UNITED STATES FOOD & DRUG ADMINISTRATION

Submission of Information on Pediatric Uses of Medical Devices

OMB Control No. 0910-0748 - Revision

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports section 515A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360e-1), as well as associated implementing regulations. Section 515A 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. Applicants are also required to provide the number of affected pediatric patients. Section 515A applies to requests for a humanitarian device exemption (HDE) submitted under section 520(m) of the FD&C Act; premarket approval application (PMA), amendment to a 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. The Food and Drug Administration (FDA, the agency, us or we) is required to provide an annual report to Congress with this information (§ 515A(a)(3) of the FD&C Act). Additionally, within the annual report, FDA must include any information regarding devices used in pediatric patients outside the approved indication for use (§ 515A(a)(3)(B) of the FD&C Act).

To assist respondents to the information collection we developed the guidance document entitled "*Providing Information About Pediatric Uses of Medical Devices—Guidance for Industry and Food and Drug Administration Staff*," which describes how to compile and submit the required readily available pediatric use information. The guidance explains that submission of 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 is also permitted. Information collection associated with the guidance is currently approved under OMB control number 0910-0762 (*Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug and Cosmetic Act*). We are revising this information collection to consolidate these similar elements.

We therefore request approval for the information collection provisions in section 515A(a) of the FD&C Act; the implementing regulations in 21 CFR part 814; and the associated guidance, as discussed in this supporting statement

2. Purpose and Use of the Information Collection

Respondents to the information collection are from the private sector (for-profit businesses). We use the information submitted to ensure that PMA, PDP, and HDE applications include readily available information concerning pediatric uses. We also use the 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, we 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, we 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.

Additionally, section 515A(a)(3) of the FD&C Act requires FDA 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

In accordance with statutory requirements as well as current standard industry practice, submissions are made electronically and therefore we estimate that 100% of submissions will be made in this way.

4. Efforts to Identify Duplication and Use of Similar Information

Currently we maintain related information collection requests under OMB control number 0910-0231 (*Premarket Approval of Medical Devices* and *Product Development Protocols*) and 0910-0332 (*Humanitarian Device Exemptions*) – both supporting regulations in part 814 (21 CFR 814). We will evaluate these collections and make appropriate consolidations prior to a subsequent renewal request.

5. Impact on Small Businesses or Other Small Entities

Although we estimate few respondents are small businesses, we believe no undue burden is imposed as a result of the information collection. Additionally, our Center for Devices and Radiological Health (CDRH), Division of Industry and Consumer Education (DICE) provides technical and non-technical assistance to small firms (and firms of any size) expressly to aid them in complying with regulatory requirements of the FD&C Act. We also aids small business in dealing with the requirements of the regulations by providing guidance and information through the DICE (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice), through the scientific and administrative staff, and through the CDRH website at http://www.fda.gov/cdrh.

6. Consequences of Collecting the Information Less Frequently

Information collection schedule is consistent with statutory and regulatory requirements.

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

There are no special circumstances relating to the guidelines of 5 CFR 1320.5.

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

In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the Federal Register of December 2, 2019 (84 FR 65986). One comment was received asking the effect of listed products on children and was therefore beyond the scope of the information collection topics for which public comment was solicited.

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

In consultation with our Privacy Office we have determined that, although personally identifiable information (PII) is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g. point of contact). The PII submitted is name, address, email address, telephone number. Additionally, we do not use name or any other personal identifier to routinely retrieve records from the information collected.

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). 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

12a. Annualized Hour Burden Estimate

Table 1.—Estimated Annual Reporting Burden[1]					
Activity/21 CFR Section or Guidance	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)	11	1	11	8	88
Pediatric information in a PMA amendment--814.37(b)(2)	5	1	5	8	40
Pediatric information in a PMA supplement--814.39(c)(2)	928	1	928	2	1,856
Pediatric information in an HDE--814.104(b)(6)	1	1	1	8	8
Pediatric information for uses outside approved indication—guidance "*Providing Information About Pediatric Uses of Medical Devices*"	800	1	800	.5	400
Total					2,392

We expect to receive approximately 31 original PMA/PDP/HDE applications each year, 1 of which we expect to be an HDE. This estimate is based on the average number of submissions received. We estimate that 5 of the 31 original PMA submissions will require amendments to provide the required pediatric use information. We also expect to receive 928 supplements that will include the pediatric use information required by 515A(a) of the FD&C Act, and 800 uses outside approved indication.

We assume 8 hours will be necessary for gathering, organizing, and submitting information that is readily available, using any approach that meets the requirements of section 515A(a) of the FD&C Act. Because supplements and information for uses outside approved indications may incorporate by reference readily-available information on pediatric populations if submitted in a prior submission, we assume an average time to obtain and submit the information required in a supplement to be 2 hours and for outside uses to be 30 minutes.

Our estimate of the "Average Burden per Response" is based on our 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 information collection 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 information collection will be $94,125 annually. ($39.35 x 2,392 = $66,528). The hourly wage rate for a compliance officer was taken from the U.S. Bureau of Labor Statistics, 2018 National Industry-Specific Occupational Employment and Wage Estimates, SOC 13-1041 (https://www.bls.gov/oes/current/naics4_339100.htm).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Compliance Officer	2,392	$39.20	$94,125

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

There are no 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 is $25,026. This figure was derived by multiplying an average hourly rate of a GS-13 ($57.40 per hour, https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/16Tables/html/DCB_h.aspx) by the amount of time it would take to review pediatric information in the 1,745 submissions (436 hours (rounded) at 15 minutes per submission).

15. Explanation for Program Changes or Adjustments

The information collection reflects changes and adjustments. We have consolidated burden from 0910-0762, and adjusted individual elements to reflect current data values. This results in an additional 1,000 responses and 632 hours annually to this information collection, and we will discontinue control number 0910-0762 upon approval of our request.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.