



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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule 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.

DATES: This rule is effective [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Sheila Brown, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1651, Silver Spring, MD 20993, 301-796-6563.

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration Amendments Act of 2007 (FDAAA)¹ (Public Law 110-85) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by among other things, adding section 515A of the FD&C Act (21 U.S.C. 360e-1). Section 515A(a) of the FD&C Act requires persons who submit certain medical device applications 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. The information submitted under section 515A(a) of the FD&C Act will be essential to completing the annual report that FDA is required to submit to Congress under section 515A(a)(3) of the FD&C Act, including:

- 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; and
- The review time for each such device application.

On April 1, 2010, FDA published a proposed rule, along with a companion direct final rule, with a 75-day comment period to request input from interested parties (75 FR 16365, April 1, 2010) as a step towards implementing section 515A(a) of the FD&C Act. A few months later, FDA withdrew the direct final rule because we received significant adverse comment (75 FR 41986, July 20, 2010.)

Due to the changes made since the April 1, 2010, proposed rule, particularly changes to the scope of applications to which this requirement applies (see section II), a supplemental notice of proposed rulemaking was issued on February 19, 2013 (78 FR 11612 at 11616), to allow for public comment on the re-drafted proposed rule. In addition to providing FDA's revised proposal for implementing section 515A(a) of the FD&C Act, that document served to

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

supplement the proposed rule that issued with the companion direct final rule (75 FR 16365, April 1, 2010). FDA received four additional comments on the supplemental notice of proposed rulemaking that were considered when developing this final rule.

II. How Are Pediatric Patients and Pediatric Subpopulations Defined?

Section 515A(c) of the FD&C 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 FD&C Act (21 U.S.C. 360j(m)(6)(E)(ii)). Section 520(m)(6)(E)(ii) of the FD&C Act defines the term "pediatric subpopulation" to mean one of the following populations:

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

Section 515A additionally requires that the descriptions of pediatric subpopulations include the number of affected "pediatric patients." Section 515A does not define the term "pediatric patients." The term "pediatric patients", however, is defined for purposes of section 520(m)(6)(E)(i) of the FD&C Act (relating to humanitarian device exemptions for pediatric patients) as patients who are 21 years of age or younger at the time of the diagnosis or treatment. The definition for "pediatric patients" in section 520(m)(6)(E)(i) is consistent with the definition of "pediatric subpopulations" in section 520(m)(6)(E)(ii).

These definitions of pediatric subpopulation and pediatric patient are reflected in FDA's previously issued 2004 guidance on pediatric medical devices, which recommended the age range for each of the populations included in the term "pediatric subpopulation." Those age ranges span from birth to 21 years of age (that is, from birth through the 21st year of life, up to

but not including the 22nd birthday). See "Premarket Assessment of Pediatric Medical Devices" (May 14, 2004);

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089740.htm>.

For purposes of the requirements in this final rule, FDA is codifying a definition of the term "pediatric patients" as patients who are 21 years of age or younger (that is, from birth through the 21st year of life, up to but not including the 22nd birthday) at the time of the diagnosis or treatment.

III. What Applications Are Subject to This Final Rule?

In accordance with the FD&C Act, the requirements 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 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 FD&C Act;
- Any premarket approval application (PMA) or supplement to a PMA submitted under section 515 of the FD&C Act; and
- Any product development protocol (PDP) submitted under section 515 of the FD&C Act.

FDA concludes that section 515A applies to all submission types listed in the statute---PMA, HDE, PDP, and all PMA supplements---not just the subset of PMA supplements that propose a new indication for use, as was proposed in the April 1, 2010, proposed rule. The Agency also wants to clarify that it does not interpret 30-day notices submitted under § 814.39(f) (21 CFR 814.39(f)) to be PMA supplements for purposes of this final rule. Section 515(d)(6)(A)

of the FD&C Act (21 U.S.C. 360e(d)(6)(A)) distinguishes between modifications to manufacturing procedures or methods of manufacture that affect the safety and effectiveness of a device subject to an approved PMA, which require the submission of a written notice, and other changes that affect safety and effectiveness that require the submission of a "supplemental application." Because of this statutory distinction, 30-day notices are not considered PMA supplements for purposes of this final rule and, therefore, are not required to include readily available pediatric information.

Moreover, an applicant submitting a PMA supplement that previously submitted information satisfying the pediatric subpopulation requirements for the device may include that information by referencing the previous application 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 premarket approval applications 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 FD&C Act in the final PMA module (i.e., the module that includes final clinical data, proposed labeling, and the Summary of Safety and Effectiveness Data).

