De Novo Classification Process (Evaluation of Automatic Class III Designation)

0910-NEW

SUPPORTING STATEMENT

Terms of Clearance: n/a.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The authorizing statute for this information collection is section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

The "Draft Guidance for Industry and Food and Drug Administration Staff – De Novo Classification Process (Evaluation of Automatic Class III Designation)" provides guidance on the process for the submission and review of a De Novo classification request (hereafter a "De Novo request") under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), also known as the De Novo classification process. This process provides a pathway to Class I or Class II classification for medical devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

A device may be classified in class III and be subject to premarket approval (PMA) via several different regulatory vehicles. In accordance with the criteria at section 513(a)(1)(C) of the FD&C Act, FDA may promulgate a regulation classifying, or issue an order reclassifying, a device type into class III based on the risks posed by the device and the inability of general and special controls to provide reasonable assurance of the safety and effectiveness of the device. All particular devices of such a type are considered to be in class III and such devices are not eligible for the De Novo classification process.

Alternatively, devices of a new type that FDA has not previously classified based on the criteria at section 513(a)(1) of the FD&C Act are "automatically" or "statutorily" classified into class III by operation of section 513(f)(1) of the FD&C Act, regardless of the level of risk they pose or the ability of general and special controls to assure safety and effectiveness. This is because, by definition, a new type of device would not be within a type that was on the market before the 1976 Medical Device Amendments or that has since been classified into class I or class II. Thus, there would be no available predicate device.

This second scenario is what Congress targeted when it enacted section 513(f)(2) of the FD&C Act as part of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The process created by this provision, which was referred to in FDAMA as the Evaluation of Automatic Class III Designation, will be referred to as the "De Novo

classification process" throughout this guidance document. Congress included this section to limit unnecessary expenditure of FDA and industry resources that could occur if devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness were subject to premarket approval under section 515 of the FD&C Act. Section 513(f)(2) of the FD&C Act has allowed manufacturers to submit a De Novo request to FDA for devices "automatically" classified into Class III by operation of section 513(f)(1). As enacted by FDAMA, in order to submit a De Novo request, a device first had to be found not substantially equivalent (NSE) to legally-marketed predicate devices through a premarket notification (510(k)). The 21st Century Cures Act of 2016 removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination.

Section 513(f)(2) was modified by section 607 of FDASIA, which created an alternative mechanism for submitting a De Novo request that does not require that a device be reviewed first under a 510(k) and found NSE prior to submission of a De Novo request. If a person believes their device is appropriate for classification into Class I or Class II and determines, based on currently available information, there is no legally marketed predicate device, they may submit a De Novo request without a preceding 510(k) and NSE (hereafter "Direct De Novo").

FDA is issuing the guidance to provide updated recommendations for interactions with FDA related to the De Novo classification process, including what information to submit when seeking a path to market via the De Novo classification process.

The proposed collections of information are necessary to satisfy the previously mentioned statutory requirements for implementing this voluntary submission program.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

A medical device manufacturer may voluntarily submit a De Novo request under 513(f)(2) in order to seek market entry for a new medical device. Section 513(f)(2) was modified by section 607 of FDASIA, which created an alternative mechanism for submitting a De Novo request that does not require that a device be reviewed first under a 510(k) and found NSE prior to submission of a De Novo request. A manufacturer may submit a De Novo request (1) if they have previously submitted a premarket notification in accordance with section 510(k) of the FD&C Act, and for which FDA has "automatically" or "statutorily" classified into class III by operation of section 513(f)(1) of the FD&C Act or (2) if a person believes their device is appropriate for classification into Class I or Class II and determines, based on currently available information, there is no legally marketed predicate device, they may submit a De Novo request without a preceding 510(k) and NSE. FDA is issuing this guidance to provide updated recommendations for interactions with FDA related to the De Novo classification process, including what information to submit when seeking a path to market via the De Novo classification process.

