DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1873]

Select Updates for the Medical Device User Fee Small Business Qualification and Certification Guidance; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Select Updates for the Medical Device User Fee Small Business Qualification and Certification Guidance.'' The guidance includes select updates to the guidance ''Medical Device User Fee Small Business Qualification and Certification'' which describe how FDA plans to determine if a small business is experiencing ''financial hardship'' which makes them eligible for a waiver of their registration fee. The guidance will detail what information FDA will review and consider in making this determination. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by April 22, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by April 22, 2024.

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–2018–D–1873 for ''Select Updates for the Medical Device User Fee Small Business Qualification and Certification Guidance.'' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

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

Submit written requests for single copies of this draft guidance document entitled ''Select Updates for the Medical Device User Fee Small Business Qualification and Certification Guidance'' to Office of Policy, 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-addressed adhesive label to assist that office in processing your request or include a Fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance: Jason Brookbank, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5234, Silver Spring, MD 20993–0002, 301–796–5498, *Jason.Brookbank@fda.hhs.gov* or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

With regard to the proposed collection of information: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Select Updates for the Medical Device User Fee Small Business Qualification and Certification Guidance.'' On December 29, 2022, the Food and Drug

Omnibus Reform Act of 2022 was signed into law as part of the Consolidated Appropriations Act, 2023, Public Law 117–328. section 3309 of the Omnibus—''Small Business Fee Waiver''—amended section 738(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding clause (ii) ''Small business fee waiver.'' The amended language gave FDA the discretion, beginning in fiscal year 2025, to waive the annual registration fee for device establishments that are small businesses if FDA determines that paying such fee represents a financial hardship. Additionally, the amended statute acknowledges that device establishments may be located in countries without a national taxing authority (NTA). As a result of this amended statutory language, FDA is issuing this draft guidance to propose select updates to the guidance ''Medical Device User Fee Small Business Qualification and Certification'' which will describe how FDA plans to determine if a small business is experiencing ''financial hardship'' which makes them eligible for a waiver of their registration fee. The guidance details what information FDA will review and consider in making this determination.

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 Select Updates for the Medical Device User Fee Small Business Qualification and Certification guidance. 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.

II. 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/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Select Updates for the Medical Device User Fee Small Business Qualification and Certification Guidance'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00018007 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

Under the PRA (44 U.S.C. 3501–3521), 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.

MDUFMA Small Business Qualification Certification

OMB Control Number 0910–0508—Revision

This information collection helps support implementation of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250), most recently reauthorized in 2022 from October 1, 2022, until September 30, 2027. To qualify as a ''small business,'' and therefore be eligible for reduced or waived fees, respondents submit information to FDA so we can determine whether the applicant is a small business. Sections 738(d)(2)(A) and (e)(2)(A) of the FD&C Act (21 U.S.C. 379j(d)(2)(A) and (e)(2)(A)) define a ''small business'' as an entity that reported $100 million or less of gross receipts or sales in its most recent Federal income tax return, including such returns of its affiliates, partners, and parent firms. If a firm's gross receipts or sales are no more than $30 million (including all affiliates, partners, and parent firms), they will also qualify for a waiver of the fee for their first (ever) premarket application (PMA), product development protocol (PDP), biological licensing application (BLA), or premarket report.

The proposed updates to the Small Business Guidance describe how small businesses can show ''financial hardship'' to qualify for a small business waiver of the registration fee. Manufacturers seeking the small business fee waiver may provide evidence of a reported $1 million or less of gross receipts or sales in its most recent Federal income tax return, as well as evidence that they have filed a petition for bankruptcy and that the bankruptcy is currently active.

The proposed updates also reflect how firms based in jurisdictions without an NTA need not submit a certification from their NTA to be eligible for fee waivers or reductions.

Additionally, FDA intends to consolidate the forms previously known as FDA 3602 and FDA 3602A into a single form to be completed by foreign as well as U.S. businesses/applicants.

We propose the following revisions to the information collection:

- Consolidation of forms FDA 3602 and FDA 3602A into a single form, FDA 3602, to be completed by foreign as well as domestic businesses; and
- Addition of a ''Registration & Listing Fee Waiver'' section in the revised form, which asks if the business/applicant will apply for a registration and listing fee waiver and whether they have registered in the past. FDA recommends that applicants seeking this waiver include documentation supporting eligibility, including evidence that applicants have filed a petition for bankruptcy in United States Bankruptcy Court and that the bankruptcy is currently active (debts have yet to be discharged or a reorganization plan has not been confirmed) as well as evidence of prior registration as applicable.

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	4,500	1	4,500	1	4,500

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

Because we assume that current bankruptcy documentation is readily available to applicants, we assume no change to the Average Burden per Response for this information collection. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our total burden estimate.

Dated: February 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–03619 Filed 2–21–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–0584]

Assessing COVID–19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID–19 Prevention or Treatment; Guidance for Industry; 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 for industry entitled ''Assessing COVID–19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID–19 Prevention or Treatment.'' Although the public health emergency declared by the Department of Health and Human Services under section 319 of the Public Health Services Act has ended, COVID–19 remains an ongoing public health problem with continued prevention and treatment efforts. FDA is issuing this guidance to provide sponsors and investigators with considerations for approaches on how common COVID–19-related symptoms can be measured and analyzed in clinical trials evaluating drugs or biological products for the prevention or treatment of COVID–19 in outpatient adult and adolescent subjects. This guidance supersedes the guidance of the same name issued on September 29, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on February 22, 2024.

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

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- *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.*
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Instructions: All submissions received must include the Docket No. FDA–2024–D–0584 for ''Assessing COVID–19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID–19 Prevention or Treatment.'' 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, 240–402–7500.

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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