IV. What Does This Final Rule Do?

This final rule implements section 515A(a) of the FD&C Act by amending part 814 (21 CFR part 814), Premarket Approval of Medical Devices, to include requirements relating to the submission of readily available 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 the Applicant Provide?

This final 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. FDA is codifying a definition of "readily available" and will be issuing a guidance document entitled "Guidance for Industry and Food and Drug Administration Staff: Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act" to explain the Agency's current thinking on the meaning of "readily available information" and how to comply with the requirements set forth in section 515A of the FD&C Act.

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

If the applicant does not submit the information required by section 515A(a) of the FD&C Act, FDA may not approve the application until the applicant provides the required information. The Agency intends to contact the applicant during the normal course of our review to inform the applicant that the submission lacks the information required by section 515A(a) of the FD&C Act and by this final rule, and to ask the applicant to amend the application to provide the required information. If the application has no other deficiencies and otherwise meets applicable statutory and regulatory requirements for approval, but still lacks information required by section 515A(a), the Agency intends to send the applicant an "approvable" letter informing

them that FDA will approve the application after the applicant provides the information required by section 515A(a). If the application has other deficiencies or does not meet all applicable statutory and regulatory requirements for approval, the Agency intends to send the applicant a "not approvable" letter or a "major deficiency" letter describing what information or data the applicant needs to provide before FDA can approve the application; the "not approvable" or "major deficiency" letter may cite the absence of section 515A(a) information in the section listing minor deficiencies. 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>.

V. How Has FDA Addressed Comments Received on the Proposed Rule?

A number of comments recommended using age 18 as the upper boundary for the definition of "pediatric patients" instead of age 21 for reasons such as attainment of skeletal maturity by age 18 and how the phrase is understood in certain professional communities. After considering this suggestion, FDA has opted to keep age 21 as the definitional upper boundary "pediatric patients." FDA oversees a wide array of medical devices and combination products including various medical devices that are used in pediatric populations. With this in mind, and as part of initiatives designed to help FDA achieve the intent of several pediatric provisions added to the FD&C Act by the Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250, 116 Stat. 1588 (2002)), CDRH established the definition of the pediatric population in the 2004 Guidance "Premarket Assessment of Pediatric Medical Devices" (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm0>

[89740.htm](#)). Beyond setting the upper age limit, the Guidance document further defines the pediatric population as comprising the following subpopulations: Neonate, infant, child, and adolescent. The definition mirrors that used by the American Academy of Pediatrics and takes into consideration the different pediatric subpopulations that make up the pediatric population. This definition ensures that the term "pediatric" applies to populations who may be mature skeletally or according to other measures, but who remain developmentally immature in certain anatomical or physiological systems.

This definition reflects the scientific evidence that children are not merely young adults, but that there are unique host characteristics across the various pediatric subpopulations that should be considered before using medical devices in the pediatric population or subpopulation. FDA recognizes that not all 18- to 21-year-olds are identical: Different rates of pubertal development may be encountered; different disease processes may cause delayed maturation, or conversely, accelerated maturation (e.g. precocious puberty). Moreover, Congress also used age 21 as the upper boundary for a pediatric population when it enacted FDAAA (section 303(a)(3)).

One comment stated that FDA should not have removed the proposed requirement on "potential pediatric uses" in the supplemental notice of proposed rulemaking because providing readily available information on potential pediatric uses is easily achievable and would pose no serious burden to applicants. FDA declines to accept the recommendation in the comment because section 515A of the FD&C Act does not require sponsors to speculate as to possible pediatric uses and possible subpopulations. However, if such information were readily available and provided in a premarket submission, FDA would find the information useful in support of advancing pediatric device development. Therefore, in the forthcoming guidance document, "Guidance for Industry and Food and Drug Administration: Providing Information About

Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act," FDA invites applicants to include pediatric use information for uses of the device outside the approved or proposed indication if such uses are described or acknowledged in acceptable sources of readily available information.

One comment proposed that FDA require applicants to state whether each new PMA supplement relates to a new device and that PMA applicants provide the number of new devices approved under the PMA during the preceding year in the PMA annual report. The comment also requested that, in order to ease the administrative burden on FDA and applicants, PMA supplements filed subsequent to the initial submission of pediatric population information update this information only if there is new information readily available that results in a change in the identification of pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, or the number of affected pediatric patients. FDA appreciates the suggested additions to the rule, but declines to include a requirement that applicants state whether each supplement relates to a new device because each applicant could interpret the types of changes that could be considered a "new device" differently. To better ensure consistency for reporting purposes, FDA's internal tracking system will be used for the collection and compilation of data regarding the number of devices approved each year. FDA also declines to require applicants to provide information in their PMA annual report regarding the number of new devices approved under the PMA in the prior year because, while FDA must provide a report to Congress once per year, PMA annual reports can be due at different times throughout the calendar year as the report is due on the anniversary of the initial PMA approval. Since the PMA annual reports would each address different time periods for the prior year, this information would not enable FDA to compile the data needed for the report to Congress.

