.
C. Appropriate staffing and resources to enforce laws and regulations.

IV. Conduct of inspections:

A. Adequate preinspection preparation, including appropriate expertise of investigator/team, review of firm/product and databases, and availability of appropriate inspection equipment.
B. Adequate conduct of inspection, including statutory access to facilities, effective response to refusals, depth and competence of evaluation of operations, systems and documentation; collection of evidence; appropriate duration of inspection and completeness of written report of observations to firm management.
C. Adequate postinspection activities, including completeness of inspectors' report, inspection report review where appropriate, and conduct of followup inspections and other activities where appropriate, assurance of preservation and retrieval of records.

V. Execution of regulatory enforcement actions to achieve corrections, designed to prevent future violations, and to remove products found in violation of requirements from the market.

VI. Effective use of surveillance systems:

A. Sampling and analysis.
B. Recall monitoring.
C. Product defect reporting system.
D. Routine surveillance inspections.
E. Verification of approved manufacturing process changes to marketing authorizations/approved applications.

VII. Additional specific criteria for preapproval inspections:

A. Satisfactory demonstration through a jointly developed and administered training program and joint inspections to assess the regulatory authorities' capabilities.
B. Preinspection preparation includes the review of appropriate records, including site plans and drug master file or similar documentation to enable adequate inspections.
C. Ability to verify chemistry, manufacturing, and control data supporting an application is authentic and complete.
D. Ability to assess and evaluate research and development data as scientifically sound, especially transfer technology of pilot, scale up and full scale production batches.
E. Ability to verify conformity of the onsite processes and procedures with those described in the application.
F. Review and evaluate equipment installation, operational and performance qualification data, and evaluate test method validation.

Appendix E of Subpart A—Elements to be Considered in Developing a Two-Way Alert System.

1. Documentation

- Definition of a crisis/emergency and under what circumstances an alert is required
- Standard Operating Procedures (SOP's)
- Mechanism of health hazards evaluation and classification
- Language of communication and transmission of information

2. Crisis Management System

- Crisis analysis and communication mechanisms
- Establishment of contact points
- Reporting mechanisms

3. Enforcement Procedures

- Followup mechanisms
- Corrective action procedures

4. Quality Assurance System

- Pharmacovigilance programme
- Surveillance/monitoring of implementation of corrective action

5. Contact Points

For the purpose of subpart A of this part, the contact points for the alert system will be:

A. For the European Community:

the Executive Director of the European Agency for the Evaluation of Medicinal Products, 7, Westferry Circus, Canary Wharf, UK - London E14 4HB, England. Telephone 44–171–418 8400, Fax 418–8416.

B. For the United States :

Biologics: Director, Office of Compliance and Biologics Quality (HFM–600), 1401 Rockville Pike, Rockville, MD 20852, phone: 301–827–6190, fax: 301–594-1944.
Human Drugs: Director, Office of Compliance (HFD–300), MPN I, 7520 Standish Pl., Rockville, MD 20855–2737, phone: 301–594–0054, fax: 301–594–2114.
Veterinary Drugs: Director, Office of Surveillance and Compliance (HFV–200), MPN II, 7500 Standish Pl., Rockville, MD 20855–2773, phone: 301–827–6644, fax: 301–594–1807.

Subpart B—Specific Sector Provisions for Medical Devices

§ 26.31 Purpose.

(a) The purpose of this subpart is to specify the conditions under which a party will accept the results of quality system-related evaluations and inspections and premarket evaluations of the other party with regard to medical devices as conducted by listed conformity assessment bodies (CAB's) and to provide for other related cooperative activities.

(b) This subpart is intended to evolve as programs and policies of the parties evolve. The parties will review this subpart periodically, in order to assess progress and identify potential enhancements to this subpart as Food and Drug Administration (FDA) and European Community (EC) policies evolve over time.

§ 26.32 Scope.

(a) The provisions of this subpart shall apply to the exchange and, where appropriate, endorsement of the following types of reports from conformity assessment bodies (CAB's) assessed to be equivalent:

(1) Under the U.S. system, surveillance/postmarket and initial/preapproval inspection reports;

(2) Under the U.S. system, premarket (510(k)) product evaluation reports;

(3) Under the European Community (EC) system, quality system evaluation reports; and

(4) Under the EC system, EC type examination and verification reports.

(b) Appendix A of this subpart names the legislation, regulations, and related procedures under which:

(1) Products are regulated as medical devices by each party;

(2) CAB's are designated and confirmed; and

(3) These reports are prepared.

(c) For purposes of this subpart, equivalence means that: CAB's in the EC are capable of conducting product and quality systems evaluations against U.S. regulatory requirements in a manner equivalent to those conducted by FDA; and CAB's in the United States are capable of conducting product and quality systems evaluations against EC regulatory requirements in a manner equivalent to those conducted by EC CAB's.

§ 26.33 Product coverage.

(a) There are three components to this subpart each covering a discrete range of products:

(1) *Quality System Evaluations*. U.S.-type surveillance/postmarket and initial/preapproval inspection reports and European Community (EC)-type quality system evaluation reports will be exchanged with regard to all products regulated under both U.S. and EC law as medical devices.

(2) *Product Evaluation*. U.S.-type premarket (510(k)) product evaluation reports and EC-type-testing reports will be exchanged only with regard to those products classified under the U.S. system as Class I/Class II-Tier 2 medical devices which are listed in Appendix B of this subpart.

(3) *Postmarket Vigilance Reports*. Postmarket vigilance reports will be exchanged with regard to all products regulated under both U.S. and EC law as medical devices.

(b) Additional products and procedures may be made subject to this subpart by agreement of the parties.

§ 26.34 Regulatory authorities.

The regulatory authorities shall have the responsibility of implementing the provisions of this subpart, including the designation and monitoring of conformity assessment bodies (CAB's). Regulatory authorities will be specified in Appendix C of this subpart. Each party will promptly notify the other party in writing of any change in the regulatory authority for a country.

§ 26.35 Length and purpose of transition period.

There will be a 3-year transition period immediately following the date described in § 26.80(a). During the transition period, the parties will engage in confidence-building activities for the purpose of obtaining sufficient evidence to make determinations concerning the equivalence of conformity assessment bodies (CAB's) of the other party with respect to the ability to perform quality system and product evaluations or other reviews resulting in reports to be exchanged under this subpart.

§ 26.36 Listing of CAB's.

Each party shall designate conformity assessment bodies (CAB's) to participate in confidence building activities by transmitting to the other party a list of CAB's which meet the criteria for technical competence and independence, as identified in Appendix A of this subpart. The list shall be accompanied by supporting evidence. Designated CAB's will be listed in Appendix D of this subpart for participation in the confidence building activities once confirmed by the importing party. Nonconfirmation would have to be justified based on documented evidence.

§ 26.37 Confidence building activities.

(a) At the beginning of the transitional period, the Joint Sectoral Group will establish a joint confidence building program calculated to provide sufficient evidence of the capabilities of the designated conformity assessment bodies (CAB's) to perform quality system or product evaluations to the specifications of the parties.

(b) The joint confidence building program should include the following actions and activities:

(1) Seminars designed to inform the parties and CAB's about each party's regulatory system, procedures, and requirements;

(2) Workshops designed to provide the parties with information regarding requirements and procedures for the designation and surveillance of CAB's;

(3) Exchange of information about reports prepared during the transition period;

(4) Joint training exercises; and

(5) Observed inspections.

(c) During the transition period, any significant problem that is identified with a CAB may be the subject of cooperative activities, as resources allow and as agreed to by the regulatory authorities, aimed at resolving the problem.

(d) Both parties will exercise good faith efforts to complete the confidence building activities as expeditiously as possible to the extent that the resources of the parties allow.

(e) Both the parties will each prepare annual progress reports which will describe the confidence building activities undertaken during each year of the transition period. The form and content of the reports will be determined by the parties through the Joint Sectoral Committee.

§ 26.38 Other transition period activities.

(a) During the transition period, the parties will jointly determine the necessary information which must be present in quality system and product evaluation reports.

(b) The parties will jointly develop a notification and alert system to be used in case of defects, recalls, and other problems concerning product quality that could necessitate additional actions (e.g., inspections by the parties of the importing country) or suspension of the distribution of the product.

§ 26.39 Equivalence assessment.

(a) In the final 6 months of the transition period, the parties shall proceed to a joint assessment of the equivalence of the conformity assessment bodies (CAB's) that participated in the confidence building activities. CAB's will be determined to be equivalent provided they have demonstrated proficiency through the submission of a sufficient number of adequate reports. CAB's may be determined to be equivalent with regard to the ability to perform any type of quality system or product evaluation covered by this subpart and with regard to any type of product covered by this subpart. The parties shall develop a list contained in Appendix E of this subpart of CAB's determined to be equivalent, which shall contain a full explanation of the scope of the equivalency determination, including any appropriate limitations, with regard to performing any type of quality system or product evaluation.

(b) The parties shall allow CAB's not listed for participation in this subpart, or listed for participation only as to certain types of evaluations, to apply for participation in this subpart once the necessary measures have been taken or sufficient experience has been gained, in accordance with § 26.46.

(c) Decisions concerning the equivalence of CAB's must be agreed to by both parties.

§ 26.40 Start of the operational period.

(a) The operational period will start at the end of the transition period after the parties have developed the list of conformity assessment bodies (CAB's) found to be equivalent. The provisions of §§ 26.40, 26.41, 26.42, 26.43, 26.44, 26.45, and 26.46 will apply only with regard to listed CAB's and only to the extent of any specifications and

limitations contained on the list with regard to a CAB.

