Annual Reporting for Custom Device Exemption

[OMB Approval No. 0910-NEW]

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Effective on July 9, 2012, section 617 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144) required the implementation of changes to the custom device exemption contained in section 520(b) of the FD&C Act. Section 520(b) sets forth the requirements that must be met in order for a device to qualify for a custom device exemption. Section 520(b) of the FD&C Act exempts "custom devices" from performance standard or premarket approval requirements under section 514 and 515 of the FD&C Act, if these devices meet the enumerated statutory requirements, including, among others, the following for each device: (1) is "created or modified in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing)"; (2) must not be "generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution"; (3) must be for the purpose of treating a "unique pathology or physiological condition that no other device is domestically available to treat"; and (4) must be manufactured for the "special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of the physician or dentist (or other specially qualified person so designated)" or by an individual patient named in such order.

In addition to the new requirements for establishing a custom device, manufacturers will have limitations for use of a custom device to only for the purpose of treating a "sufficiently rare condition, such that conducting clinical investigations on such device would be impracticable" and production of the device must be limited to no more than 5 units per year of a particular device type.

As a result of the statutory requirement of a manufacturer producing no more than 5 units per year of a device type, FDA will need to monitor manufacturers' distribution of these devices in a way that is different from the usual requirement of registration and listing of medical devices. Due to the lack of consistent information gathering in the past for custom devices, which represent a narrow category of devices, the legislative intent of this statute was to allow FDA to collect information for each device through an annual report submitted by the manufacturer under the new provision in section 520(b)(2)(C) of the FD&C Act. To assist manufacturers, FDA will provide a detailed explanation of all the information that will need to be included in the annual reports in the final guidance.

Each annual report will cover a given calendar year. The first report may have available retrospective information on the custom devices provided by manufacturers from the date of enactment of FDASIA to the date of the first report. For all subsequent reporting periods, the reports will need to be submitted within the first calendar year. FDA will not enforce the new annual reporting until the end of the calendar year following publication of the final guidance.

Premarket Approval- 21 CFR Part 814

Under section 520(b) of the FD&C Act, custom devices are exempt from PMA requirements, as well as conformance to mandatory performance standards. Section 515 of the FD&C Act and 21 CFR 841.20 require a manufacturer to show that a device has been shown to be safe and effective and that otherwise meet the statutory criteria for approval and due to the level of risk, the FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices. The annual reporting requirement of a custom device exemption will inform industry and FDA of the devices entering the market place designed to meet the needs of the narrow populations too small to be adequately served by the standard premarket development pathways.

2. Purpose and Use of the Information Collection

Currently, many manufactures of devices in particular industries, like dental and orthopedic, are uncertain as to whether their device meets all the qualifications for a custom device exemption. In addition, historically, practitioners and manufacturers have sought custom device exemptions for devices that are more properly considered under a compassionate use protocol. The annual report will allow FDA to determine whether a device qualifies as a custom device exemption and assist a manufacturer ascertain whether the device meets the qualifications for exemption or if they the need to submit a PMA application or qualify for compassionate use for the device.

Furthermore, under the amended section 520(b) a manufacturer is “limited to no more than 5 units per year of a particular type” that otherwise meet all the requirements necessary to qualify for the exemption. The interpretation of five units in a custom device is difficult because in some cases a patient requires multiple devices of the same type, which may be considered one unit for that unique case; however, a manufacturer may be unable to determine this on their own and the annual report will assist both the manufacturer and FDA in determining the correct number of units allowed.

Without the annual reporting, the FDA will be unable to identifying appropriate patient population and accounting to ensure they aren’t abusing this as a way of fully marketing devices without showing they are safe and effective.

Respondents to this collection of information are private sector for-profit businesses.

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 implemented eCopy requirements on January 1, 2013, with the issuance of the final eCopy guidance (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf). Since the eCopy requirement only applies to premarket submission, the FDA office overseeing submission plans to create an e-mail for manufacturers to submit their annual reports.

FDA intends to encourage manufacturers to send one or both of their copies of their annual reports in electronically to a specified FDA e-mail address.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency responsible for the collection of this information, and there are no requirements for the submission of similar information. Therefore, no duplication of data exists. No data exists from any source, other than the premarket notification submitter, that can be used to provide FDA with information regarding an annual reports for custom devices.

