Providing Information about Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act
0910 - 0762

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 USC 360e–1. http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/html/USCODE-2010-title21-chap9-subchapV-partA-sec360e-1.htm

The 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.

The guidance document that is the subject of this ICR suggests that applicants who submit certain medical device applications include, if readily available, pediatric use information for diseases or conditions that the device is being used to treat, diagnose, or cure that are *outside* the device's approved or proposed indications for use, as well as an estimate of the number of pediatric patients with such diseases or conditions.

This relevant medical device applications include: (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

This information involves a guidance document and there is no direct CFR citation.

2. Purpose and Use of the Information Collection

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

The information submitted will allow FDA to identify pediatric uses of devices outside their approved or proposed indication for use in order to determine areas where further pediatric device development could be useful.

In addition, information about pediatric populations that suffer from the disease or condition may warrant limitations or even warnings or contraindications against use in pediatric populations if available evidence suggests there is a potential for harm from off-label use in such populations.

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 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% 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 International and Consumer

Education (DICE) 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 DICE, and through the scientific and administrative staff, and through the CDRH website at http://www.fda.gov/cdrh .

DICE 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 have the option to provide 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, FDA will not have the most current information to make policy decisions regarding pediatric patients.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 12/05/16 (81 FR 87575). No comments related to this information collection were received.

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 74 hours.

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

Table 1.—Estimated Annual Reporting Burden[1]					
Description	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Uses outside approved indication	148	1	148	0.5	74

Respondents are permitted to submit information relating to uses of the device outside the approved or proposed indication if such uses are described or acknowledged in acceptable sources of readily available information. We estimate that 20% of respondents submitting information required by section 515A of the FD&C Act will choose to submit this information and that it will take 30 minutes for them to do so.

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 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 $2,797.20 annually ($37.80 x 74 = $2,797.20). The hourly wage rate for a compliance officer was taken from the U.S. Bureau of Labor Statistics, 2015 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	74	$37.80	$2,311.02

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 information collection.

14. Annualized Cost to the Federal Government

Based on a GS-13, step 10, level government employee review of the information submitted, the annualized cost to FDA would be about $354. This figure was derived by multiplying an average hourly rate of a GS-13, step 10, employee ($59.05) by the amount of time it would take to review pediatric information in the 74 submissions (6 hours at 5 minutes per submission). [5 minutes per submission x 74 submissions = 6 hours] [6 hours x $59.05 per hour = $354 (rounded)].

15. Explanation for Program Changes or Adjustments

There are no program changes

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.