(b) The operational period will apply to quality system evaluation reports and product evaluation reports generated by CAB's listed in accordance with this subpart for the evaluations performed in the respective territories of the parties, except if the parties agree otherwise.

§ 26.41 Exchange and endorsement of quality system evaluation reports.

(a) Listed European Community (EC) conformity assessment bodies (CAB's) will provide FDA with reports of quality system evaluations, as follows:

(1) For preapproval quality system evaluations, EC CAB's will provide full reports; and

(2) For surveillance quality system evaluations, EC CAB's will provide abbreviated reports.

(b) Listed U.S. CAB's will provide to the EC Notified Body of the manufacturer's choice:

(1) Full reports of initial quality system evaluations;

(2) Abbreviated reports of quality systems surveillance audits.

(c) If the abbreviated reports do not provide sufficient information, the importing party may request additional clarification from the CAB.

(d) Based on the determination of equivalence in light of the experience gained, the quality system evaluation reports prepared by the CAB's listed as equivalent will normally be endorsed by the importing party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies or inadequacies in a report, quality defects identified in postmarket surveillance or other specific evidence of serious concern in relation to product quality or consumer safety. In such cases, the importing party may request clarification from the exporting party which may lead to a request for reinspection. The parties will endeavor to respond to requests for clarification in a timely manner. Where divergence is not clarified in this process, the importing party may carry out the quality system evaluation.

§ 26.42 Exchange and endorsement of product evaluation reports.

(a) European Community (EC) conformity assessment bodies (CAB's) listed for this purpose will, subject to the specifications and limitations on the list, provide to FDA 510(k) premarket notification assessment reports prepared to U.S. medical device requirements.

(b) U.S. CAB's will, subject to the specifications and limitations on the list, provide to the EC Notified Body of the manufacturer's choice, type examination, and verification reports prepared to EC medical device requirements.

(c) Based on the determination of equivalence in light of the experience gained, the product evaluation reports prepared by the CAB's listed as equivalent will normally be endorsed by the importing party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies, inadequacies, or incompleteness in a product evaluation report, or other specific evidence of serious concern in relation to product safety, performance, or quality. In such cases, the importing party may request clarification from the exporting party which may lead to a request for a reevaluation. The parties will endeavor to respond to requests for clarification in a timely manner. Endorsement remains the responsibility of the importing party.

§ 26.43 Transmission of quality system evaluation reports.

Quality system evaluation reports covered by § 26.41 concerning products covered by this subpart shall be transmitted to the importing party within 60-calendar days of a request by the importing party. Should a new inspection be requested, the time period shall be extended by an additional 30-calendar days. A party may request a new inspection, for cause, identified to the other party. If the exporting party cannot perform an inspection within a specified period of time, the importing party may perform an inspection on its own.

§ 26.44 Transmission of product evaluation reports.

Transmission of product evaluation reports will take place according to the importing party's specified procedures.

§ 26.45 Monitoring continued equivalence.

Monitoring activities will be carried out in accordance with § 26.69.

§ 26.46 Listing of additional CAB's.

(a) During the operational period, additional conformity assessment bodies (CAB's) will be considered for equivalence using the procedures and criteria described in §§ 26.36, 26.37, and 26.39, taking into account the level of confidence gained in the overall regulatory system of the other party.

(b) Once a designating authority considers that such CAB's, having undergone the procedures of §§ 26.36, 26.37, and 26.39, may be determined to be equivalent, it will then designate those bodies on an annual basis. Such procedures satisfy the procedures of § 26.66(a) and (b).

(c) Following such annual designations, the procedures for confirmation of CAB's under § 26.66(c) and (d) shall apply.

§ 26.47 Role and composition of the Joint Sectoral Committee.

(a) The Joint Sectoral Committee for this subpart is set up to monitor the activities under both the transitional and operational phases of this subpart.

(b) The Joint Sectoral Committee will be cochaired by a representative of the Food and Drug Administration (FDA) for the United States and a representative of the European Community (EC) who will each have one vote. Decisions will be taken by unanimous consent.

(c) The Joint Sectoral Committee's functions will include:

(1) Making a joint assessment of the equivalence of conformity assessment bodies (CAB's);

(2) Developing and maintaining the list of equivalent CAB's, including any limitation in terms of their scope of activities and communicating the list to all authorities and the Joint Committee described in subpart C of this part;

(3) Providing a forum to discuss issues relating to this subpart, including concerns that a CAB may no longer be equivalent and opportunity to review product coverage; and

(4) Consideration of the issue of suspension.

§ 26.48 Harmonization.

During both the transitional and operational phases of this subpart, both parties intend to continue to participate in the activities of the Global Harmonization Task Force (GHTF) and utilize the results of those activities to the extent possible. Such participation involves developing and reviewing documents developed by the GHTF and jointly determining whether they are applicable to the implementation of this subpart.

§ 26.49 Regulatory cooperation.

(a) The parties and authorities shall inform and consult with one another, as permitted by law, of proposals to introduce new controls or to change existing technical regulations or inspection procedures and to provide the opportunity to comment on such proposals.

(b) The parties shall notify each other in writing of any changes to Appendix A of this subpart.

§ 26.50 Alert system and exchange of postmarket vigilance reports.

(a) An alert system will be set up during the transition period and maintained thereafter by which the parties will notify each other when there is an immediate danger to public health. Elements of such a system will be described in an Appendix F of this subpart. As part of that system, each party shall notify the other party of any confirmed problem reports, corrective actions, or recalls. These reports are regarded as part of ongoing investigations.

(b) Contact points will be agreed between both parties to permit authorities to be made aware with the appropriate speed in case of quality defect, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the product.

Appendix A of Subpart B—Relevant Legislation, Regulations, and Procedures.

1. For the European Community (EC) the following legislation applies to § 26.42(a) of this subpart:

[Copies of EC documents may be obtained from the European Document Research, 1100 17th St. NW., suite 301, Washington, DC 20036.]

a. Council Directive 90/385/EEC of 20 June 1990 on active implantable medical devices
OJ No. L 189, 20.7. 1990, p. 17. Conformity assessment procedures.
Annex 2 (with the exception of section 4)
Annex 4
Annex 5

b. Council Directive 93/42/EEC of 14 June 1993 on Medical Devices OJ No. L 169,12.7.1993, p.1. Conformity assessment procedures.
Annex 2 (with the exception of section 4)
Annex 3
Annex 4
Annex 5
Annex 6

2. For the United States, the following legislation applies to § 26.32(a):

[Copies of FDA documents may be obtained from the Government Printing Office, 1510 H St. NW., Washington, DC 20005. FDA documents may be viewed on FDA's Internet web site at ''http://www.fda.gov''.]

a. The Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321 *et seq.*

b. The Public Health Service Act, 42 U.S.C. 201 *et seq.*

c. Regulations of the United States Food and Drug Administration found at 21 CFR, in particular, Parts 800 to 1299.

d. Medical Devices; Third Party Review of Selected Premarket Notifications; Pilot Program, 61 FR 14789–14796 (April 3, 1996).

e. Draft Guidance Document on Accredited Persons Program, 63 FR 28392 (May 22, 1998).

f. Draft Guidance for Staff, Industry and Third Parties, Third Party Programs under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA), 63 FR 36240 (July 2, 1998).

g. Guidance Document on Use of Standards, 63 FR 9561 (February 25, 1998).

Appendix B of Subpart B—Scope of Product Coverage.

1. Initial Coverage of the Transition Period

Upon entry into force of this subpart as described in § 26.80 (it is understood that the date of entry into force will not occur prior to June 1, 1998, unless the parties decide otherwise), products qualifying for the transitional arrangements under this subpart include:

a. All Class I products requiring premarket evaluations in the United States—see Table 1.
b. Those Class II products listed in Table 2.

2. During the Transition Period

The parties will jointly identify additional product groups, including their related accessories, in line with their respective priorities as follows:

a. Those for which review may be based primarily on written guidance which the parties will use their best efforts to prepare expeditiously; and
b. Those for which review may be based primarily on international standards, in order for the parties to gain the requisite experience.

The corresponding additional product lists will be phased in on an annual basis. The parties may consult with industry and other interested parties in determining which products will be added.

3. Commencement of the Operational Period

a. At the commencement of the operational period, product coverage shall extend to all Class I/II products covered during the transition period.
b. FDA will expand the program to categories of Class II devices as is consistent with the results of the pilot, and with FDA's ability to write guidance documents if the device pilot for the third party review of medical devices is successful. The MRA will cover to the maximum extent feasible all Class II devices listed in Table 3 for which FDA-accredited third party review is available in the United States.

4. Unless explicitly included by joint decision of the parties, this part does not cover any U.S. Class II-tier 3 or any Class III product under either system.

[The lists of medical devices included in these tables are subject to change as a result of the Food and Drug Administration Modernization Act of 1997.]

