**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**
**21 CFR PART 814**
**OMB No. 0910- NEW**
**SUPPORTING STATEMENT**

**Terms of Clearance:** none.

## A. Justification

1. Circumstances Making the Collection of Information Necessary


Abstract

The Food and Drug Administration (FDA) is requesting Office of Management and Budget (OMB) approval of the requirements set for the in this information collection. This collection enforces the requirements of Title III of the Food and Drug Administration Amendments Act of 2007 (FDAAA)(Public Law 110-85). http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm.

FDAAA amended Chapter V of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351 et seq.) inserting section 515A Pediatric Uses of Devices, 21 USC 360e–1. http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/html/USCODE-2010-title21-chap9-subchapV-partA-sec360e-1.htm

This new provision 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.

This new requirement applies to the following applications: (1) Any request for a humanitarian device exemption (HDE) submitted under section 520(m) of the FD&C Act; (2) any premarket approval application (PMA) or supplement to a PMA submitted under section 515 of the FD&C Act; and (3) any product development protocol (PDP) submitted under section 515 of the FD&C Act.


The Food and Drug Administration (FDA) is requesting approval from the Office of Management and Budget (OMB) for the following information collection requirements, contained in 21 CFR, Part 814.
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=814

**21 CFR 814.20(b)(13) - Reporting**

This specifies the information concerning pediatric uses required in PMA applications. PMA applications shall 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.

**21 CFR 814.37(b)(2) - Reporting**

This specifies the procedures for amending an incomplete PMA or resubmitting a withdrawn PMA. FDA may request the applicant to amend a PMA or PMA supplement with any information concerning pediatric uses that is required by §814.20(b)(13) and which is readily available to the applicant.

**21 CFR 814.39(c)(2) - Reporting**

PMA supplements are required for all changes that affect safety and effectiveness unless such changes involve modifications to manufacturing procedures or method of manufacture. Whenever a supplement is submitted, the applicant shall include the information required in §814.20(b)(13).

**21 CFR 814.104 (b)(6) -Reporting**

Original HDE applications must include readily available information concerning pediatric uses of the device, as required by §814.20(b)(13).

2. Purpose and Use of the Information Collection

   The respondents for this information collection are from the private sector (businesses).

   The purpose of the information submitted pursuant to section 515A(a) is to ensure that PMA, PDP, and HDE applications include readily available information concerning pediatric uses. FDA will use this information 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 pursuant to section 738(a)(2)(B)(v); and the review time for each such device. Ultimately, FDA would like to use this data to perform a needs assessment and determine unmet pediatric needs in medical device development. Once unmet needs are identified, FDA will be better able to coordinate efforts of stakeholders, device manufacturers and FDA staff to promote new device development and proper labeling of existing medical devices for pediatric use.
3. Use of Improved Information Technology and Burden Reduction

The agency is not yet equipped to receive all investigational and marketing applications/submissions electronically; therefore these reporting requirements will not mandate the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FDA estimates that 50% of the respondents will use electronic means to fulfill the agency's requirement or request.

4. Efforts to Identify Duplication and Use of Similar Information

The FDA is the only authorized Agency to regulate the manufacturer and distribution of medical devices. The information collected cannot be obtained from any other source other than the manufacturer, therefore this effort is not duplicated anywhere else.

5. Impact on Small Businesses or Other Small Entities

100% of the respondents would be businesses, 6% are small businesses.

This information collection will have a minimal impact on a substantial number of small entities. The efforts described below help to assure that the burden on all manufacturers, including small manufacturers, are minimized.

FDA also maintains a fax on demand system (FACTS) which provides firms with information pertaining to medical devices and radiological health. FDA, as required by the 1976 Amendments to the Act, has established the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) to provide technical and non-technical assistance to small firms (and firms of any size) expressly to aid them in complying with requirements of the Act.

FDA also aids small business in dealing with the requirements of the regulations by providing guidance and information through the DSMICA, and through the scientific and administrative staff, and through the CDRH website at http://www.fda.gov/cdrh .

DSMICA participates in and presents conferences, workshops, and seminars on the application and interpretation of relevant regulations, consults with individual firms/sponsors, and develops and disseminates educational materials. Staff is available to respond to questions and a toll free telephone number was established to facilitate this communication link.

6. Consequences of Collecting the Information Less Frequently

Respondents will respond to this information whenever they submit a new application or supplement under sections 515 or 520(m) of the FD&C Act (occasionally). If the collection is not conducted, or is conducted less frequently, the sponsor/applicant/submitter will not be in compliance with section 515A(a) of the FD&C Act (21 U.S.C. 360e-1.)

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Requirements under Section 5 CFR Part 1320.5(d)(2) are met with the exception regarding the number of copies of information submitted. 5 CFR 1320.5 requires that not more than one original and two copies be submitted.