Utilizing the De Novo classification pathway promotes innovation and decreases regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or PMA in order to market the same type of device unless the new device has a new intended use or technological characteristics that raise different questions of safety or effectiveness (see 21 U.S.C. 360c(i), defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

FDA uses the information in the De Novo request to evaluate whether the medical device may be reclassified from Class III to Class I or II, and if applicable, to determine the general and/or special controls necessary to sufficiently regulate the medical device.

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

3. Use of Improved Information Technology and Burden Reduction

For De Novo requests, sponsors must submit at least one valid electronic copy (eCopy). See section 745A(b) of the FD&C Act and FDA's eCopy guidance, "eCopy Program for Medical Device Submissions", available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf. Therefore, 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

FDA is the only federal agency responsible for premarket review of medical devices; as such, there is no duplication of effort.

The information related to the De Novo request may, in some cases, overlap with information previously included in a related 510(k) submission for the medical device. Wherever possible, FDA will not require that this information be re-submitted but instead may rely on the 510(k) submission as a reference. Therefore, duplication with other data sources available to FDA is expected to be minimal.

5. Impact on Small Businesses or Other Small Entities

Approximately 95% of U.S. medical device manufacturing establishments have fewer than 500 employees and would, therefore, be considered small businesses.

Submission of a De Novo request is voluntary. Any impact on small businesses should be offset by the guidance and consumer assistance available through CDRH Learn training tools and the information posted on FDA's website. FDA aids small business by providing guidance and information through the Division of International and Consumer Education (DICE) within the Center for Devices and Radiological Health. DICE provides technical and non-financial assistance to small manufacturers, through a comprehensive

program that includes seminars, workshops, and educational conferences, information materials, contact via email and the use of a toll-free telephone number. Other members of the Center staff are also available to respond to questions at any time.

Additionally, the Manufacturers Assistance Branch in the Center for Biologics Evaluation and Research (CBER) provides assistance and training to industry, including large and small manufacturers and trade associations, and responds to requests for information regarding CBER policies and procedures.

6. Consequences of Collecting the Information Less Frequently

The frequency of FDA's receipt of De Novo requests will be determined by the frequency with which medical device manufacturers submit the requests (i.e., occasionally). Because the information in the De Novo request provides a basis for FDA's decision regarding whether to grant market entry for the subject device, the frequency of the information collection is appropriate. The consequence of collecting the information less frequently would potentially be a delay of market entry for the subject device.

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 August 14, 2014 (79 FR 47651). Seven organizations commented on the draft guidance document. None of the comments were related to the information collection.

Upon further review of the information collection, it has come to our attention that the 60-day notice did not include an estimated hour burden for requests for withdrawal or estimated operating and maintenance costs for eCopy,[1] printing, and shipping of De Novo requests. To correct this oversight, we have included these estimates in the 30-day notice requesting public comment August 02, 2017, 82 FR 35971.

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

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.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from

[1] See the eCopy guidance, "eCopy Program for Medical Device Submissions; Guidance for Industry and Food and Drug Administration Staff," at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm313794.pdf.

mandatory public disclosure of government records (5 U.S.C. 552(b)(1)-(b)(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 FD&C Act prohibits FDA from disclosing any information exempted from public disclosure under 5 U.S.C. 552(b)(4).

11. Justification for Sensitive Questions

This information collection does not include questions that are of a sensitive nature, such as, 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 estimates from past experience with the De Novo classification program that the complete process involved with the program under section 513(f)(2)(i) of the FD&C Act takes approximately 100 hours and the complete process under section 513(f)(2)(ii) FD&C Act takes approximately 180 hours. This includes the time for any supplements or amendments to the original submission. We estimate that requests for withdrawal take approximately 10 minutes. The average burdens per response are based upon estimates by FDA administrative and technical staff who are familiar with the requirements for submission of a De Novo request (and related materials), have consulted and advised manufacturers on submissions, and have reviewed the documentation submitted. Respondents to the information collection are medical device manufacturers seeking to market medical device products that have been classified into class III under section 513(f)(2) of the FD&C Act. It is expected that the number of De Novo requests will reach a steady rate of approximately 52 submissions per year. We expect that we will receive approximately five requests for withdrawal per year.