Table 1.—Class I Products Requiring Premarket Evaluations in the United States, Included in Scope of Product Coverage at Beginning of Transition Period[1]

21 CFR Section No.	Regulation Name Product Code—Device Name
Anesthesiology Panel (21 CFR Part 868)	
868.1910	Esophageal Stethoscope BZW—Stethoscope, Esophageal
868.5620	Breathing Mouthpiece BYP—Mouthpiece, Breathing
868.5640	Medicinal Nonventilatory Nebulizer (Atomizer) CCQ—Nebulizer, Medicinal, Nonventilatory (Atomizer)
868.5675	Rebreathing Device BYW—Device, Rebreathing
868.5700	Nonpowered Oxygen Tent FOG—Hood, Oxygen, Infant BYL—Tent, Oxygen
868.6810	Tracheobronchial Suction Catheter BSY—Catheters, Suction, Tracheobronchial
Cardiovascular Panel	
(None)	
Dental Panel (21 CFR Part 872)	
872.3400	Karaya and Sodium Borate With or Without Acacia Denture Adhesive KOM—Adhesive, Denture, Acacia and Karaya With Sodium Borate

Table 1.—Class I Products Requiring Premarket Evaluations in the United States, Included in Scope of Product Coverage at Beginning of Transition Period[1]—Continued

21 CFR Section No.	Regulation Name Product Code—Device Name
872.3700	Dental Mercury (U.S.P.) ELY—Mercury
872.4200	Dental Handpiece and Accessories EBW—Controller, Food, Handpiece and Cord EFB—Handpiece, Air-Powered, Dental EFA—Handpiece, Belt and/or Gear Driven, Dental EGS—Handpiece, Contra- and Right-Angle Attachment, Dental EKX—Handpiece, Direct Drive, AC-Powered EKY—Handpiece, Water-Powered
872.6640	Dental Operative Unit and Accessories EIA—Unit, Operative Dental
Ear, Nose, and Throat Panel (21 CFR Part 874)	
874.1070	Short Increment Sensitivity Index (SISI) Adapter ETR—Adapter, Short Increment Sensitivity Index (SISI)
874.1500	Gustometer ETM—Gustometer
874.1800	Air or Water Caloric Stimulator KHH—Stimulator, Caloric-Air ETP—Stimulator, Caloric-Water
874.1925	Toynbee Diagnostic Tube ETK—Tube, Toynbee Diagnostic
874.3300	Hearing Aid LRB—Face Plate Hearing-Aid ESD—Hearing-aid, Air-Conduction
874.4100	Epistaxis Balloon EMX—Balloon, Epistaxis
874.5300	ENT Examination and Treatment Unit ETF—Unit, Examining/Treatment, ENT
874.5550	Powered Nasal Irrigator KMA—Irrigator, Powered Nasal
874.5840	Antistammering Device KTH—Device, Anti-Stammering
Gastroenterology—Urology Panel (21 CFR Part 876)	
876.5160	Urological Clamp for Males FHA—Clamp, Penile
876.5210	Enema Kit FCE—Kit, Enema, (for Cleaning Purpose)
876.5250	Urine Collector and Accessories FAQ—Bag, Urine Collection, Leg, for External Use
General Hospital Panel (21 CFR Part 880)	
880.5270	Neonatal Eye Pad FOK—Pad, Neonatal Eye
880.5420	Pressure Infusor for an I.V. Bag KZD—Infusor, Pressure, for I.V. Bags
880.5680	Pediatric Position Holder FRP—Holder, Infant Position
880.6250	Patient Examination Glove LZB—Finger Cot FMC—Glove, Patient Examination LYY—Glove, Patient Examination, Latex LZA—Glove, Patient Examination, Poly LZC—Glove, Patient Examination, Speciality LYZ—Glove, Patient Examination, Vinyl
880.6375	Patient Lubricant KMJ—Lubricant, Patient
880.6760	Protective Restraint BRT—Restraint, Patient, Conductive FMQ—Restraint, Protective
Neurology Panel (21 CFR Part 882)	
882.1030	Ataxiagraph GWW—Ataxiagraph
882.1420	Electroencephalogram (EEG) Signal Spectrum Analyzer GWS—Analyzer, Spectrum, Electroencephalogram Signal
882.4060	Ventricular Cannula HCD—Cannula, Ventricular
882.4545	Shunt System Implantation Instrument GYK—Instrument, Shunt System Implantation
882.4650	Neurosurgical Suture Needle HAS—Needle, Neurosurgical Suture

Table 1.—Class I Products Requiring Premarket Evaluations in the United States, Included in Scope of Product Coverage at Beginning of Transition Period[1]—Continued

21 CFR Section No.	Regulation Name Product Code—Device Name
882.4750	Skull Punch GXJ—Punch, Skull
Obstetrics and Gynecology Panel	
(None)	
Ophthalmology Panel (21 CFR Part 886)	
886.1780	Retinoscope HKM—Retinoscope, Battery-Powered
886.1940	Tonometer Sterilizer HKZ—Sterilizer, Tonometer
886.4070	Powered Corneal Burr HQS—Burr, Corneal, AC-Powered HOG—Burr, Corneal, Battery-Powered HRG—Engine, Trephine, Accessories, AC-Powered HFR—Engine, Trephine, Accessories, Battery-Powered HLD—Engine, Trephine, Accessories, Gas-Powered
886.4370	Keratome HNO—Keratome, AC-Powered HMY—Keratome, Battery-Powered
886.5850	Sunglasses (Nonprescription) HQY—Sunglasses (Nonprescription Including Photosensitive)
Orthopedic Panel (21 CFR Part 888)	
888.1500	Goniometer KQX—Goniometer, AC-Powered
888.4150	Calipers for Clinical Use KTZ—Caliper
Physical Medicine Panel (21 CFR Part 890)	
890.3850	Mechanical Wheelchair LBE—Stroller, Adaptive IOR—Wheelchair, Mechanical
890.5180	Manual Patient Rotation Bed INY—Bed, Patient Rotation, Manual
890.5710	Hot or Cold Disposable Pack IMD—Pack, Hot or Cold, Disposable
Radiology Panel (21 CFR Part 892)	
892.1100	Scintillation (Gamma) Camera IYX—Camera, Scintillation (Gamma)
892.1110	Positron Camera IZC—Camera, Positron
892.1300	Nuclear Rectilinear Scanner IYW—Scanner, Rectilinear, Nuclear
892.1320	Nuclear Uptake Probe IZD—Probe, Uptake, Nuclear
892.1330	Nuclear Whole Body Scanner JAM—Scanner, Whole Body, Nuclear
892.1410	Nuclear Electrocardiograph Synchronizer IVY—Synchronizer, Electrocardiograph, Nuclear
892.1890	Radiographic Film Illuminator IXC—Illuminator, Radiographic-Film JAG—Illuminator, Radiographic-Film, Explosion-Proof
892.1910	Radiographic Grid IXJ—Grid, Radiographic
892.1960	Radiographic Intensifying Screen EAM—Screen, Intensifying, Radiographic
892.1970	Radiographic ECG/Respirator Synchronizer IXO—Synchronizer, ECG/Respirator, Radiographic
892.5650	Manual Radionuclide Applicator System IWG—System, Applicator, Radionuclide, Manual
General and Plastic Surgery Panel (21 CFR Part 878)	
878.4200	Introduction/Drainage Catheter and Accessories KGZ—Accessories, Catheter GCE—Adaptor, Catheter FGY—Cannula, Injection GBA—Catheter, Balloon Type GBZ—Catheter, Cholangiography GBQ—Catheter, Continuous Irrigation GBY—Catheter, Eustachian, General & Plastic Surgery JCY—Catheter, Infusion GBX—Catheter, Irrigation GBP—Catheter, Multiple Lumen

Table 1.—Class I Products Requiring Premarket Evaluations in the United States, Included in Scope of Product Coverage at Beginning of Transition Period[1]—Continued

21 CFR Section No.	Regulation Name
	Product Code—Device Name
	GBO—Catheter, Nephrostomy, General & Plastic Surgery
	GBN—Catheter, Pediatric, General & Plastic Surgery
	GBW—Catheter, Peritoneal
	GBS—Catheter, Ventricular, General & Plastic Surgery
	GCD—Connector, Catheter
	GCC—Dilator, Catheter
	GCB—Needle, Catheter
878.4320	Removable Skin Clip
	FZQ—Clip, Removable (Skin)
878.4460	Surgeon's Gloves
	KGO—Surgeon's Gloves
878.4680	Nonpowered, Single Patient, Portable Suction Apparatus
	GCY—Apparatus, Suction, Single Patient Use, Portable, Nonpowered
878.4760	Removable Skin Staple
	GDT—Staple, Removable (Skin)
878.4820	AC–Powered, Battery-Powered, and Pneumatically Powered Surgical Instrument Motors and Accessories/Attachments
	GFG—Bit, Surgical
	GFA—Blade, Saw, General & Plastic Surgery
	DWH—Blade, Saw, Surgical, Cardiovascular
	BRZ—Board, Arm (With Cover)
	GFE—Brush, Dermabrasion
	GFF—Bur, Surgical, General & Plastic Surgery
	KDG—Chisel (Osteotome)
	GFD—Dermatome
	GFC—Driver, Surgical, Pin
	GFB—Head, Surgical, Hammer
	GEY—Motor, Surgical Instrument, AC-Powered
	GET—Motor, Surgical Instrument, Pneumatic Powered
	DWI—Saw, Electrically Powered
	KFK—Saw, Pneumatically Powered
	HAB—Saw, Powered, and Accessories
878.4960	Air or AC-Powered Operating Table and Air or AC-Powered Operating Chair & Accessories
	GBB—Chair, Surgical, AC-Powered
	FQO—Table, Operating-Room, AC-Powered
	GDC—Table, Operating-Room, Electrical
	FWW—Table, Operating-Room, Pneumatic
	JEA—Table, Surgical with Orthopedic Accessories, AC-Powered
880.5090	Liquid Bandage
	KMF—Bandage, Liquid

[1]Descriptive information on product codes, panel codes, and other medical device identifiers may be viewed on FDA's Internet Web Site at ''http://www.fda.gov/cdrh/prodcode.html''.

