21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
820	Quality System Regulation	0910–0073
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''	De Novo classification process	0910–0844
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756

Dated: April 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08465 Filed 4–25–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4206]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device User Fee Small Business Qualification and Certification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 28, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0508 and title ''Medical Device User Fee Small Business Qualification and Certification.'' Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device User Fee Small Business Qualification and Certification

OMB Control Number 0910–0508—Extension

Medical device user fees were first established in 2002 by the Medical Device User Fee and Modernization Act (MDUFMA) (Pub. L. 107–250). User fees were renewed in 2007, with the Medical Device User Fee Amendments to the Food and Drug Administration Amendments Act of 2007 (MDUFA II), in 2012 with the Medical Device User Fee Amendments to the FDA Safety and Innovation Act (MDUFA III), and in 2017 with the Medical Device User Fee Amendments to the FDA Reauthorization Act of 2017 (MDUFA IV). MDUFA IV will be in place from October 1, 2017, until September 30, 2022.

A business that is qualified and certified as a ''small business'' is eligible for a substantial reduction in most of these user fees. The guidance document entitled ''Medical Device User Fee Small Business Qualification and Certification Guidance for Industry, Food and Drug Administration Staff and Foreign Governments'' describes the criteria FDA will use to decide whether an entity is eligible for a reduction in user fees and the process by which a business may request certification as a small business.

An applicant can qualify for a small business fee discount under MDUFMA if they reported gross receipts or sales of no more than $100 million on their Federal income tax return for the most recent tax year. If they have any affiliates, partners, or parent firms, the applicant must add the gross receipts or sales of the affiliates, partners, or parent firms to the applicant's, and the total must be no more than $100 million. If the applicant's gross receipts or sales are no more than $30 million, including all of their affiliates, partners, and parent firms, they will also qualify for a waiver of the fee for their first (ever) premarket application (product development protocol, biologics licensing application, or premarket report). An applicant must pay the full standard fee unless it provides evidence demonstrating to FDA that it meets the small business criteria (Form FDA 3602, ''MDUFA Small Business Certification Request for a Business Headquartered in the United States''). The evidence required by MDUFMA is a copy of the most recent Federal income tax return of the applicant, and any affiliate, partner, or parent firm. FDA will review these materials and decide whether an applicant is a small business within the meaning of MDUFMA.

MDUFA II provided an alternative way for a foreign business to qualify as a small business eligible to pay a significantly lower fee when a medical device user fee must be paid (Form FDA 3602A, ''MDUFA Foreign Small Business Certification Request for a Business Headquartered Outside the United States''). Before passage of MDUFA II, the only way a business could qualify as a small business was to submit a Federal (U.S.) income tax return showing its gross receipts or sales that did not exceed a statutory threshold, currently, $100 million. If a business could not provide a Federal income tax return, it did not qualify as a small business and had to pay the standard (full) fee. Because many foreign businesses have not, and cannot, file a Federal (U.S.) income tax return, this requirement effectively prevented those businesses from qualifying for the small business fee rates. Thus, foreign governments, including the European Union, objected. In lieu of a Federal income tax return, the MDUFA II allowed a foreign business to qualify as a small business by submitting a certification from its national taxing authority, the foreign equivalent of our Internal Revenue Service. This certification, referred to as a ''National Taxing Authority Certification,'' must: (1) Be in English; (2) be from the national taxing authority of the country in which the business is headquartered; (3) provide the business' gross receipts

or sales for the most recent year, in both the local currency and in U.S. dollars, and the exchange rate used in converting local currency to U.S. dollars; (4) provide the dates during which the reported receipts or sales were collected; and (5) bear the official seal of the national taxing authority.

Forms FDA 3602 and FDA 3602A are accessible through the guidance document entitled ''Medical Device User Fee Small Business Qualification and Certification Guidance for Industry, Food and Drug Administration Staff and Foreign Governments'' on the internet at: *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm456779.pdf.*

The estimated burden is based on the number of applications received in the last 3 years and includes time required to collect the required information. Based on our experience with Form FDA 3602, FDA believes it will take each respondent 1 hour to complete the form. Based on our experience with Form FDA 3602A, FDA also believes that it will take each respondent 1 hour to complete.

In the **Federal Register** of November 14, 2018 (83 FR 56852), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3602—MDUFA Small Business Certification Request for a Business Headquartered in the United States	5,000	1	5,000	1	5,000
FDA 3602A—MDUFA Foreign Small Business Certification Request for a Business Headquartered Outside the United States	2,000	1	2,000	1	2,000
Total					7,000

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

Our estimated burden for the information collection reflects an overall increase of 2,000 hours and a corresponding increase of 2,000 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: April 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08471 Filed 4–25–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4048]

Unique Device Identification: Convenience Kits; 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 a final guidance entitled ''Unique Device Identification: Convenience Kits; Guidance for Industry and Food and Drug Administration Staff.'' The unique device identification system regulations require that the label and device package of a device must bear a unique device identifier (UDI), unless an exception or alternative applies. An exception is provided for devices packaged within the immediate container of a convenience kit, if the label of the convenience kit bears a UDI. This guidance document describes FDA's interpretation of the definition of ''convenience kit.'' This guidance does not apply to in vitro diagnostic (IVD) devices that are subject to IVD labeling requirements nor does it apply to combination products.

DATES: The announcement of the guidance is published in the **Federal Register** on April 26, 2019.

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 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–2015–D–4048 for ''Unique Device Identification: Convenience Kits: 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