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
De Novo request under 21 U.S.C. 513(f)(2)(i)					
CDRH	25	1	25	100	2,500
CBER	1	1	1	100	100
De Novo request under 21 U.S.C. 513(f)(2)(ii)					
CDRH	25	1	25	180	4,500
CBER	1	1	1	180	180
Total De Novo requests			52		7,280
Request for withdrawal	5	1	5	10	50
Total					7,330

12b. Annualized Cost Burden Estimate

To estimate the wage rate for the industry personnel that prepare the De Novo submissions, we used median hourly wage rates from the Bureau of Labor Statistics (BLS) May 2016 National Occupational Employment and Wage Estimates for the Medical Equipment and Supplies Manufacturing industry (North American Industry Classification, NAICS, code 339100) of $61.20.* To account for benefits and overhead, we doubled this value to $122.40 (= $61.20 x 2). Therefore, we estimate that the annualized cost burden is $897,192 ($122.40 x 7,330 hours).

* Bureau of Labor Statistics. National Occupational Employment and Wage Estimates. Occupational Employment Statistics, General and Operations Managers (North American Industry Classification, NAICS, code 339100, occupation code 11-1021) May 2016. https://www.bls.gov/oes/current/naics4_339100.htm#11-0000, accessed June 30, 2017.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General and operations managers	7,330	$122.40	$897,192

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

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

The operating and maintenance cost for a De Novo request includes the cost of printing, shipping, and the eCopy. We estimate the cost burden for a De Novo request to be $121.30 ($90 printing + $30 shipping + $1.30 eCopy).

We estimate that printing a submission requires an average of 2 reams of paper, or 1,000 pieces of paper. A piece of paper costs $0.03 per page on average. The cost of printing a single page is $0.06 on average.[2] The average total cost of printing per page is, therefore, $0.09 per page ($0.03 paper + $0.06 printing). Therefore, we estimate that printing an average De Novo request will cost approximately $90.

The Agency's eCopy guidance recommends sending all applications using priority shipping. Using shipping calculators on the websites of the US Postal Service, UPS, and FedEx, FDA finds the shipping cost of a single piece of paper to range from $0.01 to $0.05, with an average of $0.03. The average cost of shipping a full paper copy of submissions is, therefore, $30 (1,000 pages shipped × $0.03 per page).

The least expensive type of eCopy media is a CD, which costs on average $0.25 per CD. DVDs cost $0.48 per unit on average and flash drives cost an average of $2.50 per unit. All forms of eCopy media cost roughly $0.22 to ship. Therefore, the cost per eCopy

[2] Quality Logic, "Cost of Ink Per Page Analysis, United States," available at https://www.qualitylogic.com/wp-content/uploads/2016/07/QualityLogic-Cost-of-Ink-Per-Page-Analysis_US_1-Jun-2012.pdf, June 2012.

ranges from $0.47 to $2.72 per eCopy. If eCopies are one-third CDs, one-third DVDs, and one-third flash drives, the average cost per eCopy is $1.30.

We estimate the cost for a request for withdrawal to be $1 (rounded) ($0.09 printing 1 page + $0.03 shipping + $1.30 eCopy).

The annual cost estimate for De Novo requests is $6,308 (rounded) (52 submissions x $121.30). The annual cost estimate for requests for withdrawal is $5. Therefore, we estimate the total annual operating and maintenance costs of this information collection to be $6,313.

14. Annualized Cost to the Federal Government

Using FDA's Fully Loaded FTE Cost Model (Domestic) for FY 2016, we estimate that the total cost including pay, information and management technology, general and administrative overhead, and rent for a medical device reviewer is $260,286 annually. FDA estimates that an average of 20 full time equivalent employees (FTEs) will review and process De Novo requests and related information. Therefore, the burden to government of this information collection is projected to cost approximately $5,205,720 per year ($260,286 x 20 FTEs).

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

No publication of information for statistical use is planned.

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

FDA is not seeking an exemption from displaying the expiration date of OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.