Table 2.—Class II Medical Devices Included in Scope of Product Coverage at Beginning of Transition Period (United States to develop guidance documents identifying U.S. requirements and European Community (EC) to identify standards needed to meet EC requirements)[1]

Panel	21 CFR Section No.	Regulation Name
		Product Code—Device Name
RA	892.1000	Magnetic Resonance Diagnostic Device
		MOS—COIL, Magnetic Resonance, Specialty
		LNH—System, Nuclear Magnetic Resonance Imaging
		LNI—System, Nuclear Magnetic Resonance Spectroscopic
Diagnostic Ultrasound:		
RA	892.1540	Nonfetal Ultrasonic Monitor
		JAF—Monitor, Ultrasonic, Nonfetal
RA	892.1550	Ultrasonic Pulsed Doppler Imaging System
		IYN—System, Imaging, Pulsed Doppler, Ultrasonic
RA	892.1560	Ultrasonic Pulsed Echo Imaging System
		IYO—System, Imaging, Pulsed Echo, Ultrasonic
RA	892.1570	Diagnostic Ultrasonic Transducer
		ITX—Transducer, Ultrasonic, Diagnostic

Table 2.—Class II Medical Devices Included in Scope of Product Coverage at Beginning of Transition Period (United States to develop guidance documents identifying U.S. requirements and European Community (EC) to identify standards needed to meet EC requirements)[1]—Continued

Panel	21 CFR Section No.	Regulation Name
		Product Code—Device Name
Diagnostic X-Ray Imaging Devices (except mammographic x-ray systems):		
RA	892.1600	Angiographic X-Ray System IZI—System, X-Ray, Angiographic
RA	892.1650	Image-Intensified Fluoroscopic X-Ray System MQB—Solid State X-Ray Imager (Flat Panel/Digital Imager) JAA—System, X-Ray, Fluoroscopic, Image-Intensified
RA	892.1680	Stationary X-Ray System KPR—System, X-Ray, Stationary
RA	892.1720	Mobile X-Ray System IZL—System, X-Ray, Mobile
RA	892.1740	Tomographic X-Ray System IZF—System, X-Ray, Tomographic
RA	892.1750	Computed Tomography X-Ray System JAK—System, X-Ray, Tomography, Computed
ECG-Related Devices:		
CV	870.2340	Electrocardiograph DPS—Electrocardiograph MLC—Monitor, ST Segment
CV	870.2350	Electrocardiograph Lead Switching Adaptor DRW—Adaptor, Lead Switching, Electrocardiograph
CV	870.2360	Electrocardiograph Electrode DRX—Electrode, Electrocardiograph
CV	870.2370	Electrocardiograph Surface Electrode Tester KRC—Tester, Electrode, Surface, Electrocardiographic
NE	882.1400	Electroencephalograph GWQ—Electroencephalograph
HO	880.5725	Infusion Pump (external only) MRZ—Accessories, Pump, Infusion FRN—Pump, Infusion LZF—Pump, Infusion, Analytical Sampling MEB—Pump, Infusion, Elastomeric LZH—Pump, Infusion, Enteral MHD—Pump, Infusion, Gallstone Dissolution LZG—Pump, Infusion, Insulin MEA—Pump, Infusion, PCA
Ophthalmic Instruments:		
OP	886.1570	Ophthalmoscope HLI—Ophthalmoscope, AC-Powered HLJ—Ophthalmoscope, Battery-Powered
OP	886.1780	Retinoscope HKL—Retinoscope, AC-Powered
OP	886.1850	AC-Powered Slit-Lamp Biomicroscope HJO—Biomicroscope, Slit-Lamp, AC-Powered
OP	886.4150	Vitreous Aspiration and Cutting Instrument MMC—Dilator, Expansive Iris (Accessory) HQE—Instrument, Vitreous Aspiration and Cutting, AC-Powered HKP—Instrument, Vitreous Aspiration and Cutting, Battery-Powered MLZ—Vitrectomy, Instrument Cutter
OP	886.4670	Phacofragmentation System HQC—Unit, Phacofragmentation
SU	878.4580	Surgical Lamp HBI—Illuminator, Fiberoptic, Surgical Field FTF—Illuminator, Nonremote FTG—Illuminator, Remote HJE—Lamp, Fluorescein, AC-Powered FQP—Lamp, Operating-Room FTD—Lamp, Surgical GBC—Lamp, Surgical, Incandescent FTA—Light, Surgical, Accessories FSZ—Light, Surgical, Carrier FSY—Light, Surgical, Ceiling Mounted FSX—Light, Surgical, Connector FSW—Light, Surgical, Endoscopic FST—Light, Surgical, Fiberoptic FSS—Light, Surgical, Floor Standing

Table 2.—Class II Medical Devices Included in Scope of Product Coverage at Beginning of Transition Period (United States to develop guidance documents identifying U.S. requirements and European Community (EC) to identify standards needed to meet EC requirements)[1]—Continued

Panel	21 CFR Section No.	Regulation Name
		Product Code—Device Name
		FSQ—Light, Surgical, Instrument
NE	882.5890	Transcutaneous Electrical Nerve Stimulator for Pain Relief GZJ—Stimulator, Nerve, Transcutaneous, For Pain Relief
		Noninvasive Blood Pressure Measurement Devices:
CV	870.1120	Blood Pressure Cuff DXQ—Cuff, Blood-Pressure
CV	870.1130	Noninvasive Blood Pressure Measurement System (except nonoscillometric) DXN—System, Measurement, Blood-Pressure, Noninvasive
HO	880.6880	Steam Sterilizer (greater than 2 cubic feet) FLE—Sterilizer, Steam
Clinical Thermometers:		
HO	880.2910	Clinical Electronic Thermometer (except tympanic or pacifier) FLL—Thermometer, Electronic, Clinical
AN	868.5630	Nebulizer CAF—Nebulizer (Direct Patient Interface)
AN	868.5925	Powered Emergency Ventilator
Hypodermic Needles and Syringes (except antistick and self-destruct):		
HO	880.5570	Hypodermic Single Lumen Needle MMK—Container, Sharpes FMI—Needle, Hypodermic, Single Lumen MHC—Port, Intraosseous, Implanted
HO	880.5860	Piston Syringe FMF—Syringe, Piston
OR	888.3020	Intramedullary Fixation Rod HSB—ROD, Fixation, Intramedullary and Accessories
External Fixators (except devices with no external components):		
OR	888.3030	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories KTT—Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component
OR	888.3040	Smooth or Threaded Metallic Bone Fixation Fastener JEC—Component, Traction, Invasive HTY—Pin, Fixation, Smooth JDW—Pin, Fixation, Threaded
Selected Dental Materials:		
DE	872.3060	Gold-Based Alloys and Precious Metal Alloys for Clinical Use EJT—Alloy, Gold Based, For Clinical Use EJS—Alloy, Precious Metal, For Clinical Use
DE	872.3200	Resin Tooth Bonding Agent KLE—Agent, Tooth Bonding, Resin
DE	872.3275	Dental Cement EMA—Cement, Dental EMB—Zinc Oxide Eugenol
DE	872.3660	Impression Material ELW—Material, Impression
DE	872.3690	Tooth Shade Resin Material EBF—Material, Tooth Shade, Resin
DE	872.3710	Base Metal Alloy EJH—Metal, Base
Latex Condoms:		
OB	884.5300	Condom HIS—Condom

[1]Descriptive information on product codes, panel codes, and other medical device identifiers may be viewed on FDA's Internet Web Site at ''http://www.fda.gov/cdrh/prodcode.html''.

Table 3.—Medical Devices for Possible Inclusion in Scope of Product Coverage During Operational Period[1]

Product Family	21 CFR Section No	Device Name	Tier
Anesthesiology Panel			
Anesthesia Devices	868.5160	Gas machine for anesthesia or analgesia	2
	868.5270	Breathing system heater	2

Table 3.—Medical Devices for Possible Inclusion in Scope of Product Coverage During Operational Period[1]—Continued

