

Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT:

Sergio de del Castillo, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1538, Silver Spring, MD 20993–0002, 301–796–6419; and Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 301–240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

The automatic class III designation for devices of a new type occurs by operation of law and without any action by FDA, regardless of the level of risk posed. Any device that is of a new type that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device section 513(f)(1) of the FD&C Act (21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976.

FDA may classify a device through the De Novo classification process, which is the pathway authorized under section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)). A person may submit a De Novo request after submitting a premarket notification under section 510(k) of the FD&C Act and receiving a not substantially equivalent (NSE) determination (section 513(f)(2)(A)(i) of the FD&C Act). A person may also submit a De Novo request without first submitting a premarket notification under section 510(k), if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence (section 513(f)(2)(A)(ii) of the FD&C Act).

Upon receipt of a De Novo request, FDA is required to classify the device by written order (section 513(f)(2)(A)(iii) of the FD&C Act). The classification will be according to the criteria under section 513(a)(1) of the FD&C Act (21 U.S.C. 360c(a)(1)). Per section 513(f)(2)(B)(i) of the FD&C Act, the classification is the initial classification of the device for the purposes of section 513(f)(1) of the FD&C Act.

We believe De Novo classification will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo classification process, the device can serve as a predicate for future devices of that type, including for 510(k)s (section 513(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 a substantially equivalent device (see 21 U.S.C. 360c(i), defining “substantial equivalence”). Instead, sponsors can use the less-burdensome 510(k) process, when applicable, as a pathway to market their device.

FDA is issuing this document to provide guidance on the process for the submission and review of a De Novo request under section 513(f)(2) of the FD&C Act, also known as the De Novo classification process. This guidance also provides 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. This guidance will provide clarity regarding the Agency’s review process and expectations for information to be submitted in a De Novo request and ensures predictability and consistency for sponsors.

FDA considered comments received on the draft guidance that appeared in the **Federal Register** (79 FR 47651) of August 14, 2014. FDA revised the guidance as appropriate in response to the comments. This document supersedes “New Section 513(f)(2)—Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff” dated February 19, 1998.

II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the De Novo Classification Process (Evaluation of Automatic Class III Designation). It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological

Health guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of “De Novo Classification Process (Evaluation of Automatic Class III Designation)” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1760 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910–0844. The collections of information in the guidance document “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff” have been approved under OMB control number 0910–0756. The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

Dated: October 24, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–23492 Filed 10–27–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5975]

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey of Alumni Commissioner’s Fellowship Program Fellows

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Survey of Alumni Commissioner's Fellowship Program Fellows.

DATES: Submit either electronic or written comments on the collection of information by December 29, 2017.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 29, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of December 29, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-5975 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Survey of Alumni Commissioner's Fellowship Program Fellows." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the

electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Survey of Alumni Commissioner's Fellowship Program Fellows—OMB Control Number 0910—NEW

FDA is requesting approval from OMB to gather information from Alumni Commissioner's Fellowship Program (CFP) Fellows. The information from Alumni CFP Fellows will allow FDA's Office of the Commissioner (OC) to

easily and efficiently elicit and review program feedback. The online voluntary survey will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their experience with the FDA while a Commissioner's Fellow. The process will reduce the time and cost of submitting written documentation to the Agency and lessen the likelihood of

surveys being misrouted within the Agency mail system. The information gathered by the survey will be used to gain insights into, and to document, impacts that the CFP has had and is having on former CFP fellows and contributions and impacts that the former fellows are making in their current work. The voluntary surveys include questions to assess the

following measures: Post-fellowship employment (e.g., employment type); number of awards; number of contributions while a CFP fellow (e.g., number of publications, guidance documents authored or co-authored); and contributions in their field (e.g., list of publications).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Fellowship Program Survey	35	1	35	* 0.50	17.5

¹ There are no capital costs or operating maintenance costs associated with this collection of information.

* 30 minutes.

FDA based these estimates on the number of fellows who have graduated and left the Agency over the past 5 years.

Dated: October 24, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–23515 Filed 10–27–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4180]

Voluntary Medical Device Manufacturing and Product Quality Program; Public Workshop; Request for Comments; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period provided in the notice entitled “Voluntary Medical Device Manufacturing and Product Quality Program; Public Workshop; Request for Comments,” published in the **Federal Register** of July 25, 2017 (82 FR 34531). That notice announced the public workshop to be held on October 10, 2017, and requested comments by October 18, 2017. The Agency is taking this action to allow interested parties additional time to submit comments.

DATES: FDA is reopening the comment period for the public workshop “Voluntary Medical Device

Manufacturing and Product Quality Program; Public Workshop; Request for Comments” published on July 25, 2017 (82 FR 34531). Submit either electronic or written comments on this public workshop by December 14, 2017.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 14, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of December 14, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

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- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2017–N–4180 for “Voluntary Medical Device Manufacturing and Product Quality Program; Public Workshop; Request for Comments; Reopening of Comment Period.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS