Dated: March 24, 1999.

Aida Alvarez,

Administrator.

[FR Doc. 99–8148 Filed 4–1–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 98N–0583]

RIN 0910–AB16

Exports: Notification and Recordkeeping Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing new regulations that would establish the notification and recordkeeping requirements for persons exporting human drugs, biologics, devices, animal drugs, food, and cosmetics that may not be marketed or sold in the United States. These regulations would implement recent changes in the statutory requirements applicable to certain exports, and would also codify recordkeeping requirements for exports of products that cannot be marketed or sold in the United States generally.

DATES: Submit written comments by June 16, 1999. Submit written comments on the information collection requirements by May 3, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20502, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION:

I. Introduction

Enacted and later amended in 1996, the FDA Export Reform and Enhancement Act (Pub. L. 104–134, as amended by Pub. L. 104–180) significantly changed the export requirements for unapproved human drugs, biologics, devices, and animal drugs. For example, before the law was enacted, most exports of unapproved new drug products could only be made to the 21 countries then identified in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382), and these exports were subject to numerous restrictions. The FDA Export Reform and Enhancement Act amended section 802 of the act to allow, among other things, the export of unapproved new human drugs to any country in the world if the drug complies with the laws of the importing country and has valid marketing authorization from any of the following countries: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and the countries in the European Union (EU) and the European Economic Area (EEA) and certain other requirements are met (see section 802(b)(1)(A) of the act). Currently, the EU countries are Austria, Belgium, Denmark, Germany, Greece, Finland, France, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom. The EEA countries are the EU countries, Iceland, Liechtenstein, and Norway. The list of countries will expand automatically if any country accedes to the EU or becomes a member of the EEA. This provision of section 802 of the act also applies to the export of certain devices that cannot be sold or marketed in the United States.

The FDA Export Reform and Enhancement Act also modified the export authority in section 801 of the act (21 U.S.C. 381). Before enactment of the FDA Export Reform and Enhancement Act, section 801(e)(1) of the act applied to the exportation of certain foods, drugs, devices, and cosmetics. Products exported under section 801(e) of the act are not considered adulterated or misbranded if the product intended for export: (1) Meets the foreign purchaser's specifications, (2) is not in conflict with the laws of the country to which it is being exported, (3) is labeled on the outside of the shipping package that the product is intended for export, and (4) is not sold or offered for sale in domestic commerce (see section 801(e)(1) of the act). Additional requirements apply to certain devices (see section 801(e)(2) of the act). The FDA Export Reform and Enhancement Act extended these four basic requirements to all exports under sections 801 and 802 of the act, and to exports of partially processed biologics under section 351(h) of the Public Health Service Act (the PHS Act) (see section 801(e) and (f) of the act); section 802(f)(3) of the act; and section 351(h) of the PHS Act (42 U.S.C. 262(h))), and made section 801(e) of the act the principal export authority for the exportation of unapproved animal drugs other than animal drugs banned in the United States. It also imposed additional labeling requirements on certain exports of approved drugs (see section 801(f) of the act).

The FDA Export Reform and Enhancement Act also established recordkeeping and notification requirements. Products exported under section 802 of the act are subject to certain requirements under section 802(f) and (g) of the act. Section 802(f) of the act prohibits a drug or device from being exported under section 802 of the act if it: (1) Does not conform with current good manufacturing practices, (2) is adulterated under certain provisions in section 501 of the act (21 U.S.C. 351), (3) does not comply with section 801(e)(1) of the act, (4) is the subject of a determination by FDA or the United States Department of Agriculture (with respect to veterinary biologics) that the probability of reimportation of the exported drug or device would present an imminent hazard to the public health and safety of the United States, (5) would present an imminent hazard to the public health of the foreign country, (6) fails to comply with labeling requirements in the country receiving the exported drug or device, or (7) is not promoted in accordance with labeling requirements.

Section 802(g) of the act requires an exporter of a drug or device under section 802(b)(1)(A) of the act to provide a ''simple notification'' to the agency ''identifying the drug or device when the exporter first begins to export such drug or device'' to any of the 25 countries identified in section 802(b)(1)(A) of the act. For exports to other, nonlisted countries, section 802(g) of the act requires the exporter to provide a simple notification ''identifying the drug or device and the country to which such drug or device is being exported.'' This section also requires persons export under any provision of section 802 of the act to ''maintain records of all drugs or devices exported and the countries to which they were exported.''