Product Family	21 CFR Section No	Device Name	Tier
	868.5440	Portable oxygen generator	2
	868.5450	Respiratory gas humidifier	2
	868.5630	Nebulizer	2
	868.5710	Electrically powered oxygen tent	2
	868.5880	Anesthetic vaporizer	2
Gas Analyser	868.1040	Powered Algesimeter	2
	868.1075	Argon gas analyzer	2
	868.1400	Carbon dioxide gas analyzer	2
	868.1430	Carbon monoxide gas analyzer	2
	868.1500	Enflurane gas analyzer	2
	868.1620	Halothane gas analyzer	2
	868.1640	Helium gas analyzer	2
	868.1670	Neon gas analyzer	2
	868.1690	Nitrogen gas analyzer	2
	868.1700	Nitrous oxide gas analyzer	2
	868.1720	Oxygen gas analyzer	2
	868.1730	Oxygen uptake computer	2
Peripheral Nerve Stimulators	868.2775	Electrical peripheral nerve stimulator	2
Respiratory Monitoring	868.1750	Pressure plethysmograph	2
	868.1760	Volume plethysmograph	2
	868.1780	Inspiratory airway pressure meter	2
	868.1800	Rhinoanemometer	2
	868.1840	Diagnostic spirometer	2
	868.1850	Monitoring spirometer	2
	868.1860	Peak-flow meter for spirometry	2
	868.1880	Pulmonary-function data calculator	2
	868.1890	Predictive pulmonary-function value calculator	2
	868.1900	Diagnostic pulmonary-function interpretation calculator	2
	868.2025	Ultrasonic air embolism monitor	2
	868.2375	Breathing frequency monitor (except apnea detectors)	2
	868.2480	Cutaneous carbon dioxide ($PcCO_2$) monitor	2
	868.2500	Cutaneous oxygen monitor (for an infant not under gas anesthesia)	2
	868.2550	Pneumotachomometer	2
	868.2600	Airway pressure monitor	2
	868.5665	Powered percussor	2
	868.5690	Incentive spirometer	2
Ventilator	868.5905	Noncontinuous ventilator (IPPB)	2
	868.5925	Powered emergency ventilator	2
	868.5935	External negative pressure ventilator	2
	868.5895	Continuous ventilator	2
	868.5955	Intermittent mandatory ventilation attachment	2
	868.6250	Portable air compressor	2
Cardiovascular Panel			
Cardiovascular Diagnostic	870.1425	Programmable diagnostic computer	2
	870.1450	Densitometer	2
	870.2310	Apex cardiograph (vibrocardiograph)	2
	870.2320	Ballistocardiograph	2
	870.2340	Electrocardiograph	2
	870.2350	Electrocardiograph lead switching adaptor	1
	870.2360	Electrocardiograph electrode	2
	870.2370	Electrocardiograph surface electrode tester	2
	870.2400	Vectorcardiograph	1
	870.2450	Medical cathode-ray tube display	1
	870.2675	Oscillometer	2
	870.2840	Apex cardiographic transducer	2
	870.2860	Heart sound transducer	2

Table 3.—Medical Devices for Possible Inclusion in Scope of Product Coverage During Operational Period[1]—Continued

Product Family	21 CFR Section No	Device Name	Tier
Cardiovascular Monitoring		Valve, pressure relief, cardiopulmonary bypass	
	870.1100	Blood pressure alarm	2
	870.1110	Blood pressure computer	2
	870.1120	Blood pressure cuff	2
	870.1130	Noninvasive blood pressure measurement system	2
	870.1140	Venous blood pressure manometer	2
	870.1220	Electrode recording catheter or electrode recording probe	2
	870.1270	Intracavitary phonocatheter system	2
	870.1875	Stethoscope (electronic)	2
	870.2050	Biopotential amplifier and signal conditioner	2
	870.2060	Transducer signal amplifier and conditioner	2
	870.2100	Cardiovascular blood flow-meter	2
	870.2120	Extravascular blood flow probe	2
	870.2300	Cardiac monitor (including cardiotachometer and rate alarm)	2
	870.2700	Oximeter	2
	870.2710	Ear oximeter	2
	870.2750	Impedance phlebograph	2
	870.2770	Impedance plethysmograph	2
	870.2780	Hydraulic, pneumatic, or photo-electric plethysmographs	2
	870.2850	Extravascular blood pressure transducer	2
	870.2870	Catheter tip pressure transducer	2
	870.2880	Ultrasonic transducer	2
	870.2890	Vessel occlusion transducer	2
	870.2900	Patient transducer and electrode cable (including connector)	2
	870.2910	Radiofrequency physiological signal transmitter and receiver	2
	870.2920	Telephone electrocardiograph transmitter and receiver	2
	870.4205	Cardiopulmonary bypass bubble detector	2
	870.4220	Cardiopulmonary bypass heart-lung machine console	2
	870.4240	Cardiovascular bypass heat exchanger	2
	870.4250	Cardiopulmonary bypass temperature controller	2
	870.4300	Cardiopulmonary bypass gas control unit	2
	870.4310	Cardiopulmonary bypass coronary pressure gauge	2
	870.4330	Cardiopulmonary bypass on-line blood gas monitor	2
	870.4340	Cardiopulmonary bypass level sensing monitor and/or control	2
	870.4370	Roller-type cardiopulmonary bypass blood pump	2
	870.4380	Cardiopulmonary bypass pump speed control	2
	870.4410	Cardiopulmonary bypass in-line blood gas sensor	2
Cardiovascular Therapeutic	870.5050	Patient care suction apparatus	2
	870.5900	Thermal regulation system	2
Defibrillator	870.5300	DC-defibrillator (including paddles)	2
	870.5325	Defibrillator tester	2
Echocardiograph	870.2330	Echocardiograph	2
Pacemaker & Accessories	870.1750	External programmable pacemaker pulse generator	2
	870.3630	Pacemaker generator function analyzer	2

Table 3.—Medical Devices for Possible Inclusion in Scope of Product Coverage During Operational Period[1]—Continued

Product Family	21 CFR Section No	Device Name	Tier
	870.3640	Indirect pacemaker generator function analyzer	2
	870.3720	Pacemaker electrode function tester	2
Miscellaneous	870.1800	Withdrawal-infusion pump	2
	870.2800	Medical magnetic tape recorder	2
	None	Batteries, rechargeable, class II devices	
Dental Panel			
Dental Equipment	872.1720	Pulp tester	2
	872.1740	Caries detection device	2
	872.4120	Bone cutting instrument and accessories	2
	872.4465	Gas-powered jet injector	2
	872.4475	Spring-powered jet injector	2
	872.4600	Intraoral ligature and wire lock	2
	872.4840	Rotary scaler	2
	872.4850	Ultrasonic scaler	2
	872.4920	Dental electrosurgical unit and accessories	2
	872.6070	Ultraviolet activator for polymerization	2
	872.6350	Ultraviolet detector	2
Dental Material	872.3050	Amalgam alloy	2
	872.3060	Gold-based alloys and precious metal alloys for clinical use	2
	872.3200	Resin tooth bonding agent	2
	872.3250	Calcium hydroxide cavity liner	2
	872.3260	Cavity varnish	2
	872.3275	Dental cement (other than zinc oxide-eugenol)	2
	872.3300	Hydrophilic resin coating for dentures	2
	872.3310	Coating material for resin fillings	2
	872.3590	Preformed plastic denture tooth	2
	872.3660	Impression material	2
	872.3690	Tooth shade resin material	2
	872.3710	Base metal alloy	2
	872.3750	Bracket adhesive resin and tooth conditioner	2
	872.3760	Denture relining, repairing, or re-basing resin	2
	872.3765	Pit and fissure sealant and conditioner	2
	872.3770	Temporary crown and bridge resin	2
	872.3820	Root canal filling resin (other than chloroform use)	2
	872.3920	Porcelain tooth	2
Dental X-ray	872.1800	Extraoral source x-ray system	2
	872.1810	Intraoral source x-ray system	2
Dental Implants	872.4880	Intraosseous fixation screw or wire	2
	872.3890	Endodontic stabilizing splint	2
Orthodontic	872.5470	Orthodontic plastic bracket	2
Ear/Nose/Throat Panel			
Diagnostic Equipment	874.1050	Audiometer	2
	874.1090	Auditory impedance tester	2
	874.1120	Electronic noise generator for audiometric testing	2
	874.1325	Electroglottograph	2
	874.1820	Surgical nerve stimulator/locator	2
Hearing Aids	874.3300	Hearing aid (for bone-conduction)	2
	874.3310	Hearing aid calibrator and analysis system	2
	874.3320	Group hearing aid or group auditory trainer	2
	874.3330	Master hearing aid	2
Surgical Equipment	874.4250	Ear, nose, and throat electric or pneumatic surgical drill	1
	874.4490	Argon laser for otology, rhinology, and laryngology	2

Table 3.—Medical Devices for Possible Inclusion in Scope of Product Coverage During Operational Period[1]—Continued

Product Family	21 CFR Section No	Device Name	Tier
	874.4500	Ear, nose, and throat microsurgical carbon dioxide laser	2
Gastroenterology/Urology Panel			
Endoscope (including angioscopes, laparscopes, ophthalmic endoscopes)	876.1500	Endoscope and accessories	2
	876.4300	Endoscopic electrosurgical unit and accessories	2
Gastroenterology	876.1725	Gastrointestinal motility monitoring system	1
Hemodialysis	876.5600	Sorbent regenerated dialysate delivery system for hemodialysis	2
	876.5630	Peritoneal dialysis system and accessories	2
	876.5665	Water purification system for hemodialysis	2
	876.5820	Hemodialysis system and accessories	2
	876.5830	Hemodialyzer with disposable insert (kiil-type)	2
Lithotriptor	876.4500	Mechanical lithotriptor	2
Urology Equipment	876.1620	Urodynamics measurement system	2
	876.5320	Nonimplanted electrical continence device	2
	876.5880	Isolated kidney perfusion and transport system and accessories	2
General Hospital Panel			
Infusion Pumps and Systems	880.2420	Electronic monitor for gravity flow infusion systems	2
	880.2460	Electrically powered spinal fluid pressure monitor	2
	880.5430	Nonelectrically powered fluid injector	2
	880.5725	Infusion pump	2
Neonatal Incubators	880.5400	Neonatal incubator	2
	880.5410	Neonatal transport incubator	2
	880.5700	Neonatal phototherapy unit	2
Piston Syringes	880.5570	Hypodermic single lumen needle	1
	880.5860	Piston syringe (except antistick)	1
	880.6920	Syringe needle introducer	2
Miscellaneous	880.2910	Clinical electronic thermometer	2
	880.2920	Clinical mercury thermometer	2
	880.5100	AC-powered adjustable hospital bed	1
	880.5500	AC-powered patient lift	2
	880.6880	Steam sterilizer (greater than 2 cubic feet)	2
Neurology Panel			
	882.1020	Rigidity analyzer	2
	882.1610	Alpha monitor	2
Neuro-Diagnostic	882.1320	Cutaneous electrode	2
	882.1340	Nasopharyngeal electrode	2
	882.1350	Needle electrode	2
	882.1400	Electroencephalograph	2
	882.1460	Nystagmograph	2
	882.1480	Neurological endoscope	2
	882.1540	Galvanic skin response measurement device	2
	882.1550	Nerve conduction velocity measurement device	2
	882.1560	Skin potential measurement device	2
	882.1570	Powered direct-contact temperature measurement device	2
	882.1620	Intracranial pressure monitoring device	2
	882.1835	Physiological signal amplifier	2
	882.1845	Physiological signal conditioner	2

Table 3.—Medical Devices for Possible Inclusion in Scope of Product Coverage During Operational Period[1]—Continued

Product Family	21 CFR Section No	Device Name	Tier
	882.1855	Electroencephalogram (EEG) telemetry system	2
	882.5050	Biofeedback device	2
Echoencephalography	882.1240	Echoencephalograph	2
RPG	882.4400	Radiofrequency lesion generator	2
Neuro Surgery	none	Electrode, spinal epidural	2
	882.4305	Powered compound cranial drills, burrs, trephines, and their accessories	2
	882.4310	Powered simple cranial drills burrs, trephines, and their accessories	2
	882.4360	Electric cranial drill motor	2
	882.4370	Pneumatic cranial drill motor	2
	882.4560	Stereotaxic instrument	2
	882.4725	Radiofrequency lesion probe	2
	882.4845	Powered rongeur	2
	882.5500	Lesion temperature monitor	2
Stimulators	882.1870	Evoked response electrical stimulator	2
	882.1880	Evoked response mechanical stimulator	2
	882.1890	Evoked response photic stimulator	2
	882.1900	Evoked response auditory stimulator	2
	882.1950	Tremor transducer	2
	882.5890	Transcutaneous electrical nerve stimulator for pain relief	2
Obstetrics/Gynecology Panel			
Fetal Monitoring	884.1660	Transcervical endoscope (amnioscope) and accessories	2
	884.1690	Hysteroscope and accessories (for performance standards)	2
	884.2225	Obstetric-gynecologic ultrasonic imager	2
	884.2600	Fetal cardiac monitor	2
	884.2640	Fetal phonocardiographic monitor and accessories	2
	884.2660	Fetal ultrasonic monitor and accessories	2
	884.2675	Fetal scalp circular (spiral) electrode and applicator	1
	884.2700	Intrauterine pressure monitor and accessories	2
	884.2720	External uterine contraction monitor and accessories	2
	884.2740	Perinatal monitoring system and accessories	2
	884.2960	Obstetric ultrasonic transducer and accessories	2
Gynecological Surgery Equipment	884.1720	Gynecologic laparoscope and accessories	2
	884.4160	Unipolar endoscopic coagulator-cutter and accessories	2
	884.4550	Gynecologic surgical laser	2
	884.4120	Gynecologic electrocautery and accessories	2
	884.5300	Condom	2
Ophthalmic Implants	886.3320	Eye sphere implant	2
Contact Lens	886.1385	Polymethylmethacrylate (PMMA) diagnostic contact lens	2
	886.5916	Rigid gas permeable contact lens (daily wear only)	2
Diagnostic Equipment	886.1120	Opthalmic camera	1
	886.1220	Corneal electrode	1
	886.1250	Euthyscope (AC-powered)	1
	886.1360	Visual field laser instrument	1
	886.1510	Eye movement monitor	1
	886.1570	Ophthalmoscope	1
	886.1630	AC-powered photostimulator	1
	886.1640	Ophthalmic preamplifier	1

Table 3.—Medical Devices for Possible Inclusion in Scope of Product Coverage During Operational Period[1]—Continued

Product Family	21 CFR Section No	Device Name	Tier
	886.1670	Ophthalmic isotope uptake probe	2
	886.1780	Retinoscope (AC-powered device)	1
	886.1850	AC-powered slit lamp biomicroscope	1
	886.1930	Tonometer and accessories	2
	886.1945	Transilluminator (AC-powered device)	1
	886.3130	Ophthalmic conformer	2
(Diagnostic/Surgery Equipment)	886.4670	Phacofragmentation system	2
Ophthalmic Implants	886.3340	Extraocular orbital implant	2
	886.3800	Scleral shell	2
Surgical Equipment	880.5725	Infusion pump (performance standards)	2
	886.3100	Ophthalmic tantalum clip	2
	886.3300	Absorbable implant (scleral buckling method)	2
	886.4100	Radiofrequency electrosurgical cautery apparatus	2
	886.4115	Thermal cautery unit	2
	886.4150	Vitreous aspiration and cutting instrument	2
	886.4170	Cryophthalmic unit	2
	886.4250	Ophthalmic electrolysis unit (AC-powered device)	1
	886.4335	Operating headlamp (AC-powered device)	1
	886.4390	Ophthalmic laser	2
	886.4392	Nd:YAG laser for posterior capsulotomy	2
	886.4400	Electronic metal locator	1
	886.4440	AC-powered magnet	1
	886.4610	Ocular pressure applicator	2
	886.4690	Ophthalmic photocoagulator	2
	886.4790	Ophthalmic sponge	2
	886.5100	Ophthalmic beta radiation source	2
	none	Ophthalmoscopes, replacement batteries, hand-held	1
Orthopedic Panel			
Implants	888.3010	Bone fixation cerclage	2
	888.3020	Intramedullary fixation rod	2
	888.3030	Single/multiple component metallic bone fixation appliances and accessories	2
	888.3040	Smooth or threaded metallic bone fixation fastener	2
	888.3050	Spinal interlaminal fixation orthosis	2
	888.3060	Spinal intervertebral body fixation orthosis	2
Surgical Equipment	888.1240	AC-powered dynamometer	2
	888.4580	Sonic surgical instrument and accessories/attachments	2
	none	Accessories, fixation, spinal interlaminal	2
	none	Accessories, fixation, spinal intervertebral body	2
	none	Monitor, pressure, intracompartmental	1
	none	Orthosis, fixation, spinal intervertebral fusion	2
	none	Orthosis, spinal pedicle fixation	
	none	System, cement removal extraction	1
Physical Medicine Panel			
Diagnostic Equipment or (Therapy) Therapeutic Equipment	890.1225	Chronaximeter	2
	890.1375	Diagnostic electromyograph	2
	890.1385	Diagnostic electromyograph needle electrode	2

Table 3.—Medical Devices for Possible Inclusion in Scope of Product Coverage During Operational Period[1]—Continued

Product Family	21 CFR Section No	Device Name	Tier
	890.1450	Powered reflex hammer	2
	890.1850	Diagnostic muscle stimulator	2
or (Therapy)	890.5850	Powered muscle stimulator	2
Therapeutic Equipment	890.5100	Immersion hydrobath	2
	890.5110	Paraffin bath	2
	890.5500	Infrared lamp	2
	890.5720	Water circulating hot or cold pack	2
	890.5740	Powered heating pad	2
Radiology Panel			
MRI	892.1000	Magnetic resonance diagnostic device	2
Ultrasound Diagnostic	884.2660	Fetal ultrasonic monitor and accessories	2
	892.1540	Nonfetal ultrasonic monitor	
	892.1560	Ultrasonic pulsed echo imaging system	2
	892.1570	Diagnostic ultrasonic transducer	2
	892.1550	Ultrasonic pulsed doppler imaging system	
Angiographic	892.1600	Angiographic x-ray system	2
Diagnostic X-Ray	892.1610	Diagnostic x-ray beam-limiting device	2
	892.1620	Cine or spot fluorographic x-ray camera	2
	892.1630	Electrostatic x-ray imaging system	2
	892.1650	Image-intensified fluoroscopic x-ray system	2
	892.1670	Spot film device	2
	892.1680	Stationary x-ray system	2
	892.1710	Mammographic x-ray system	2
	892.1720	Mobile x-ray system	2
	892.1740	Tomographic x-ray system	1
	892.1820	Pneumoencephalographic chair	2
	892.1850	Radiographic film cassette	1
	892.1860	Radiographic film/cassette changer	1
	892.1870	Radiographic film/cassette changer programmer	2
	892.1900	Automatic radiographic film processor	2
	892.1980	Radiologic table	1
CT Scanner	892.1750	Computed tomography x-ray system	2
Radiation Therapy	892.5050	Medical charged-particle radiation therapy system	2
	892.5300	Medical neutron radiation therapy system	2
	892.5700	Remote controlled radionuclide applicator system	2
	892.5710	Radiation therapy beam-shaping block	2
	892.5730	Radionuclide brachytherapy source	2
	892.5750	Radionuclide radiation therapy system	2
	892.5770	Powered radiation therapy patient support assembly	2
	892.5840	Radiation therapy simulation system	2
	892.5930	Therapeutic x-ray tube housing assembly	1
Nuclear Medicine	892.1170	Bone densitometer	2
	892.1200	Emission computed tomography system	2
	892.1310	Nuclear tomography system	1
	892.1390	Radionuclide rebreathing system	2
General/Plastic Surgery Panel			
Surgical Lamps	878.4630	Ultraviolet lamp for dermatologic disorders	2
	890.5500	Infrared lamp	2
	878.4580	Surgical lamp	2

Table 3.—Medical Devices for Possible Inclusion in Scope of Product Coverage During Operational Period[1]—Continued

Product Family		21 CFR Section No	Device Name	Tier
Electrosurgical Equipment	Cutting	878.4810	Laser surgical instrument for use in general and plastic surgery and in dermatology	2
		878.4400	Electrosurgical cutting and coagulation device and accessories	2
Miscellaneous		878.4780	Powered suction pump	2

[1]Descriptive information on product codes, panel codes, and other medical device identifiers may be viewed on FDA's Internet Web Site at ''http://www.fda.gov/cdrh/prodcode.html''.

