(2) *Indications for use*. For the treatment of otitis externa associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (coagulase-positive staphylococci, *Pseudomonas aeruginosa*, and *Enterococcus faecalis*).

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: March 24, 2010.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2010–7163 Filed 3–31–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 814

[Docket No. FDA–2009–N–0458]

RIN 0910–AG29

Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended to Treat, Diagnose, or Cure; Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations on premarket approval of medical devices to include requirements relating to the submission of information on pediatric subpopulations that suffer from the disease or condition that a device is intended to treat, diagnose, or cure. Elsewhere in this issue of the **Federal Register**, we are publishing a companion proposed rule under FDA's usual procedure for notice and comment to provide a procedural framework to finalize the rule in the event we receive significant adverse comment and withdraw this direct final rule.

DATES: This rule is effective August 16, 2010. Submit electronic or written comments on the direct final rule by June 15, 2010. Submit electronic or written comments on the information collection requirements by June 1, 2010. If we receive no significant adverse comments within the specified comment period, we intend to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If we receive any timely significant adverse comment, we will withdraw this final rule in part or in whole by publication of a document in the **Federal Register** within 30 days after the comment period ends.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2009–N–0458, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and docket number and regulatory information number (RIN) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert Gatling, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1640, Silver Spring, MD 20993, 301–796–6560.

SUPPLEMENTARY INFORMATION:

I. What Is the Background of This Rule?

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA)[1] (Public Law 110–85) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding, among other things, a new section 515A of the act (21 U.S.C. 360e–1). Section 515A(a) of the act requires persons who submit certain medical device applications to include readily available information providing a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients. This rule amends FDA's regulations to implement the requirements of section 515A(a) of the act.

Section 515A(c) of the act states that, for the purposes of that section, the term "pediatric subpopulation" has the meaning given the term in section 520(m)(6)(E)(ii) of the act (21 U.S.C. 360j(m)(6)(E)(ii)). Section 520(m)(6)(E)(ii) of the act defines the term "pediatric subpopulation" to mean one of the following populations:

- Neonates;
- Infants;
- Children; or
- Adolescents.

We have previously issued guidance recommending the age range for each of the populations included in the term "pediatric subpopulation." See *Premarket Assessment of Pediatric Medical Devices* (May 14, 2004); (*http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089740.htm*).

The term "pediatric patient" is defined, for purposes of section 520(m)(6)(E)(i) of the act as patients who are 21 years of age or younger at the time of the diagnosis or treatment. Because no other definition of "pediatric patient" is included in the Pediatric Medical Device Safety and Improvement Act of 2007, and because the definition in section 520(m)(6)(E)(i) of the act is consistent with the definition of pediatric subpopulations in section 520(m)(6)(E)(ii), FDA has concluded that the term "pediatric patient" in section 515A of the act refers to patients who are 21 years of age or younger at the time of the diagnosis or treatment.

The information submitted under section 515A(a) of the act will help FDA track the following information that it is required to report annually to Congress, in accordance with section 515A(a)(3) of the act:

- The number of approved devices for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure;
- The number of approved devices labeled for use in pediatric patients;
- The number of approved pediatric devices that were exempted from a review fee under section 738(a)(2)(B)(v) of the act (21 U.S.C. 379j(a)(2)(B)(v)); and
- The review time for each such device.

[1] Title III of FDAAA, which includes new section 515A, is also known as the Pediatric Medical Device Safety and Improvement Act of 2007.

II. What Applications Are Subject to This Rule?

In accordance with the act, these requirements apply to the following applications when submitted on or after the effective date of this rule:

- Any request for a humanitarian device exemption (HDE) submitted under section 520(m) of the act;
- Any premarket approval application (PMA) or supplement to a PMA submitted under section 515 of the act; and
- Any product development protocol (PDP) submitted under section 515 of the act.

If the applicant of a supplement to a PMA has previously submitted information satisfying these requirements, the applicant may incorporate that information by reference rather than resubmitting the same information. However, if additional information has become readily available to the applicant since the previous submission, the applicant must submit that information as part of the supplement.

Many PMAs begin with the submission of one or more PMA modules; see *Premarket Approval Application Modular Review—Guidance for Industry and FDA Staff*, available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089764.htm*. Applicants who choose to use the modular approach should submit the information required by section 515A(a) of the act in the final PMA module (i.e., the module that includes final clinical data, proposed labeling, and the summary of safety and effectiveness).

