add comments and then send it to the Manager, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permit

(d) Special flight permits may be issued per sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on January 9, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1235 Filed 1–12–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 807

[Docket No. 00N–1625]

Medical Devices; Rescission of Substantially Equivalent Decisions and Rescission Appeal Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing regulations under which FDA may rescind a decision issued under the Federal Food, Drug, and Cosmetic Act (the act) that a device is substantially equivalent to a legally marketed device, and, therefore, may be marketed. In addition, under this proposal, a premarket notification (commonly known as a ''510(k)'') holder may request administrative review of a proposed rescission action. This proposed rule is being issued in order to standardize the procedures for considering rescissions.

DATES: Submit written comments by April 16, 2001.

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

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

The Medical Device Amendments (Public Law 94–295) (the amendments) to the act (21 U.S.C. 301 *et seq.*) were enacted on May 28, 1976. Among other things, the amendments directed FDA to issue regulations classifying all medical devices into one of three regulatory control categories. The classification depends upon the degree of regulation necessary to provide reasonable assurance of the safety and effectiveness of the device.

Under section 513(a)(1)(A) of the act (21 U.S.C. 360c(a)(1)(A)), class I devices are subject to a comprehensive set of regulatory provisions applicable to all classes of devices, e.g., registration and listing, prohibitions against adulteration and misbranding, and good manufacturing practice requirements. A class I device is exempt from the premarket notification requirements of the act unless it is intended for a use which is of substantial importance in preventing impairment of human health, or the device presents a potential unreasonable risk of illness or injury under section 510(l) of the act (21 U.S.C. 360(l)). Class II devices are subject to special controls as well as general controls. These special controls may consist of performance standards, postmarket surveillance, patient registries, FDA guidelines, or other appropriate controls under section 513(a)(1)(B) of the act. Class III devices require premarket approval (PMA) or a completed product development protocol by FDA before they may be marketed, unless they are class III devices for which we have not called for PMA's under section 515(b) of the act (21 U.S.C. 360e(b)).

II. Premarket Notification Requirements

Section 510(k) of the act requires each person who is required to register and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use to submit a 510(k).

Throughout this proposal, we use the following terms:

1. The ''510(k) submitter.''—the person who submitted the 510(k) to the FDA.

2. The ''510(k) holder''—the person who possesses the rights to market the device that is the subject of a 510(k) substantial equivalence order. (The 510(k) submitter and the 510(k) holder may or may not be the same person.)

3. The ''510(k) holder of record''—the person whom FDA has on file as being the 510(k) holder.

The proposed rule adds these definitions to 21 CFR 807.3.

There may be instances when 510(k) ownership has changed without FDA's knowledge. In the event of a proposed rescission, FDA would provide notice to the 510(k) holder of record. FDA would attempt to notify the holder of record by registered letter. FDA would also post notice of a proposed rescission on FDA's Center for Devices and Radiological Health's (CDRH) home page on the Internet at http://www.fda.gov/cdrh/index.html. To protect the privacy of the 510(k) holder, only the proposed rescission would be listed; the factual basis and reasons for the rescission would not be posted on CDRH's home page on the Internet.

Under the 510(k) process, the 510(k) submitter may claim that its new device is substantially equivalent to a legally marketed class I or class II device or to a preamendments class III device that is not yet required to be the subject of an approved premarket approval application. If, after reviewing the 510(k), the agency determines that the device is substantially equivalent to the legally marketed device (as defined in 21 CFR 807.92(a)(3)), the agency will issue an order permitting the 510(k) submitter to market its device without the need for the more rigorous premarket approval under section 515 of the act.

The criteria the agency must use to determine substantial equivalence are in section 513(i) of the act. Section 513(i) of the act defines substantial equivalence to mean that the device has the same intended use as the predicate device and that FDA, by order, has found that the device—(i) has the same technological characteristics as the predicate device, or (ii)—(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including clinical data if deemed necessary by FDA, that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the legally marketed device.

The statute allows 510(k) marketing clearance only for devices that FDA determines are comparable in safety and effectiveness to a legally marketed device. New devices that are not substantially equivalent must remain in class III and meet the premarket approval requirements under section 515 of the act before they can be marketed, unless the device is reclassified under section 513(f) of the act.

III. Authority to Rescind

On October 25, 1994, the Health Industry Manufacturers Association (HIMA) submitted a petition [Docket No. 94A–0388] to FDA in which they requested that FDA issue an advisory opinion stating that the act does not provide authority for FDA to withdraw a premarket notification (510(k)) order. In the alternative, HIMA requested that, if FDA determined that it did have the authority to withdraw a premarket notification order, FDA should: (1) Refrain from rescinding such a decision without establishing procedures assuring the 510(k) holder due process rights; (2) provide the 510(k) holder an opportunity for an informal hearing under section 201(x) (formerly 201(y)) of the act (21 U.S.C. 321(x)) before issuing a rescission order; and (3) issue a regulation providing the 510(k) holder with the opportunity to request a hearing to challenge a proposed withdrawal.