II. Description of the Proposed Rule

The proposed rule would amend 21 CFR part 1 to create a new § 1.101 entitled ''Notification and recordkeeping.''

Proposed § 1.101(a) would describe the provision's scope as covering notifications and records required for human drug, biologic, device, animal drug, food, and cosmetic exports under

sections 801 or 802 of the act or section 351 of the PHS Act. In general, the export provisions in sections 801 and 802 of the act and section 351 of the PHS Act apply to persons exporting unapproved or otherwise violative products, products approved in the United States that will be used for unapproved uses in the foreign country, and partially processed biologics. Products that meet all applicable requirements of the act or the PHS Act for marketing and sale in the United States and are exported for the same approved indications are not subject to the export restrictions in sections 801 and 802 of the act and section 351 of the PHS Act.

Proposed § 1.101(b) would establish the recordkeeping requirements for human drugs, biologics, devices, animal drugs, foods, and cosmetics exported under or subject to section 801(e)(1) of the act. These recordkeeping requirements are intended to facilitate an evaluation of whether a person has complied with section 801(e)(1) of the act, and would apply to all products exported under sections 801 or 802 of the act. For example, to demonstrate that the exported product meets the foreign purchaser's specifications, proposed § 1.101(b)(1) would require records describing or listing the product specifications requested by the foreign purchaser, including details about the product (e.g., dosage strength, dosage form, purity, quality, operating parameters, composition, etc.) and any manufacturing specifications requested by the foreign purchaser (e.g., type of sterilization process to be used, compliance with a particular manufacturing standard, etc.). Proposed § 1.101(b)(2) would require the exporter to maintain documentation that demonstrates that the exported product does not conflict with the importing country's laws, such as a letter from the appropriate foreign government agency, department, or other authorized body stating that the product has marketing approval from the foreign government or does not conflict with that country's laws. The proposal would not consider letters or other documents from nongovernmental bodies or persons, such as company officials or attorneys in the foreign country, to be satisfactory for this purpose. Proposed § 1.101(b)(3) would require the records to include copies of any labels or labeling statements that are placed on the shipping packages that show that the packages are intended for export. Statements such as ''For export only'' may be sufficient for this purpose. Proposed § 1.101(b)(4) would require records showing that the product is not sold or offered for sale in the United States; these records could pertain to the product, its labeling, and similar products sold in the United States. Proposed § 1.101(b) would require the records to be maintained for at least 5 years from the date of exportation, and would require that the records be made available to FDA, upon request, during an inspection for review and copying.

Proposed § 1.101(c) would establish recordkeeping requirements, in addition to those required under proposed § 1.101(b), for partially processed biologics exported under section 351(h) of the PHS Act. Proposed § 1.101(c)(1) would require persons exporting a partially processed biologic under section 351(h) of the PHS Act to maintain records demonstrating that the product for export is a partially processed biological product, that is, ''not in a form applicable to the prevention, treatment, or cure of disease or injuries of man.'' This may consist of evidence showing the product's need for inactivation, fractionation, purification, or significant chemical modification before it can be used in the formulation of a final finished product for use outside the United States. Proposed § 1.101(c)(2) would require records to demonstrate that the product was manufactured in conformity with applicable good manufacturing practice requirements. Such records could include manufacturing records that allow the partially processed biological product to be traced from the assignment of a batch or lot numbering system at the U.S. firm, temperature stability data for the product during conditions of transit, and records of periodic checks of the capacity of shipping containers. Proposed § 1.101(c)(3) would require distribution records of the exported partially processed biologics, while proposed § 1.101(c)(4) would require copies of all labeling that accompanies the partially processed biological product for export, such as a container label with the statement, ''Caution: For Further Manufacturing Use Only,'' and any package insert. As in the case of records under proposed § 1.101(b), proposed § 1.101(c) would require these records to be maintained for at least 5 years from the date of exportation and that the records be made available to FDA, upon request, during an inspection for review and copying.

Proposed § 1.101(d) would establish the notification requirements for drugs, biologics, and devices exported under section 802 of the act. In brief, proposed § 1.101(d)(1) would require exporters to provide written notification to the agency that identifies the article's name, identifies its generic name if the article is a drug or the article's type if the product is a device, describes the product's strength and dosage form (if the product is a drug or biologic) or the product's model number (if the product is a device), and identifies the country that is to receive the exported article. Proposed § 1.101(d)(2) would list the addresses to which the notifications should be sent. However, these notification requirements would not apply to investigational drugs or devices exported under section 802(c) of the act. FDA published a final rule regarding investigational device exports in the **Federal Register** of May 13, 1997 (62 FR 26228).

The proposed rule would require persons exporting a product in anticipation of market authorization in a list country under section 802(d) of the act to comply with the notification requirements in proposed § 1.101(d)(1). This requirement would be consistent with an interpretation of section 802(g) of the act that considers the nexus between section 802(b)(1) and (d) of the act. Section 802(g) of the act requires exporters of drugs, biologics, and devices to provide a simple notification to the agency when they export a product to a listed country or to an unlisted country under section 802(b)(1) of the act. Section 802(b)(1) of the act permits exports when the drug, biologic, or device has received market authorization in a listed country, whereas section 802(d) of the act permits exports to a listed country in anticipation of market authorization. A literal interpretation of section 802(g) of the act would not require an exporter to notify FDA when it shipped a product to a listed country in anticipation of market authorization, but would instead require the exporter to notify FDA when the exporter shipped the same product to the same country once it receives market authorization. The agency has concluded that it would be more simple and efficient, both for exporters and FDA, if exporters notify FDA when they export a product in anticipation of market authorization under section 802(d) of the act, rather than wait for market authorization in the listed country and then notify FDA when the product is exported under section 802(b)(1) of the act. This interpretation is consistent with section 802 of the act as a whole, as well as section 701(a) of the act (21 U.S.C. 371), which authorizes regulations for the efficient enforcement of the act.

The agency acknowledges that, for exports to listed countries under section 802(b)(1) of the act, section 802(g) of the

act requires the notification to identify only the drug, biologic, or device being exported and does not expressly require the notification to identify the country to which the drug, biologic, or device is being exported. (In contrast, for drugs, biologics, or devices exported to nonlisted countries under section 802 of the act, section 802(g) of the act requires both identification of the exported product and the country to which the product is being exported.) Nevertheless, FDA is proposing to require that all export notifications under section 802(g) of the act identify the product and the importing country. FDA is taking this action because section 802(a)(2) of the act requires FDA to notify the ''appropriate public health official'' in the foreign country receiving an exported drug, biologic, or device if FDA disapproves a marketing application for the drug, biologic, or device. Additionally, section 802(f) of the act requires FDA to consult with the ''appropriate public health official in the affected country'' in the event that an exported drug, biologic, or device presents an imminent hazard to the public health. Similar consultation obligations exist if the product's labeling is not in accordance with the requirements and conditions for use in the country in which the drug, biologic, or device has valid marketing authorization and the country to which the drug, biologic, or device is being exported or if the drug, biologic, or device is not promoted in accordance with the labeling requirements of section 802(f) of the act. Thus, to facilitate these notifications and consultations with foreign officials (particularly in the event that FDA disapproves a drug, biologic, or device that has been exported, or the exported product presents an imminent hazard to the public health of the receiving country), FDA must know where the products have been exported. Consequently, proposed § 1.101(d)(1)(iv) would require all notifications to identify the country or countries that are to receive the exported product.

FDA, however, invites comment on possible alternatives to this notification requirement that would satisfy the consultation, notification, and recordkeeping obligations and requirements in section 802 of the act. The agency is especially interested in alternatives that would reduce the paperwork burden, such as electronic submissions and recordkeeping or periodic notifications (e.g., monthly, quarterly, etc.), and the details of such alternatives.

Proposed § 1.101(e) would establish additional recordkeeping requirements for exported drugs, biologics, and devices subject to section 802(g) of the act. These records would include, but not be limited to, records concerning the product's name; its generic name if the product is a drug or a biologic or the type of device if the product is a device; a description of its strength and dosage form and the product's lot or control number (if the product is a drug or biologic) or the product's model number (if the product is a device); the consignee's name and address; and the date on which the product was exported and the quantity of product exported. The proposal would require these records to be kept at the site from which the products were exported and be maintained for 5 years after the date of exportation. The proposal would require that these records be made readily available for review and copying by FDA during an inspection, and these records would be in addition to those records required under proposed § 1.101(b).

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA). The title, description, and respondent description of the information collection requirements are shown as follows, with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Exports: Notification and Recordkeeping Requirements.

Description: The proposed rule would establish the notification and recordkeeping requirements for persons exporting a human drug, biologic, device, animal drug, food, or cosmetic under section 801(e) or 802 of the act or section 351(h) of the PHS Act.

Description of Respondents: Businesses.

TABLE 1.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1.101(b)	316	2.8	885	1	885
1.101(c)	8	2	16	2	32
1.101(d)	244	2.4	586	1	586
1.101(e)	175	3.3	578	2	1,156
Total					2,659

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimates are based on the number of notifications received by the relevant FDA centers in 1996 or 1997 (depending on the last year for which figures were available) as well as consultations with industry sources.

As required by section 3507(d) of the PRA, FDA has submitted a copy of this proposed rule to OMB for its review of these previously approved information collection requirements. The agency solicits comments on the information collection requirements in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those

who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of reports.

V. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). 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 new benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes this proposed rule is consistent with the regulatory philosophy and the principles identified in the Executive Order. In addition, the proposed rule is a significant regulatory action as defined in the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. The proposed rule will not have a significant economic impact on a substantial number of small entities, but FDA has conducted an initial regulatory flexibility analysis to ensure that impacts on small entities were assessed and to alert any potentially impacted small entities to the opportunity to submit comments to FDA.

The proposed rule would implement the notification and recordkeeping aspects of the FDA Export Reform and Enhancement Act. The proposal requires firms that export unapproved new drugs, biologics, and devices under section 802 to notify FDA. The notification would identify the product being exported (name and description) and the product's destination. The proposal would also require firms that export human drugs, biologics, devices, animal drugs, foods, and cosmetics to maintain records demonstrating their compliance with the statutory requirements in sections 801(e) or 802 of the act or section 351(h) of the PHS Act (whichever is applicable).

FDA's initial determination that the rule will not have a significant economic impact on a substantial number of small entities is based on the estimated reporting and recordkeeping costs for the rule. Industry sources suggest that an average notification under the rule would require 1 hour to prepare and that the average wage is $30 per hour. Combining this information with information from FDA's export records (which suggest approximately 2.4 exports per firm), an exporting firm's notification cost would be $72 ($30 x 2.4).

FDA's export records also suggest that the average number of records varies (depending on the product involved) from 2.8 to 5.1 records per firm. Industry sources project the average recordkeeping cost to be $100 per record, so the recordkeeping cost per firm ranges from $280 for firms exporting products that are subject only to section 801(e) of the act to $510 for firms exporting products under section 802 of the act and to $480 for firms exporting products under section 351(h) of the PHS Act.

Thus, because the estimated proposed notification and recordkeeping costs are low, the proposed rule, if finalized, should not have a significant economic impact on a substantial number of small entities.

FDA considered alternatives that would require less information to be retained in the required records. For example, one alternative would be to require the notification to provide only the product's name and destination. However, because drug products may vary in dosage strength and size and yet still share the same name, a notice that merely named the product would not be sufficiently revealing to inform FDA about the exported drug. Another alternative would be to shorten the recordkeeping period, but because FDA's inspection resources have a wide range of obligations, from factory inspections to examining imports, a shorter time period would increase the likelihood of records being lost or destroyed before FDA could inspect an exporting firm.

The Unfunded Mandates Reform Act (Pub. L. 104–114) requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation). FDA estimates that the total recordkeeping costs for industry under the proposed rule would be $207,300. This estimate is based on a projected 2,073 records per year, multiplied by an industry cost of $100 per record. The total estimated reporting cost to industry is $17,580. This estimate is derived from the estimated total burden hours for reports (586) multiplied by a wage of $30 per hour per report. Because these expenditures will not result in a 1-year expenditure of $100 million or more, FDA is not required to perform a cost-benefit analysis under the Unfunded Mandates Reform Act.

VI. Requests for Comments

Interested persons may, on or before June 16, 1999, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs (address above).

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 is revised to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 343, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Section 1.101 is added to subpart E to read as follows:

§ 1.101 Notification and recordkeeping.

(a) *Scope.* This section pertains to notifications and records required for human drug, biologic, device, animal drug, food, and cosmetic exports under sections 801 or 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381 and 382) or section 351 of the Public Health Service Act (42 U.S.C. 262) .

(b) *Recordkeeping requirements for human drugs, biologics, devices, animal drugs, foods, and cosmetics exported under or subject to section 801(e)(1) of the act.* Persons exporting an article under section 801(e)(1) of the act or an article otherwise subject to section 801(e)(1) of the act shall maintain records as enumerated in paragraphs (b)(1) through (b)(4) of this section demonstrating that the product meets the requirements of section 801(e)(1) of the act. Such records shall be

maintained for at least 5 years from the date of exportation. The records shall be made available to the Food and Drug Administration (FDA), upon request, during an inspection for review and copying by FDA.

(1) Records demonstrating that the product meets the foreign purchaser's specifications. Such records shall include descriptions or lists of product specifications requested by the foreign purchaser, such as product details (e.g., dosage strength, dosage form, purity, quality, operating parameters, composition, etc.) and manufacturing specifications requested by the foreign purchaser (e.g., type of sterilization process to be used, compliance with a particular manufacturing standard, etc.);

(2) Records demonstrating that the product does not conflict with the laws of the importing country, such as a letter from an appropriate foreign government agency, department, or other authorized body stating that the product has marketing approval from the foreign government or does not conflict with that country's laws. Letters or other documents from nongovernmental bodies or persons, such as company officials or attorneys in the foreign country, are not acceptable. If the letter or other document from the foreign government is not in English, the person exporting the article must have an English-language translation of that document or be prepared to translate the document into English at the time of any FDA inspection;

(3) Records demonstrating that the product is labeled on the outside of the shipping package that it is intended for export, including copies of any labels or labeling statements, such as ''For export only,'' that are placed on the shipping packages; and

(4) Records demonstrating that the product is not sold or offered for sale in the United States, such as documentation concerning the product, its labeling, and similar products sold in the United States.

(c) *Additional recordkeeping requirements for partially processed biologics exported under section 351(h) of the Public Health Service Act.* In addition to the requirements in paragraph (b) of this section, persons exporting a partially processed biologic under section 351(h) of the Public Health Service Act shall maintain, for at least 5 years from the date of exportation and make available to FDA, upon request, during an inspection for review and copying by FDA, the following records:

(1) Records demonstrating that the product for export is a partially processed biological product and not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man;

(2) Records that demonstrate that the partially processed biological product was manufactured in conformity with current good manufacturing practice requirements;

(3) Distribution records of the exported partially processed biological products; and

(4) Copies of all labeling that accompanies the exported partially processed biological product, such as a container label with the statement, ''Caution: For Further Manufacturing Use Only'' and any package insert.

(d) *Notification requirements for drugs, biologics, and devices exported under section 802 of the Federal Food, Drug, and Cosmetic Act.* (1) Persons exporting a human drug, biologic, or device under section 802 of the Federal Food, Drug, and Cosmetic Act, other than a drug or a device for investigational use exported under section 802(c) of the Federal Food, Drug, and Cosmetic Act, shall provide written notification to the Food and Drug Administration. The notification shall identify:

(i) The product's name;

(ii) If the product is a drug or biologic, the product's generic name or, if the product is a device, the type of device;

(iii) If the product is a drug or biologic, a description of the product's strength and dosage form or, if the product is a device, the product's model number; and

(iv) The country that is to receive the exported article.

(2) The notification shall be sent to the following addresses:

(i) For biological drug products and devices regulated by the Center for Biologics Evaluation and Research—Division of Case Management (HFM–610), Office of Compliance, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, rm. 200N, Rockville, MD 20852–1448;

(ii) For human drug products—Division of Labeling and Nonprescription Drug Compliance (HFD–310), Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855–2737;

(iii) For devices—Division of Program Operations (HFZ–305), Center for Devices and Radiological Health, Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850.

(e) *Recordkeeping requirements for products subject to section 802(g) of the act.* (1) Any person exporting a product under any provision of section 802 of the act shall maintain records of all drugs, biologics, and devices exported and the countries to which the products were exported. In addition to the requirements in paragraph (b) of this section, such records include, but are not limited to, the following:

(i) The product's name;

(ii) If the product is a drug or biologic, the product's generic name or, if the product is a device, the type of device;

(iii) If the product is a drug or biologic, a description of its strength and dosage form and the product's lot or control number or, if the product is a device, the product's model number;

(iv) The consignee's name and address; and

(v) The date on which the product was exported and the quantity of product exported.

(2) These records shall be kept at the site from which the products were exported and be maintained at least 5 years after the date of exportation. The records shall be made available to FDA, upon request, during an inspection for review and copying by FDA.

Dated: December 23, 1998.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–8159 Filed 4–1–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 99N–0554]

Implementation of the Food and Drug Administration Modernization Act; Provisions for Use in Food Labeling of Health Claims and Nutrient Content Claims Based on Authoritative Statements; Public Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Announcement of public meeting; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of March 24, 1999 (56 FR 14178). This document announced a forthcoming public meeting concerning implementation of sections 303 and 304 of the FDA Modernization Act of 1997. The document published with an incorrect title. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce A. Strong, Office of Policy (HF–