One comment disputed FDA's estimate of the amount of time it will take to fulfill the requirements instated by this rule for original HDE and PMA applications. The comment states that reading just a single article in the medical literature to obtain a thorough understanding of a specific situation can take 1 to 2 hours and therefore the estimate that 8 hours are needed for an applicant to fulfill the requirement is unreasonably low. FDA disagrees that 8 hours is insufficient to fulfill the requirements implemented by this final rule because applicants are not expected to make an assessment of whether the information is clinically appropriate or would support a particular indication; rather, when reviewing sources, applicants are only required to identify any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, as well as the number of affected pediatric patients. Please see the forthcoming guidance document, "Guidance for Industry and Food and Drug Administration: Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act" for more information on how to comply with this requirement.

Some comments took the position that by implementing the rule, FDA, in effect, would be promoting the off-label use of devices. FDA disagrees with this comment. The rule does not ask applicants to perform any clinical studies or to use or promote the device outside its approved indications for use; rather, the rule requires the submission of information already in existence on any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure.

One comment stated that if FDA were to request an applicant to submit a PMA supplement for a PMA that was approved prior to the effective date of FDAAA solely to provide readily available pediatric information, then this would be retroactive application of law. FDA

does not intend to require any applicant to submit a PMA supplement solely to provide readily available pediatric information. However, if an applicant is submitting a PMA supplement for any of the reasons in § 814.39, it must include readily available pediatric information as required by § 814.39(c)(2).

One comment stated that the rule should provide an exemption from the requirement of submitting readily available pediatric information in instances where the device does not and will never have pediatric uses, as well as instances where the device is specifically indicated for use in pediatric patients. FDA declines to incorporate this comment because an exemption for devices that do not and are thought not to ever have pediatric uses undermines the intent of the rule. It is not possible to determine whether a device will have pediatric uses in the future as modifications to the device (e.g., design or size) and advances in medicine could change whether a device could be used in a pediatric population. Furthermore, an exemption for devices intended specifically for use in pediatric subpopulations would undermine the intent of the rule because there could be other pediatric subpopulations not included in the proposed or approved indications for use that suffer from the disease or condition that the device is intended to treat, diagnose, or cure. If there are no pediatric uses of the device at the time of the PMA or PMA supplement submission, FDA merely expects applicants to state such in the application.

VI. What Is the Legal Authority for This Final Rule?

Section 302 of FDAAA amended the FD&C Act by adding, among other things, a new section 515A. Section 515A(a) of the FD&C Act requires persons who submit certain medical device applications 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. Therefore, FDA is issuing this final rule under

section 515A(a), and section 701(a) of the FD&C Act (21 U.S.C. 371(a)) (which provides FDA the authority to issue regulations for the efficient enforcement of the FD&C Act). The Food and Drug Administration Safety and Innovation Act (Public Law 112-144, section 620(b)) directs FDA to issue a final rule implementing section 515A(a) of the FD&C Act by December 31, 2013.

VII. What is the Environmental Impact of This Final Rule?

FDA 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.

VIII. What is the Economic Impact of This Final Rule?

We have examined the impacts of this final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct 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 final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on a substantial number of small entities. Because this regulation only requires some submissions include a small amount of readily available information at about \$90 per submission, the Agency certifies that the final rule does 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 \$141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. We do not expect this 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 final 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. As explained in the Paperwork Reduction Act analysis, we expect to receive annually 40 PMAs and 5 applications for HDE. We also expect to receive 693 supplements that include the pediatric use information required by section 515A(a) of the FD&C Act and this final rule.

Based on our experience with similar requirements regarding readily available information, we estimate it will take 8 hours to gather and submit information for original applications and amendments to those applications. Because supplements can include this information by referencing a previous submission, we estimate it will take only 2 hours to obtain and submit the required information on pediatric populations.

The estimated time burden for all 45 annual applications is 360 hours. For the 693 supplements, the time burden is an estimated 1,386 hours for a total of 1,746 hours. The 2011

median wage for a compliance officer in the medical device manufacturing industry is \$31.75.² Adjusting the wage by average private sector benefits of 29.6 percent of total compensation, the benefits-adjusted wage is \$45.10.³ At this wage, the estimated cost of submitting an application with pediatric information is \$361 or \$16,236 for all applications. The estimated cost of submitting pediatric information for a supplement is \$90 or \$62,508 for all supplements. The estimated cost of this final rule is \$78,744.