5. Impact on Small Businesses or Other Small Entities

FDA does not have an estimate on the number of respondents to the information collection are small businesses. FDA aids small business in dealing with the requirements of the regulations by providing guidance and information through the Division of Industry and Consumer Education (DICE) (formerly Consumer Small Manufacturers, International, and Consumer Assistance (DSMICA), and through the scientific and administrative staff, workshops in which FDA Staff participate, and through the CDRH website at http://www.fda.gov/MedicalDevices/default.htm. These efforts help to assure that the burden on all manufacturers, including small manufacturers, is minimized.

6. Consequences of Collecting the Information Less Frequently

A manufacturer will only be required to submit the report on custom devices on an annual basis during a specific time of year determined by FDA. FDA does have the right to ask for additional information if its determined that the information submitted in the annual report is insufficient to allow for a complete review. However, if FDA only needs clarification of an issue then they may communicate on such issue via telephone or e-mail. Therefore, we estimate that the information will only be collected annually.

The information collected in the annual report is necessary for FDA to ensure that devices that meet the qualification of a custom device are exempt from PMA and IDE review. The consequence of a manufacturer not submitting an annual report would be that a manufacturer would have to submit a PMA or IDE application to allow marketing of the medical device instead of use of the custom device exemption.

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

There are no special circumstances for this collection of information.

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 1/14/2014 (79 FR 2446). FDA did not receive any comments in regards to the estimated burden hours for the annual report. Also, in 2012 FDA publish a Notice in the **FEDERAL REGISTER** of 11/19/2012 (77 FR 69488) to industry requesting comments for additional information about custom device and did not receive any information on the estimated burden hours for the annual reporting.

9. Explanation of Any Payment or Gift to Respondents

No payment of gifts in any manner or form shall be provided to respondents to this information collection.

10. Assurance of Confidentiality Provided to Respondents

For this collection, an annual report will have the same confidentiality requirements as a PMA application because it qualifies as a substitute for a manufacturer's submission submitted of a PMA. Confidentiality of information submitted to FDA under a premarket notification is governed by the provisions of 21 CFR part 20 and section 814.9, and is mandated.

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Annual Reporting for Custom Devices	33	1	33	40	1,320

These provisions do not permit disclosure of information in a premarket notification submission that is trade secret or commercial confidential unless that information has been previously disclosed or as permitted under the Federal Freedom of Information Act. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. Information provided under this collection is handled in a manner to comply with the FDA regulations on public information in 21 CFR Part 20. Data will be kept private to the fullest extent allowed by law. These provisions do not permit disclosure of information in a premarket notification

11. Justification for Sensitive Questions

This information collection does not include questions pertaining to sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA's estimate of 33 respondents is based on the number of manufacturers of custom devices currently listed in FDA's Registration and Listing database (FURLS). The estimated average burden per response, 40 hours, is based on FDA's expectation of the amount of information that will be contained in the report, on public comment received regarding the burden, on consultation with stakeholders/industry, and on FDA's experience in the creation of an annual report for use in the guidance. Our estimate also reflects that some information used to support the annual report, such as activities conducted under existing design controls, is already covered in another ICR (OMB control number 0910-0073) and is therefore not included in the burden estimate in this information collection request.

The respondents to this collection of information are custom device manufacturers. FDA estimates the burden of this collection of information as follows:

12b. Annualized Cost Burden Estimate

FDA believes that the average cost to industry per hour for this type of work is $65. This is based on May 2013 wage estimates issued by the Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_nat.htm) for the "Marketing Manager" and "Lawyer" occupations (occupation codes 11-2021 and 23-1011, respectively). Therefore, FDA estimates the total annual reporting cost to industry for submissions of an annual report on custom devices is 1,320 total hours multiplied by $65 per hour equals $85,8000. When divided by 33 submissions, this is an average of $2,600 per submission.

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

    There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

FDA's review of annual reports for custom devices will be conducted separately from the PMA submissions. There are currently no plans to increase the number of full time equivalent (FTE) positions because the office responsible for review is familiar with review of postmarket device reporting. Therefore, there is no additional cost to the Federal Government for assurance cases.

15. Explanation for Program Changes or Adjustments

This is a new information collection. Since the 60-day notice for public comment, we have not made any adjustments to the number of respondents.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish or tabulate the results of this information collection.

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

FDA 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.