III. What Does This Direct Final Rule Do?

This direct final rule implements new section 515A(a) of the act by amending 21 CFR Part 814, *Premarket Approval of Medical Devices*, to include requirements relating to the submission of information on pediatric subpopulations that suffer from the disease or condition that a device is intended to treat, diagnose, or cure.

A. What Information Must Be Provided?

This rule requires each applicant who submits an HDE, PMA, supplement to a PMA, or PDP to include, if "readily available," a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients.

B. What Are the Consequences of Not Submitting "Readily Available" Information?

If you do not submit the information required by section 515A(a) of the act, FDA may not approve your application until you provide the required information. We intend to contact you during the normal course of our review to inform you that your submission lacks the information required by section 515A(a) of the act and by this rule, and to ask you to amend your application to provide the required information. If your application has no other deficiencies and otherwise meets applicable statutory and regulatory requirements for approval, but still lacks information required by section 515A(a) of the act, we intend to send you an "approvable" letter informing you that we will approve your application after you provide the information required by section 515A(a). If your application has other deficiencies or does not meet all applicable statutory and regulatory requirements for approval, we intend to send you a "not approvable" letter or a "major deficiency" letter describing what information or data you need to provide before FDA can approve your application; the "not approvable" or "major deficiency" letter may cite the absence of 515A(a) information in the section listing minor deficiencies. For additional information concerning the interactive process we will use during our review, see *Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements*, available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm*. For additional information concerning "approvable," "not approvable," and "major deficiency" letters, see *FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals*, available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089733.htm*.

IV. What Are the Procedures for Issuing a Direct Final Rule?

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA announced the availability of the guidance document entitled "Guidance for FDA and Industry: Direct Final Rule Procedures" that described when and how we will employ direct final rulemaking. We believe that this rule is appropriate for direct final rulemaking because it is intended to make noncontroversial amendments and minor corrections to existing regulations. We anticipate no significant adverse comment.

Consistent with FDA's procedures on direct final rulemaking, we are publishing elsewhere in this issue of the **Federal Register** a companion proposed rule that is identical in substance to this direct final rule. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of any significant adverse comment. The comment period for this direct final rule runs concurrently with the comment period of the companion proposed rule. Any comments received in response to the companion proposed rule will also be considered as comments regarding this direct final rule.

If we receive any significant adverse comment, we intend to withdraw this final rule before its effective date by publishing a notice in the **Federal Register** within 30 days after the comment period ends. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without change. In determining whether an adverse comment is significant and warrants withdrawing a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, we may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

If we withdraw the direct final rule, all comments received will be considered under the companion proposed rule in developing a final rule under the usual notice-and-comment procedures under the APA (5 U.S.C. 552a *et seq.*). If we receive no significant adverse comment during the specified comment period, we intend to publish a confirmation document in the **Federal Register** within 30 days after the comment period ends.

V. What Is the Legal Authority for This Rule?

This rule, if finalized, would amend §§ 814.1, 814.2, 814.20, 814.37, 814.39, 814.44, 814.100, 814.104, and 814.116. FDA's legal authority to modify 814.1, 814.2, 814.20, 814.37, 814.39, 814.44, 814.100, 814.104 and 814.116 arises from the same authority under which FDA initially issued these regulations, the device and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 360e, 360e–1, 360j, and 371).

VI. What Is the Environmental Impact of This Rule?

FDA has determined under 21 CFR 25.30(h) and 25.34(a) 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. What Is the Economic Impact of This Rule?

We have examined the impacts of this rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), 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). We believe that this direct final rule is not a significant regulatory action as defined by 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. Because this regulation only requires that some submissions include a small amount of readily available information, creating little additional burden, the agency certifies that the direct final rule 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, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $133 million, using the most current (2008) Implicit Price Deflator for the Gross Domestic Product. We do not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

We believe that the only costs to industry are those that we account for in our Paperwork Reduction Act analysis, which immediately follows this section. The rule does not require additional clinical research or other costly efforts, and simply requires the applicant to briefly summarize readily available information that will have been reviewed by the applicant during the course of its development of the device and preparation of its application to FDA. We have also limited the rule to exclude supplements that do not involve a new intended use; if a supplement does not involve a new intended use, we do not expect the applicant will have new information pertinent to the requirement of section 515A(a) of the act and this rule, and the limitation avoids the needless submission of duplicate information to FDA. We expect FDA's additional costs will be inconsequential, as the information required here will be filed and managed as an integral part of each submission, using existing filing, storage, and data management systems and processes.

