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
OMB No. 0910-0748
SUPPORTING STATEMENT

Terms of Clearance: none.

A. Justification

1. Circumstances Making the Collection of Information Necessary

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 U.S.C. 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

Pediatric information in an original PMA or PDP--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.

Pediatric information in a PMA amendment--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.

Pediatric information in a PMA supplement--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).

Pediatric information in an HDE--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 (for-profit 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.

Section 515A(a)(3) of the FD&C Act requires the Secretary of Health and Human Services to submit to the Committee on Health, Education, Labor and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives an annual report that includes, among other information, the number of devices approved in the year preceding the year in which the report is submitted, for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure. FDA will use the 515A pediatric device use information included in regulatory submissions to identify devices that should be included in this annual report to Congress.

3. Use of Improved Information Technology and Burden Reduction

Section 745A(b) of the FD&C Act, added by section 1136 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), provides statutory authority to require eCopies after issuance of final guidance (See Public Law No: 112-144). FDA's implementing guidance (http://www.fda.gov/downloads/MedicalDevices/

DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf) describes how device companies should replace one paper copy of a device application with an eCopy and identify the required format and technical requirements of the eCopy. The eCopy requirement does not require or request any information that is not already submitted to the Agency and/or covered under an existing ICR. OMB approved this non-material/nonsubstantive change on December 17, 2012.

FDA estimates that 100% 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, and approximately 4 percent 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

After contemplating comments on scope FDA received from several parties with respect to the April 1, 2010 direct final rule (75 FR 16347) and companion proposed rule (75 FR 16365), 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 issued a supplemental notice of proposed rulemaking on February 19, 2013 (78 FR 11616) 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.

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the FEDERAL REGISTER of 02/19/2013 (Vol. 78 No. 33 FR 11612).

One comment on the supplemental notice of proposed rulemaking questioned 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 1-2 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.

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 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]

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, five 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 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 incorporate by reference readily-available information on pediatric populations if submitted in a prior 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 the "Average Burden per Response" 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.

FDA estimates that the total burden created by this final rule is 1,746 hours.

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 officers, 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 $54,528 annually. (31.23 x 1,746 = $54,528). The hourly wage rate for a compliance officer was taken from the 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.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Compliance Officer	1,746	31.23	$54,528

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].

15. Explanation for Program Changes or Adjustments

This is a new data collection.

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.