Appendix C of Subpart B [Reserved].

Appendix D of Subpart B [Reserved].

Appendix E of Subpart B [Reserved].

Appendix F of Subpart B [Reserved].

Subpart C—''Framework'' Provisions

§ 26.60 Definitions.

(a) The following terms and definitions shall apply to this subpart only:

(1) *Designating Authority* means a body with power to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies as specified under this part.

(2) *Designation* means the identification by a designating authority of a conformity assessment body to perform conformity assessment procedures under this part.

(3) *Regulatory Authority* means a government agency or entity that exercises a legal right to control the use or sale of products within a party's jurisdiction and may take enforcement action to ensure that products marketed within its jurisdiction comply with legal requirements.

(b) Other terms concerning conformity assessment used in this part shall have the meaning given elsewhere in this part or in the definitions contained in ''Guide 2: Standardization and Related Activities—General Vocabulary of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC)'' (ISO/IEC Guide 2) (1996 edition), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the International Organization for Standardization, 1, rue de Varembé, Case postale 56, CH–1211 Genève 20, Switzerland, or on the Internet at ''http://www.iso.ch'' or may be examined at the Food and Drug Administration's Medical Library, 5600 Fishers Lane, rm. 11B–40, Rockville, MD 20857, or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. In the event of an inconsistency between the ISO/IEC Guide 2 and definitions in this part, the definitions in this part shall prevail.

§ 26.61 Purpose of this part.

This part specifies the conditions by which each party will accept or recognize results of conformity assessment procedures, produced by the other party's conformity assessment bodies (CAB's) or authorities, in assessing conformity to the importing party's requirements, as specified on a sector-specific basis in subparts A and B of this part, and to provide for other related cooperative activities. The objective of such mutual recognition is to provide effective market access throughout the territories of the parties with regard to conformity assessment for all products covered under this part. If any obstacles to such access arise, consultations will promptly be held. In the absence of a satisfactory outcome of such consultations, the party alleging its market access has been denied may, within 90 days of such consultation, invoke its right to terminate the ''Agreement on Mutual Recognition Between the United States of America and the European Community,'' from which this part is derived, in accordance with § 26.80.

§ 26.62 General obligations.

(a) The United States shall, as specified in subparts A and B of this part, accept or recognize results of specified procedures, used in assessing conformity to specified legislative, regulatory, and administrative provisions of the United States, produced by the other party's conformity assessment bodies (CAB's) and/or authorities.

(b) The European Community (EC) and its Member States shall, as specified in subparts A and B of this part, accept or recognize results of specified procedures, used in assessing conformity to specified legislative, regulatory, and administrative provisions of the EC and its Member States, produced by the other party's CAB's and/or authorities.

(c) Where sectoral transition arrangements have been specified in subparts A and B of this part, the obligations in paragraphs (a) and (b) of this section will apply following the successful completion of those sectoral transition arrangements, with the understanding that the conformity assessment procedures utilized assure conformity to the satisfaction of the receiving party, with applicable legislative, regulatory, and administrative provisions of that party, equivalent to the assurance offered by the receiving party's own procedures.

§ 26.63 General coverage of this part.

(a) This part applies to conformity assessment procedures for products and/or processes and to other related cooperative activities as described in this part.

(b) Subparts A and B of this part may include:

(1) A description of the relevant legislative, regulatory, and administrative provisions pertaining to the conformity assessment procedures and technical regulations;

(2) A statement on the product scope and coverage;

(3) A list of designating authorities;

(4) A list of agreed conformity assessment bodies (CAB's) or authorities or a source from which to obtain a list of such bodies or authorities and a statement of the scope of the conformity assessment procedures for which each has been agreed;

(5) The procedures and criteria for designating the CAB's;

(6) A description of the mutual recognition obligations;

(7) A sectoral transition arrangement;

(8) The identity of a sectoral contact point in each party's territory; and

(9) A statement regarding the establishment of a Joint Sectoral Committee.

(c) This part shall not be construed to entail mutual acceptance of standards or technical regulations of the parties and, unless otherwise specified in subpart A or B of this part, shall not entail the

mutual recognition of the equivalence of standards or technical regulations.

§ 26.64 Transitional arrangements.

The parties agree to implement the transitional commitments on confidence building as specified in subparts A and B of this part.

(a) The parties agree that each sectoral transitional arrangement shall specify a time period for completion.

(b) The parties may amend any transitional arrangement by mutual agreement.

(c) Passage from the transitional phase to the operational phase shall proceed as specified in subparts A and B of this part, unless either party documents that the conditions provided in such subpart for a successful transition are not met.

§ 26.65 Designating authorities.

The parties shall ensure that the designating authorities specified in subpart B of this part have the power and competence in their respective territories to carry out decisions under this part to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies (CAB's).

§ 26.66 Designation and listing procedures.

The following procedures shall apply with regard to the designation of conformity assessment bodies (CAB's) and the inclusion of such bodies in the list of CAB's in subpart B of this part:

(a) The designating authority identified in subpart B of this part shall designate CAB's in accordance with the procedures and criteria set forth in subpart B of this part;

(b) A party proposing to add a CAB to the list of such bodies in subpart B of this part shall forward its proposal of one or more designated CAB's in writing to the other party with a view to a decision by the Joint Committee;

(c) Within 60 days following receipt of the proposal, the other party shall indicate its position regarding either its confirmation or its opposition. Upon confirmation, the inclusion in subpart B of this part of the proposed CAB or CAB's shall take effect; and

(d) In the event that the other party contests on the basis of documented evidence the technical competence or compliance of a proposed CAB, or indicates in writing that it requires an additional 30 days to more fully verify such evidence, such CAB shall not be included on the list of CAB's in subpart B of this part. In this instance, the Joint Committee may decide that the body concerned be verified. After the completion of such verification, the proposal to list the CAB in subpart B may be resubmitted to the other party.

§ 26.67 Suspension of listed conformity assessment bodies.

The following procedures shall apply with regard to the suspension of a conformity assessment body (CAB) listed in subpart B of this part.

(a) A party shall notify the other party of its contestation of the technical competence or compliance of a CAB listed in subpart B of this part and the contesting party's intent to suspend such CAB. Such contestation shall be exercised when justified in an objective and reasoned manner in writing to the other party;

(b) The CAB shall be given prompt notice by the other party and an opportunity to present information in order to refute the contestation or to correct the deficiencies which form the basis of the contestation;

(c) Any such contestation shall be discussed between the parties in the Joint Sectoral Committee described in subpart B of this part. If there is no Joint Sectoral Committee, the contesting party shall refer the matter directly to the Joint Committee. If agreement to suspend is reached by the Joint Sectoral Committee or, if there is no Joint Sectoral Committee, by the Joint Committee, the CAB shall be suspended;

(d) Where the Joint Sectoral Committee or Joint Committee decides that verification of technical competence or compliance is required, it shall normally be carried out in a timely manner by the party in whose territory the body in question is located, but may be carried out jointly by the parties in justified cases;

(e) If the matter has not been resolved by the Joint Sectoral Committee within 10 days of the notice of contestation, the matter shall be referred to the Joint Committee for a decision. If there is no Joint Sectoral Committee, the matter shall be referred directly to the Joint Committee. If no decision is reached by the Joint Committee within 10 days of the referral to it, the CAB shall be suspended upon the request of the contesting party;

(f) Upon the suspension of a CAB listed in subpart B of this part, a party is no longer obligated to accept or recognize the results of conformity assessment procedures performed by that CAB subsequent to suspension. A party shall continue to accept the results of conformity assessment procedures performed by that CAB prior to suspension, unless a regulatory authority of the party decides otherwise based on health, safety or environmental considerations or failure to satisfy other requirements within the scope of subpart B of this part; and

(g) The suspension shall remain in effect until agreement has been reached by the parties upon the future status of that body.

§ 26.68 Withdrawal of listed conformity assessment bodies.

The following procedures shall apply with regard to the withdrawal from subpart B of this part of a conformity assessment body (CAB):

(a) A party proposing to withdraw a CAB listed in subpart B of this part shall forward its proposal in writing to the other party;

(b) Such CAB shall be promptly notified by the other party and shall be provided a period of at least 30 days from receipt to provide information in order to refute or to correct the deficiencies which form the basis of the proposed withdrawal;

(c) Within 60 days following receipt of the proposal, the other party shall indicate its position regarding either its confirmation or its opposition. Upon confirmation, the withdrawal from the list in subpart B of this part of the CAB shall take effect;

(d) In the event the other party opposes the proposal to withdraw by supporting the technical competence and compliance of the CAB, the CAB shall not at that time be withdrawn from the list of CAB's in subpart B of this part. In this instance, the Joint Sectoral Committee or the Joint Committee may decide to carry out a joint verification of the body concerned. After the completion of such verification, the proposal for withdrawal of the CAB may be resubmitted to the other party; and

(e) Subsequent to the withdrawal of a CAB listed in subpart B of this part, a party shall continue to accept the results of conformity assessment procedures performed by that CAB prior to withdrawal, unless a regulatory authority of the party decides otherwise based on health, safety, and environmental considerations or failure to satisfy other requirements within the scope of subpart B of this part.