VIII. How Does the Paperwork Reduction Act of 1995 Apply to This Rule?

This direct final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting 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 each collection of information. FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection techniques, when appropriate, and other forms of information technology.

Title: Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended to Treat, Diagnose, or Cure.

Description: Section 515A(a) of FDAAA requires applicants who submit certain medical device applications to include readily available information providing a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients. The information submitted will allow FDA to track the number of approved devices for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure; the number of approved devices labeled for use in pediatric patients; the number of approved pediatric devices that were exempted from a review fee under section 738(a)(2)(B)(v) of the act; and the review time for each such device.

Description of Respondents: These requirements apply to applicants who submit the following applications when submitted on or after the effective date of this rule:

- Any request for an HDE submitted under section 520(m) of the act;
- Any PMA submitted under section 515 of the act;
- Any PDP submitted under section 515 of the act; and
- Any supplement to an HDE, PMA, or PDP that proposes a new intended use, whether for an adult population or a pediatric population.

Burden: FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
814.20(b)(3)(i)	25	1	25	4	100
814.37(b)(2)	10	1	10	4	40
814.39(h)	10	1	10	4	40
814.104(b)(6)	5	1	5	4	20
Totals					200

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

All that is required is to access, organize, and submit information that is readily available, using any approach that meets the requirements of section 515A(a) of the act and this rule. FDA expects to receive approximately 40 original PMA/PDP/HDE applications each year, 5 of which FDA expects to be HDEs. This estimate is based on the actual average of FDA's receipt of new PMA applications in FY 2007 through FY 2008. The agency estimates that 10 of those 40 original PMA submissions will fail to provide the required pediatric use information and their sponsors will therefore be required to submit PMA amendments. The agency also expects to receive 10 supplements that describe a new indication for use and will include the pediatric use information required by 515A(a) of the act and this rule. We believe that because the rule requires that the applicant organize and submit only readily available information or a description of the methodology employed to determine whether information required is readily available, no more than 4 hours will be required to comply with section 515A(a) of the act and this rule. FDA estimates that the total burden created by this rule is 200 hours.

We based this estimate on our experience with similar information collection requirements and on consultations with the Interagency Pediatric Devices Working Group which includes the Agency for Healthcare Research and Quality, FDA, National Institutes of Health, members of the Pediatric Advisory Committee, researchers, healthcare practitioners, medical device trade associations, and medical device manufacturers.

As provided in 5 CFR 1320.5(c)(1), collections of information in a direct final rule are subject to the procedures set forth in 5 CFR 1320.10. Interested persons and organizations may submit comments on the information collection requirements of this direct final rule (see **DATES**), to the Division of Dockets Management (see **ADDRESSES**).

At the close of the 60-day comment period, FDA will review the comments received, revise the information collection provisions as necessary, and submit these provisions to OMB for review. FDA will publish a notice in the **Federal Register** when the information collection provisions are submitted to OMB, and an opportunity for public comment to OMB will be provided at that time. Prior to the effective date of the direct final rule, FDA will publish a notice in the **Federal Register** of OMB's decision to approve, modify, or disapprove the information collection provisions. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IX. What Are the Federalism Impacts of This Rule?

FDA has analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

X. How Do You Submit Comments on This Rule?

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this direct final rule. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 814 is amended as follows:

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 1. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

■ 2. In § 814.1, revise paragraph (a) to read as follows:

§ 814.1 Scope.

(a) This section implements sections 515 and 515A of the act by providing procedures for the premarket approval of medical devices intended for human use.

* * * * *

■ 3. Revise § 814.2 to read as follows:

§ 814.2 Purpose.

The purpose of this part is to establish an efficient and thorough device review process—

(a) To facilitate the approval of PMAs for devices that have been shown to be safe and effective and that otherwise meet the statutory criteria for approval;

(b) To ensure the disapproval of PMAs that have not been shown to be safe and effective or that do not otherwise meet the statutory criteria for approval; and

(c) To ensure PMAs include readily available information concerning actual and potential pediatric uses of medical devices.

■ 4. In § 814.20, revise paragraph (b)(3)(i) to read as follows:

§ 814.20 Application.

* * * * *

(b) * * *

(3) * * *

(i) *Indications for use.* (A) A general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.

(B) Information concerning uses in pediatric patients who are 21 years of age or younger: The application must include the following information, if readily available:

(*1*) A description of any pediatric subpopulations (neonates, infants, children, adolescents) that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and

(*2*) The number of affected pediatric patients.

* * * * *

■ 5. In § 814.37, revise the section heading and paragraph (b) to read as follows:

§ 814.37 PMA amendments and resubmitted PMAs.

* * * * *

(b)(1) FDA may request the applicant to amend a PMA or PMA supplement with any information regarding the device that is necessary for FDA or the appropriate advisory committee to complete the review of the PMA or PMA supplement.

(2) FDA may request the applicant to amend a PMA or PMA supplement with information concerning pediatric uses as required under § 814.20(b)(3)(i).

* * * * *

■ 6. In § 814.39, add paragraph (h) to read as follows:

§ 814.39 PMA supplements.

* * * * *

(h) The application must include the following information, if readily available:

(1) A description of any pediatric subpopulations (neonates, infants, children, adolescents) that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and

(2) The number of affected pediatric patients who are 21 years of age or younger.

(3) If information concerning the device that is the subject of the supplement was previously submitted under § 814.20(b)(3)(i), that information may be incorporated by reference to the application or submission that contains the information. However, if additional information required under § 814.20(b)(3)(i) has become readily available to the applicant since the previous submission, the applicant must submit that information as part of the supplement.

■ 7. In § 814.44, redesignate paragraphs (e)(1)(ii) through (e)(1)(iv) as paragraphs (e)(1)(iii) through (e)(1)(v), respectively, and add new paragraph (e)(1)(ii) to read as follows:

§ 814.44 Procedures for review of a PMA.

* * * * *

(e) * * *

(1) * * *

(ii) The submission of additional information concerning potential pediatric uses required by § 814.20(b)(3)(i) that is readily available to the applicant;

* * * * *

■ 8. Amend § 814.100 as follows:

■ a. Redesignate paragraphs (b) through (e) as paragraphs (d) through (g), respectively;

■ b. Redesignate paragraph (a) as paragraph (b), and remove the first sentence of newly redesignated paragraph (b); and

■ c. Add new paragraphs (a) and (c) to read as follows:

§ 814.100 Purpose and scope.

(a) This subpart H implements sections 515A and 520(m) of the act.

* * * * *

(c) Section 515A of the act is intended to ensure the submission of readily available information concerning actual and potential pediatric uses of medical devices.

* * * * *

■ 9. Amend § 814.104 as follows:

■ a. Revise the last sentence of paragraph (b)(4)(ii);

■ b. Revise the last sentence of paragraph (b)(5); and

■ c. Add paragraph (b)(6) to read as follows:

§ 814.104 Original applications.

* * * * *

(b) * * *

(4) * * *

(ii) * * * The effectiveness of this device for this use has not been demonstrated.

(5) * * * If the amount charged is $250 or less, the requirement for a report by an independent certified public accountant or an attestation by a responsible individual of the organization is waived; and

(6) Readily available information concerning actual and potential pediatric uses of the device, as required by § 814.20(b)(3)(i).

* * * * *

■ 10. In § 814.116, redesignate paragraphs (c)(2) through (c)(4) as paragraphs (c)(3) through (c)(5), respectively, and add new paragraph (c)(2) to read as follows:

§ 814.116 Procedures for review of an HDE.

* * * * *

(c) * * *

(2) The submission of additional information concerning potential pediatric uses required by § 814.20(b)(3)(i) that is readily available to the applicant;

* * * * *

Dated: March 17, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–7193 Filed 3–31–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1002, 1003, 1004, 1005, 1010, 1020, 1030, 1040, and 1050

[Docket No. FDA–2010–N–0010]

Medical Devices; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending certain medical device regulations to correct statutory and regulatory references to ensure accuracy, consistency, and clarity in the agency's regulations.

DATES: This rule is effective April 1, 2010.

FOR FURTHER INFORMATION CONTACT: Bernice E. Noland, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4430, Silver Spring, MD 20993–0002, 301–796–5742.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations at part 1002 (21 CFR part 1002) to correct a regulatory reference. FDA is revising § 1002.30(b) by deleting "paragraph (c) of § 1002.61" and replacing it with "table 1 of § 1002.1." FDA updated