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.

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

This 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 in the following paragraphs 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.

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.

² U.S. Bureau of Labor Statistics, 2011 National Industry-Specific Occupational Employment and Wage Estimates, SOC 13-1041 (http://www.bls.gov/oes/current/naics4_339100.htm).

³ U.S. Bureau of Labor Statistics, Employer Costs for Employee Compensation, Table 5. Employer costs per hour worked for employee compensation and costs as a percent of total compensation: Private industry workers, by major occupational group and bargaining unit status, June 2012 (<http://www.bls.gov/news.release/ecec.t05.htm>).

Description: Section 515A(a) of the Food and Drug Administration Amendments Act of 2007 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 and the review time for each such device application.

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

- Any request for an HDE submitted under section 520(m) of the FD&C Act;
- Any PMA or supplement to a PMA submitted under section 515 of the FD&C Act;
- Any PDP submitted under section 515 of the FD&C Act.

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

Table 1.--Estimated Annual Reporting Burden¹

Activity/21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Pediatric information in an original PMA or PDP--814.20(b)(13)	30	1	30	8	240
Pediatric information in a PMA amendment--814.37(b)(2)	10	1	10	8	80
Pediatric information in a PMA supplement--814.39(c)(2)	693	1	693	2	1,386
Pediatric information in an HDE--814.104(b)(6)	5	1	5	8	40
Total			738		1,746

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

FDA expects to receive approximately 45 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 2010-2011. 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 693 supplements that will include the pediatric use information required by section 515A(a) of the FD&C Act and this final rule.

All that is required is to gather, organize, and submit information that is readily available, using any approach that meets the requirements of section 515A(a) of the FD&C Act and this final rule. We believe that because the final rule requires that the applicant organize and submit only readily available information, no more than 8 hours will be required to comply with section 515A(a) of the FD&C Act and this final rule for original applications and amendments to those applications. Furthermore, because supplements may include readily available information on pediatric populations by referencing a previous submission, FDA estimates the average time to obtain and submit the information required by this final rule in a supplement to be 2 hours. FDA estimates that the total burden created by this final rule is 1,746 hours.

We estimate the "Average Burden per Response" based on our experience with similar information collection requirements and on consultations with the Interagency Pediatric Devices Working Group that includes the Agency for Healthcare Research and Quality, FDA, National Institutes of Health, members of the Pediatric Advisory Committee, researchers, health care practitioners, medical device trade associations, and medical device manufacturers.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

Before the effective date of this final rule, FDA will publish a notice in the Federal Register announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. 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.

This final rule also refers to previously approved collections of information found in FDA regulations. The collections of information in part 814, subpart B have been approved under OMB control number 0910-0231 and the collections of information in part 814, subpart H have been approved under OMB control number 0910-0332.

X. What are the Federalism Impacts of This Final Rule?

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has 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, the Agency has 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.

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. In § 814.3, add paragraphs (s) and (t) to read as follows:

§ 814.3 Definitions.

* * * * *

(s) Pediatric patients means patients who are 21 years of age or younger (that is, from birth through the twenty-first year of life, up to but not including the twenty-second birthday) at the time of the diagnosis or treatment.

(t) Readily available means available in the public domain through commonly used public resources for conducting biomedical, regulatory, and medical product research.

4. In § 814.20, redesignate paragraph (b)(13) as paragraph (b)(14) and add new paragraph (b)(13) to read as follows:

§ 814.20 Application.

* * * * *

(b) * * *

(13) Information concerning uses in pediatric patients. The application must include the following information, if readily available:

(i) 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

(ii) 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)(13) and 814.39(c)(2).

* * * * *

6. In § 814.39, redesignate paragraph (c) as (c)(1) and add paragraph (c)(2) to read as follows:

§ 814.39 PMA supplements.

* * * * *

(c) * * *

(2) The supplement must include the following information:

(i) Information concerning pediatric uses as required under § 814.20(b)(13).

(ii) If information concerning the device that is the subject of the supplement was previously submitted under § 814.20(b)(13) or under this section in a previous supplement, that

information may be included by referencing a previous application or submission that contains the information. However, if additional information required under § 814.20(b)(13) 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 pediatric uses required by § 814.20(b)(13);

* * * * *

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 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:

(1) 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.

* * * * *

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) Information concerning pediatric uses of the device, as required by § 814.20(b)(13).

* * * * *

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 pediatric uses of the device, as required by § 814.20(b)(13);

* * * * *

Dated: January 6, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-00267 Filed 01/09/2014 at 8:45 am; Publication Date: 01/10/2014]