§ 26.69 Monitoring of conformity assessment bodies.

The following shall apply with regard to the monitoring of conformity assessment bodies (CAB's) listed in subpart B of this part:

(a) Designating authorities shall assure that their CAB's listed in subpart B of this part are capable and remain capable of properly assessing conformity of products or processes, as applicable, and as covered in subpart B of this part. In this regard, designating authorities shall maintain, or cause to maintain, ongoing surveillance over

their CAB's by means of regular audit or assessment;

(b) The parties undertake to compare methods used to verify that the CAB's listed in subpart B of this part comply with the relevant requirements of subpart B of this part. Existing systems for the evaluation of CAB's may be used as part of such comparison procedures;

(c) Designating authorities shall consult as necessary with their counterparts, to ensure the maintenance of confidence in conformity assessment procedures. With the consent of both parties, this consultation may include joint participation in audits/inspections related to conformity assessment activities or other assessments of CAB's listed in subpart B of this part; and

(d) Designating authorities shall consult, as necessary, with the relevant regulatory authorities of the other party to ensure that all technical requirements are identified and are satisfactorily addressed.

§ 26.70 Conformity assessment bodies.

Each party recognizes that the conformity assessment bodies (CAB's) listed in subpart B of this part fulfill the conditions of eligibility to assess conformity in relation to its requirements as specified in subpart B of this part. The parties shall specify the scope of the conformity assessment procedures for which such bodies are listed.

§ 26.71 Exchange of information.

(a) The parties shall exchange information concerning the implementation of the legislative, regulatory, and administrative provisions identified in subparts A and B of this part.

(b) Each party shall notify the other party of legislative, regulatory, and administrative changes related to the subject matter of this part at least 60 days before their entry into force. Where considerations of safety, health or environmental protection require more urgent action, a party shall notify the other party as soon as practicable.

(c) Each party shall promptly notify the other party of any changes to its designating authorities and/or conformity assessment bodies (CAB's).

(d) The parties shall exchange information concerning the procedures used to ensure that the listed CAB's under their responsibility comply with the legislative, regulatory, and administrative provisions outlined in subpart B of this part.

(e) Regulatory authorities identified in subparts A and B of this part shall consult as necessary with their counterparts, to ensure the maintenance of confidence in conformity assessment procedures and to ensure that all technical requirements are identified and are satisfactorily addressed.

§ 26.72 Sectoral contact points.

Each party shall appoint and confirm in writing contact points to be responsible for activities under subparts A and B of this part.

§ 26.73 Joint Committee.

(a) A Joint Committee consisting of representatives of the United States and the European Community (EC) will be established. The Joint Committee shall be responsible for the effective functioning of the ''Agreement on Mutual Recognition Between the United States of America and the European Community,'' from which this part is derived.

(b) The Joint Committee may establish Joint Sectoral Committees comprised of appropriate regulatory authorities and others deemed necessary.

(c) The United States and the EC shall each have one vote in the Joint Committee. The Joint Committee shall make its decisions by unanimous consent. The Joint Committee shall determine its own rules and procedures.

(d) The Joint Committee may consider any matter relating to the effective functioning of that agreement. In particular it shall be responsible for:

(1) Listing, suspension, withdrawal and verification of conformity assessment bodies (CAB's) in accordance with that agreement;

(2) Amending transitional arrangements in the sectoral annexes to that agreement;

(3) Resolving any questions relating to the application of that agreement not otherwise resolved in the respective Joint Sectoral Committees;

(4) Providing a forum for discussion of issues that may arise concerning the implementation of that agreement;

(5) Considering ways to enhance the operation of that agreement;

(6) Coordinating the negotiation of additional sectoral annexes to that agreement; and

(7) Considering whether to amend that agreement in accordance with § 26.80.

(e) When a party introduces new or additional conformity assessment procedures affecting a sectoral annex to that agreement, the parties shall discuss the matter in the Joint Committee with a view to bringing such new or additional procedures within the scope of that agreement and the relevant sectoral annex.

§ 26.74 Preservation of regulatory authority.

(a) Nothing in this part shall be construed to limit the authority of a party to determine, through its legislative, regulatory, and administrative measures, the level of protection it considers appropriate for safety; for protection of human, animal, or plant life or health; for the environment; for consumers; and otherwise with regard to risks within the scope of the applicable subpart A or B of this part.

(b) Nothing in this part shall be construed to limit the authority of a regulatory authority to take all appropriate and immediate measures whenever it ascertains that a product may:

(1) Compromise the health or safety of persons in its territory;

(2) Not meet the legislative, regulatory, or administrative provisions within the scope of the applicable subpart A or B of this part; or

(3) Otherwise fail to satisfy a requirement within the scope of the applicable subpart A or B of this part. Such measures may include withdrawing the products from the market, prohibiting their placement on the market, restricting their free movement, initiating a product recall, and preventing the recurrence of such problems, including through a prohibition on imports. If the regulatory authority takes such action, it shall inform its counterpart authority and the other party within 15 days of taking such action, providing its reasons.

§ 26.75 Suspension of recognition obligations.

Either party may suspend its obligations under subpart A or B of this part, in whole or in part, if:

(a) A party suffers a loss of market access for the party's products within the scope of subpart A or B of this part as a result of the failure of the other party to fulfill its obligations under this part;

(b) The adoption of new or additional conformity assessment requirements as referenced in § 26.73(e) results in a loss of market access for the party's products within the scope of subpart B of this part because conformity assessment bodies (CAB's) designated by the party in order to meet such requirements have not been recognized by the party implementing the requirements; or

(c) The other party fails to maintain legal and regulatory authorities capable of implementing the provisions of this part.

§ 26.76 Confidentiality.

(a) Each party agrees to maintain, to the extent required under its laws, the confidentiality of information exchanged under this part.

(b) In particular, neither party shall disclose to the public, nor permit a conformity assessment body (CAB) to disclose to the public, information exchanged under this part that constitutes trade secrets, confidential commercial or financial information, or information that relates to an ongoing investigation.

(c) A party or a CAB may, upon exchanging information with the other party or with a CAB of the other party, designate the portions of the information that it considers to be exempt from disclosure.

(d) Each party shall take all precautions reasonably necessary to protect information exchanged under this part from unauthorized disclosure.

§ 26.77 Fees.

Each party shall endeavor to ensure that fees imposed for services under this part shall be commensurate with the services provided. Each party shall ensure that, for the sectors and conformity assessment procedures covered under this part, it shall charge no fees with respect to conformity assessment services provided by the other party.

§ 26.78 Agreements with other countries.

Except where there is written agreement between the parties, obligations contained in mutual recognition agreements concluded by either party with a party not a party to the agreement from which this part is derived (a third party) shall have no force and effect with regard to the other party in terms of acceptance of the results of conformity assessment procedures in the third party.

§ 26.79 Territorial application.

The agreement from which this part is derived shall apply, on the one hand, to the territories in which the Treaty establishing the European Community (EC) is applied, and under the conditions laid down in that Treaty and, on the other hand, to the territory of the United States.

§ 26.80 Entry into force, amendment, and termination.

(a) The ''Agreement on Mutual Recognition Between the United States of America and the European Community,'' from which this part is derived, including its sectoral annexes on telecommunication equipment, electromagnetic compatibility, electrical safety, recreational craft, pharmaceutical Good Manufacturing Practices (GMP) inspections, and medical devices shall enter into force on the first day of the second month following the date on which the parties have exchanged letters confirming the completion of their respective procedures for the entry into force of that agreement.

(b) That agreement including any sectoral annex may, through the Joint Committee, be amended in writing by the parties to that agreement. Those parties may add a sectoral annex upon the exchange of letters. Such annex shall enter into force 30 days following the date on which those parties have exchanged letters confirming the completion of their respective procedures for the entry into force of the sectoral annex.

(c) Either party to that agreement may terminate that agreement in its entirety or any individual sectoral annex thereof by giving the other party to that agreement 6-months notice in writing. In the case of termination of one or more sectoral annexes, the parties to that agreement will seek to achieve by consensus to amend that agreement, with a view to preserving the remaining Sectoral Annexes, in accordance with the procedures in this section. Failing such consensus, that agreement shall terminate at the end of 6 months from the date of notice.

(d) Following termination of that agreement in its entirety or any individual sectoral annex thereof, a party to that agreement shall continue to accept the results of conformity assessment procedures performed by conformity assessment bodies under that agreement prior to termination, unless a regulatory authority in the party decides otherwise based on health, safety and environmental considerations or failure to satisfy other requirements within the scope of the applicable sectoral annex.

§ 26.81 Final provisions.

(a) The sectoral annexes referred to in § 26.80(a), as well as any new sectoral annexes added pursuant to § 26.80(b), shall form an integral part of the ''Agreement on Mutual Recognition Between the United States of America and the European Community,'' from which this part is derived.

(b) For a given product or sector, the provisions contained in subparts A and B of this part shall apply in the first place, and the provisions of subpart C of this part in addition to those provisions. In the case of any inconsistency between the provisions of subpart A or B of this part and subpart C of this part, subpart A or B shall prevail, to the extent of that inconsistency.

(c) The agreement from which this part is derived shall not affect the rights and obligations of the parties under any other international agreement.

(d) In the case of subpart B of this part, the parties shall review the status of such subpart at the end of 3 years from the date described in § 26.80(a).

Dated: July 23, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–29609 Filed 11–5–98; 8:45 am]

BILLING CODE 4160–01–F