On September 11, 1995, FDA issued an interim response to the HIMA petition. In this interim response, FDA said that it intended to issue a proposed rule specifying the authority for rescinding a substantial equivalence decision as well as the grounds under which such decisions can be made. The interim response also stated that, pending the completion of this rulemaking process, FDA would only rescind, or propose to rescind, substantial equivalence orders in cases involving: (1) A serious adverse risk to public health or safety, (2) data integrity or fraud, or (3) other compelling circumstances. On September 22, 1997, FDA issued a final response to the petition that restated the policy established in the interim response.

Although the act does not expressly address rescission of substantial equivalence orders, section 513(f) and (i) of the act indicate that rescission is consistent with FDA's authority under the act to allow marketing of a device under the 510(k) process only if the device is substantially equivalent to a legally marketed device.

FDA has authority under its administrative procedure regulations to reconsider the issuance of substantial equivalence orders § 10.33(a) and (h) (21 CFR 10.33(a) and (h)). Section 10.33(a) states the ''Commissioner may at any time reconsider a matter, on the Commissioner's own initiative or on the petition of an interested person.'' Section 10.33(h) states the ''Commissioner may initiate the reconsideration of all or part of a matter at any time after it has been decided or action has been taken.'' Both § 10.33(a) and (h) provide the agency with authority to reconsider and rescind an order determining a device to be substantially equivalent.

Section 10.75 (21 CFR 10.75) also provides the agency with authority for supervisory review of decisions made by an employee other than the Commissioner of Food and Drugs (the Commissioner). This internal review can be undertaken to resolve agency disputes, review policy and unusual situations affecting public interest, or as required by delegations of authority. Section 10.75 supports the agency's authority to correct the decisions that it determines were made in error by employees other than the Commissioner.

Case law also supports FDA's authority to correct inappropriate decisions even in the absence of explicit statutory or regulatory authority. In *American Therapeutics Inc.* v. *Sullivan*, 755 F. Supp. 1, 2 (D.D.C. 1990), FDA rescinded a drug approval that had been issued by mistake. The court held that, although there were no regulations or statutory provisions that expressly contemplated rescission of an approval by mistake, the agency must be given latitude to correct mistakes.

The Supreme Court has also recognized an implied authority in agencies to reconsider and rectify errors, even if the applicable statute and regulations do not expressly provide for such reconsideration. For example, in concluding that the Interstate Commerce Commission could order a refund to correct a prior error, the Supreme Court stated that ''[a]n agency, like a court, can undo what is wrongfully done by virtue of its order.'' *United Gas Improvement Co.* v. *Callery Properties, Inc.,* 382 U.S. 223, 229 (1965). See also *American Trucking Association* v. *Frisco Trans.,* 358 U.S. 133, 145 (1958) (''the presence of authority in administrative officers and tribunals to correct [inadvertent ministerial] errors has long been recognized—probably so well recognized that little discussion has ensued in the reported cases.''); *Copley* v. *Elliot,* 948 F. Supp. 586, 589 (W.D. Va. 1996) (''[i]t is generally always within the power of a government agency to correct its mistakes.'').

Other courts have similarly recognized this implied authority, *Iowa Power and Light Co.* v. *United States,* 712 F.2d 1292, 1294–97 (8th Cir. 1983) (ICC could retroactively impose higher tariff to correct legal error), cert. denied, 466 U.S. 949 (1984); *Bookman* v. *United States,* 453 F.2d 1263, 1265 (Ct. Cl. 1972) allowing agency to reconsider decisions in absence of statutory or regulatory authorization after noting general rule that ''[e]very tribunal, judicial or administrative, has some power to correct its own errors or otherwise appropriately to modify its judgment, decree, or order'') (quoting 2 K. Davis, Administrative Law Treatise, section 18.09 (1958)).

Moreover, some courts have held that FDA has a duty to correct errors if it learns its prior position was incorrect. See *United States* v. *60 28-Capsule Bottles,*. 211 F. Supp. 207, 215 (D. N.J. 1962) (FDA has a duty to change its position with reference to the efficacy of a drug if it subsequently learns that its original position was in error); see also *Bentex Pharmaceuticals Inc.* v. *Richardson,* 463 F.2d. 363, 368 n. 17 (4th Cir. 1972) *rev'd Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645 (1979) (noting FDA not estopped from alleging product was a ''new drug,'' even though the agency had given the opinion that similar drugs were not ''new drugs'').