FDA, however, requires under 21 CFR 814.20(b)(2) that each respondent must submit 6 copies of a PMA and 3 copies of a PMA supplement for review. FDA maintains the original PMA and PMA supplement in the PMA Document Mail Center in its Center for Devices and Radiological Health (CDRH). Additional copies of PMA's and PMA supplements are used for concurrent review by CDRH personnel such as the ODE Division, statisticians, GMP manufacturing inspection staff, and Bioresearch Monitoring. The final copy of a PMA or PMA supplement is retained for team review by other statisticians, physicians, and scientists.

Few manufacturers have objected to the request for additional PMA and PMA supplement copies (or more if needed) because the review process has been substantially expedited to their advantage. If FDA were required to construct review copies for concurrent review by FDA personnel or advisory committee review, substantial delays would be anticipated due to lack of computer equipment and personnel to perform the copying and collation of the documents.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   FDA published a direct final rule and companion proposed rule on April 1, 2010. Due to the receipt of adverse comment, FDA withdrew the direct final rule on July 20, 2010. FDA received one comment directed at the PRA section, requesting that FDA develop guidance further explaining FDA's interpretation of "readily-available information" in order to minimize the burden of responding to the regulation. FDA continues to consider how best to convey our interpretation of "readily-available information."

9. Explanation of Any Payment or Gift to Respondents

There is no payment or gift provided to respondents of this information collection.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality of data and disclosure regarding the existence of a PMA are governed by 21 CFR 814.9, the Freedom of Information Act (FOIA) (5 U.S.C. 552), and sections 301(j) and 520(c) and (h) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 331(j), 360(c) and (h)). Under FOIA, the public has broad access to government documents.

However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b) (1-9). One such provision, 5 U.S.C. 552(b)(4), exempts "trade secrets and commercial or financial information that is privileged or confidential" from the requirement of public disclosure.

Section 520(c) of the Act prohibits FDA from disclosing any information exempted from public disclosure under 5 U.S.C. 552(b)(4). Part 20 of FDA's regulations, 21 CFR Part 20, sets forth FDA's general policy concerning public availability of FDA records. Under section 520(h) of the Act, FDA is required to make publicly available a detailed summary of the safety and effectiveness information contained in a PMA that is the basis for an order approving, denying approval of, or withdrawing approval of a PMA.

11. Justification for Sensitive Questions

The information required in a premarket approval or premarket supplement application does not include questions about sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

The total estimated reporting burden for this information collection is 1,746 hours.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section or Description | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours Per Responses | Total Hours |
|---|---|---|---|---|---|
| 814.20(b)(13)) | 30 | 1 | 30 | 8 | 240 |
| 814.37(b)(2) | 10 | 1 | 10 | 8 | 80 |
| 814.39(c)(2) | 693 | 1 | 693 | 2 | 1,386 |
| 814.104(b)(6) | 5 | 1 | 5 | 8 | 40 |
| Totals | 738 | | 738 | | 1,746 |

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

FDA estimates are based on FDA's experience and consultation with similar information collection requirements and on consultations with the Interagency Pediatric Devices Working

Group which includes the Agency for Healthcare Research and Quality; the FDA, and the National Institutes of Health, members of the Pediatric Advisory Committee, researchers, healthcare practitioners, Medical Device Trade Associations, and Medical Device Manufacturers.

12b. Annualized Cost Burden Estimate

The salary cost burden was calculated from a compliance officer professional. The task is expected to be performed by compliance officer, who perform a literature search of relevant pediatric information, organize any readily available information, and submit it to FDA. We believe the annual cost burden to the respondents for this new information collection will be $78,745 annually. (45.10 x 1,746 = $78,745).

| Type of Respondent | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|
| Compliance Officer | 1,746 | 45.10 | $78,745 |
| Total | | | $78,745 |

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no additional capital costs or operating/maintenance costs associated with this regulation.

14. Annualized Cost to the Federal Government

Based on a GS-13 level government employee review of the information submitted, the annualized cost to FDA would be about $8,325. This figure was derived by multiplying an average hourly rate of a GS-13 FTE ($45) by the amount of time it would take to review pediatric information in the 738 submissions (185 hours at 15 minutes per submission). [15 minutes per submission x 738 submissions = 185 hours] [185 hours x $45 per hour = $8,325].

There are no additional capital costs or operating/maintenance costs associated with this regulation.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

After contemplating comments on scope FDA received from several parties with respect to the April 1, 2010 direct final rule and companion proposed rule, the agency reevaluated its interpretation of section 515A of the FD&C Act. Upon further consideration, FDA, relying on the plain language of the statute, has concluded that section 515A applied to all submissions listed in the statute, not just a subset as proposed in the April 1, 2010 proposed rule. Therefore, FDA has decided to issue a new proposed rule which bases the proposed

requirements on FDA's current interpretation of section 515A, and has a burden estimate higher than the original NPRM and DFR.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish the collection of information under these regulations for statistical use unless requested by Congress in accordance with Section 533 of the Act.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Currently, CDRH is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

B. Statistical Methods (used for collection of information employing statistical methods)

There are no statistical methods being employed in this collection of information. person(s) who will actually collect and/or analyze the information for the agency.