patient or unique to that patient's treatment or diagnosis that has been recorded, stored, processed, retrieved, and/or derived from a legally marketed medical device. This information may include, but is not limited to, recorded patient data, device usage/output statistics, health care provider inputs, incidence of alarms, and/or records of device malfunctions or failures.

FDA developed this guidance to convey FDA's position regarding manufacturers appropriately and responsibly sharing patient-specific information with that patient at that patient's request. In general, manufacturers may do so without undergoing additional premarket review in advance. FDA generally would not consider patient-specific information to be ''labeling,'' as defined in section 201(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(m)). FDA is aware that when manufacturers share patient-specific information with patients, manufacturers also may provide them with supplemental information or other materials (*e.g.,* descriptions of intended use, benefit and risk information, instructions for use) that may be considered labeling. Any labeling is subject to applicable requirements in the FD&C Act and FDA regulations.

In the **Federal Register** of June 10, 2016 (81 FR 37603), FDA announced the availability of the draft guidance formerly entitled ''Dissemination of Patient-Specific Information from Devices by Device Manufacturers'' and interested parties were invited to comment by August 9, 2016. FDA has considered all of the public comments received prior to finalizing this guidance.

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 ''Manufacturers Sharing Patient-Specific Information from Medical Devices with Patients Upon Request.'' 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 ''Manufacturers Sharing Patient-Specific Information from Medical Devices with Patients Upon Request'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500067 to identify the guidance you are requesting.

Dated: October 24, 2017.

Lauren Silvis,

Chief of Staff.

[FR Doc. 2017–23517 Filed 10–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6069]

Acceptance Review for De Novo Classification Requests; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Acceptance Review for De Novo Classification Requests.'' The purpose of this draft guidance is to explain the procedures and criteria FDA intends to use in assessing whether a request for an evaluation of automatic class III designation (De Novo classification request or De Novo request) meets a minimum threshold of acceptability and should be accepted for substantive review. This draft guidance discusses De Novo acceptance review policies and procedures, ''Refuse to Accept'' principles, and the elements of the De Novo Acceptance Checklist and the Recommended Content Checklist and is being issued to be responsive to an explicit deliverable identified in the Medical Device User Fee Amendments of 2017 (MDUFA IV). This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by December 29, 2017 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–D–6069 for ''Acceptance Review for De Novo Classification Requests; Draft Guidance for Industry and Food and Drug Administration Staff; Availability.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Acceptance Review for De Novo Classification Requests'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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; or 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, 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 by the device. 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 Federal Food, Drug, and Cosmetic Act (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. A person may submit a De Novo request after submitting a premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) 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. 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 enhances 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, after a De Novo request is granted, other device sponsors do not have to submit a De Novo request or premarket application under section 515 of the FD&C Act (21 U.S.C. 360e)) in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, other device sponsors can use the less-burdensome 510(k) process, when applicable, as a pathway to market their device.

FDA is issuing this draft guidance to provide clarity regarding the Agency's expectations for information to be submitted in a De Novo request and ensure predictability and consistency for sponsors. Focusing the Agency's review resources on complete De Novo requests will provide a more efficient approach to ensuring that safe and effective medical devices reach patients as quickly as possible. Moreover, with the enactment of MDUFA IV, FDA agreed to issuance of draft (and final) guidance which includes a submission checklist to facilitate a more efficient and timely review process to assist with new performance goals. Acceptance review therefore takes on additional importance in both encouraging quality applications from De Novo requesters and allowing the Agency to appropriately concentrate resources on complete applications.

FDA anticipates that the Agency and industry may need a period of time to operationalize the policies within this guidance, when finalized. Therefore, if all criteria necessary to meet a minimum threshold of acceptability for De Novo requests as outlined in this guidance, when finalized, are not included in a De Novo request received by FDA before or up to 60 days after the publication of this guidance, when finalized, CDRH staff does not generally intend to refuse to accept.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Acceptance Review for De Novo Classification Requests.'' 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 draft guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft 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.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Acceptance Review for De Novo Classification Requests'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 16055 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (44 U.S.C. 3501–3502), 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, including each proposed revision of an existing 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.

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

OMB Control Number 0910–0844—Revision

To aid in the acceptance review, the guidance recommends that requesters complete and submit with their De Novo request an Acceptance Checklist that identifies the location of supporting information for each acceptance element and a Recommended Content Checklist that identifies the location of supporting information for each recommended content element. Therefore, we request revision of OMB control number 0910–0844, ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' to include the Acceptance Checklist and the Recommended Content Checklist in the hourly burden estimate for De Novo requests.

We previously estimated the average burden per response for a De Novo request under 21 U.S.C. 513(f)(2)(i) to be 100 hours and under 21 U.S.C. 513(f)(2)(ii) to be 180 hours. We estimate that it will take approximately 1 hour to prepare an Acceptance Checklist and 1 hour to prepare a Recommended Content Checklist. Our estimate assumes that each De Novo request will include both checklists. Therefore, we estimate the revised average burden per response for a De Novo request under 21 U.S.C. 513(f)(2)(i) to be 102 hours and under 21 U.S.C. 513(f)(2)(ii) to be 182 hours. The revision results in a 104-hour increase in the total burden estimate. The average burden per response is based on estimates by FDA administrative and technical staff that 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.

Approved operating and maintenance costs for a De Novo request include printing, shipping, and eCopy costs. We believe any increase of the operating and maintenance cost resulting from the addition of the Acceptance Checklist and Recommended Content Checklist to be de minimis. Therefore, we are not requesting revision of the operating and maintenance cost estimate for OMB control number 0910–0844.

Respondents to the information collection are medical device manufacturers seeking to market medical device products through submission of a De Novo classification request under section 513(f)(2) of the FD&C Act.

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	Total operating and maintenance costs [2]
De Novo Request Under 21 U.S.C. 513(f)(2)(i)						
CDRH	25	1	25	102	2,550	
CBER	1	1	1	102	102	
De Novo Request Under 21 U.S.C. 513(f)(2)(ii)						
CDRH	25	1	25	182	4,550	
CBER	1	1	1	182	182	
Total De Novo requests			52		7,384	$6,308
Request for withdrawal [2]	5	1	5	10	50	$5

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs [2]
Total					7,434	$6,313

[1] There are no capital costs associated with this collection of information.
[2] No change from approved information collection. This information is retained for the convenience of the reader.

Dated: October 24, 2017.

Anna K. Abram,

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

[FR Doc. 2017–23500 Filed 10–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–3275]

Product Labeling for Certain Ultrasonic Surgical Aspirator Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Product Labeling for Certain Ultrasonic Surgical Aspirator Devices.'' FDA is providing a specific labeling recommendation in this guidance to promote the safe and effective use of ultrasonic surgical aspirator devices. The labeling recommendation is being made in light of the risk of tissue dissemination and relates to use of these devices in the removal of uterine fibroids.

DATES: The announcement of the guidance is published in the **Federal Register** on October 30, 2017.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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 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–2016–D–3275 for ''Product Labeling for Certain Ultrasonic Surgical Aspirator Devices; Guidance for Industry and Food and Drug Administration Staff.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at 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 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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Product Labeling for Certain Ultrasonic Surgical Aspirator Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-