IV. Bases for Proposing Rescission of a 510(k) Substantial Equivalence Decision

FDA examines a vast array of device technologies each year under the premarket notification (510(k)) process. Under the 510(k) process, each submitter has the burden of demonstrating that its device is at least as safe and effective as a legally marketed device. If FDA discovers that a premarket notification submission does not meet the criteria of substantial equivalence and the submission was cleared in error, FDA will issue a registered letter to the 510(k) holder of record proposing to rescind the order of substantial equivalence. FDA will also post notice of the proposed rescission on CDRH's home page on the Internet.

Under proposed § 807.103, FDA may propose rescission of a substantial equivalence decision if one or more of the following criteria are met. FDA believes that, if any one of these criteria is met, there is no longer reasonable assurance that the device is at least as safe and effective as a legally marketed device.

1. The premarket notification does not satisfy the criteria under § 807.100(b)(1) or (b)(2) for a determination of substantial equivalence.

2. Based on new safety or effectiveness information, the device is not substantially equivalent to a legally marketed device.

3. (i) FDA or the 510(k) holder has removed from the market, for safety and effectiveness reasons, one or more legally marketed device(s) on which the substantial equivalence determination

was based, or (ii) a court has issued a judicial order determining the legally marketed device(s), on which the substantial equivalence determination was based, to be misbranded or adulterated.

4. The premarket notification contained or was accompanied by an untrue statement of material fact.

5. The premarket notification included or should have included information about clinical studies and these clinical studies failed to comply with applicable Institutional Review Board regulations (21 CFR part 56) or informed consent regulations (21 CFR part 50) in a way that the rights or safety of human subjects were not adequately protected.

6. The premarket notification contained clinical data submitted by a clinical investigator who has been disqualified under 21 CFR 812.119.

These would be bases to rescind because information in the 510(k) is incorrect, incomplete, unreliable, or not evaluated properly by FDA in accordance with section 513(f) and (i) of the act.

V. Procedures for Rescinding a 510(k) Substantial Equivalence Order

Before issuing an order rescinding a 510(k) substantial equivalence decision, FDA would notify the 510(k) holder of record of its intent to rescind by registered mail. This notice would state the facts upon which the action is based and would notify the 510(k) holder of record of an opportunity for a hearing under part 16 (21 CFR part 16). The notice would include the time within which a hearing may be requested and the name, address, and telephone number of the FDA employee to whom any request for a hearing is to be addressed. FDA would also post notice of a proposed rescission on CDRH's home page on the internet. The Internet site will only state that a rescission of the 510(k) is proposed and information about the hearing and will not state the facts upon which the action is based. Because FDA may be unaware that ownership of a 510(k) has changed, the notification by Internet site would serve as an additional means of assuring that the current 510(k) holder has notice.

If FDA believes that immediate action to remove a dangerous device from the market is necessary to protect the public health, the agency may, in accordance with §§ 16.24(d), 16.60(h) and 10.19, waive, suspend, or modify any part 16 procedure or procedures stated in part 807. Ordinarily, the amount of time specified in the notice for requesting a hearing will be not less than 3 working days. FDA ordinarily would provide notice by registered mail. Under circumstances presenting the need for immediate action, FDA may, for example, attempt to contact the 510(k) holder by telephone instead of registered mail.

If a 510(k) holder fails to request a hearing within the timeframe specified by FDA in the notice of opportunity for hearing, FDA will consider the failure to request a hearing a waiver of such hearing and FDA will issue a letter rescinding the order determining substantial equivalence.

If, after a part 16 hearing is held, the agency decides to proceed with the rescission of an order determining substantial equivalence, FDA will issue to the 510(k) holder of record an order rescinding the order determining substantial equivalence. The rescission order will state each ground for rescinding the substantial equivalence determination. FDA will give the public notice of an order rescinding a determination of substantial equivalence. The notice will be placed on CDRH's home page on the Internet.

VI. 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.

VII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 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 agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities, if a rule would have a significant economic impact on a substantial number of small entities. The proposed rule will not have a significant economic impact on a substantial number of small entities. FDA has only proposed five rescissions from 1997 through 1999 and one rescission through May 2000. FDA does not believe that this level of activity represents a significant impact on a substantial number of small entities. In addition, the rule will be applied only when the criteria for rescission are met. The agency therefore certifies that this rule, if finalized, will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing 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 in any one year (adjusted annually for inflation). The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the proposed rule, because the proposed rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation.

VIII. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this proposal by April 16, 2001. 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 Dockets Management Branch between 9 a.m. and 4 p.m. Monday through Friday.

IX. Paperwork Reduction Act of 1995

FDA has tentatively determined that this proposed rule contains no collections of information. Therefore, clearance from the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner

of Food and Drugs, it is proposed that 21 CFR parts 16 and 807 be amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

2. Section 16.1 is amended in paragraph (b)(2) by numerically adding an entry for § 807.103 to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§ 807.103 relating to rescission of substantially equivalent orders and rescission appeal procedures.

* * * * *

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

3. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374.

4. Section 807.3 is amended by adding new paragraphs (t), (u), and (v) to read as follows:

§ 807.3 Definitions.

* * * * *

(t) *510(k) submitter* means the person who submitted the 510(k) to FDA.

(u) *510(k) holder* means the person who possesses the rights to market a device that is the subject of 510(k) substantial equivalence order.

(v) *510(k) holder* of record means the person FDA has on file as being the holder of the 510(k).

5. Section 807.103 is added to subpart E to read as follows:

§ 807.103 Rescission of 510(k) substantially equivalent orders and rescission appeal procedures.

(a) *Grounds for rescinding a substantially equivalent order.* FDA may issue an order rescinding a determination of substantial equivalence under this section, if FDA determines that any one of the following grounds exist:

(1) The premarket notification does not satisfy the criteria under § 807.100(b)(1) or (b)(2) for a determination of substantial equivalence.

(2) Based on new safety or effectiveness information, the device is not substantially equivalent to a legally marketed device.

(3) (i) FDA or the 510(k) holder has removed from the market, for safety and effectiveness reasons, one or more legally marketed device(s) on which the substantial equivalence determination was based, or

(ii) A court has issued a judicial order determining the legally marketed device(s) on which the substantial equivalence determination was based to be misbranded or adulterated.

(4) The premarket notification contained or was accompanied by an untrue statement of material fact.

(5) The premarket notification included or should have included information about clinical studies and these clinical studies failed to comply with applicable institutional review board regulations (part 56 of this chapter) or informed consent regulations (part 50 of this chapter) in a way that the rights or safety of human subjects were not adequately protected.

(6) The premarket notification contained clinical data submitted by a clinical investigator who has been disqualified under § 812.119 of this chapter.

(b) *Notice of proposed rescission and opportunity for a hearing.* Before issuing an order rescinding a substantial equivalence order, FDA will issue the 510(k) holder of record a notice of the agency's intent to rescind the 510(k) by registered letter, together with a notice of an opportunity for an informal hearing under part 16 of this chapter. FDA will also post notice of a proposed rescission on the FDA's Center for Devices and Radiological Health's (CDRH) home page on the Internet at http://www.fda.gov/cdrh/index.html. If FDA believes that immediate action to remove a dangerous device from the market is necessary to protect the public health, the agency may, in accordance with §§ 16.24(d), 16.60(h), and 10.19 of this chapter, waive, suspend, or modify any part 16 procedure and, in accordance with this section, waive, suspend, or modify any part 807 procedure.

(c) *Failure to request a hearing.* If a 510(k) holder fails to request a hearing within the timeframe specified by FDA in the notice of opportunity for hearing, FDA will consider the failure to request a hearing a waiver of such hearing and FDA will issue a letter rescinding the order determining substantial equivalence.

(d) *Rescission order.* If the 510(k) holder does not request a hearing or if, after proceedings in accordance with this part and part 16 of this chapter are completed, the agency decides to proceed with the rescission of an order determining substantial equivalence, FDA will issue to the 510(k) holder of record an order rescinding the order determining substantial equivalence. The rescission order will state each ground for rescinding the substantial equivalence determination.

(e) *Public notice of final action.* FDA will give the public notice of the order rescinding a determination of substantial equivalence. If FDA determines not to finalize a proposed rescission, FDA will also give the public notice of this determination. These notices will be placed on FDA's home page on the Internet.

Dated: January 5, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–1128 Filed 1–12–01; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 136, 141, and 143

[FRL–6918–1]

RIN 2040–AD59

Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act; National Primary Drinking Water Regulations; and National Secondary Drinking Water Regulations; Methods Update

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing action on a methods update rule that approves revised versions of test procedures (*i.e.,* analytical methods) for the determination of chemical, radiological, and microbiological pollutants and contaminants in wastewater and drinking water. The revisions concern methods published by one or more of the following organizations: American Society for Testing Materials (ASTM), United States Geological Survey (USGS), United States Department of Energy (DOE), American Public Health Association (APHA), American Water Works Association (AWWA), and Water Environment Federation (WEF). Previously approved versions of the methods remain approved. This rule will give the analytical community a larger selection of analytical methods. Today's action also corrects typographical errors and updates references where appropriate.