7,226. (For policy questions regarding this collection contact Debbie Vanhoven at 410–786–6625.)

Dated: October 24, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–23572 Filed 10–28–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–4258]

Type V Drug Master Files for Center for Drug Evaluation and Research-Led Combination Products Using Device Constituent Parts With Electronics or Software; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Type V DMFs for CDER-Led Combination Products Using Device Constituent Parts With Electronics or Software.'' A drug master file (DMF) is a voluntary submission to FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs. This draft guidance explains when a Type V DMF may be used to submit information regarding a combination product for which the Center for Drug Evaluation and Research (CDER) has primary jurisdiction (*i.e.,* a CDER-led combination product) and which features a device constituent part with electronics and/or software that is planned to be used as a platform, that is, may be used in multiple CDER-led combination products. The draft guidance also describes the administrative process and outlines the recommended content for these Type V DMF submissions and amendments.

DATES: Submit either electronic or written comments on the draft guidance by December 30, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–2019–D–4258 for ''Type V DMFs for CDER-Led Combination Products Using Device Constituent Parts With Electronics or Software.'' 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)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Kimberly Peters, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 51, Rm. 4314, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6350.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Type V DMFs for CDER-Led Combination Products Using Device

Constituent Parts With Electronics or Software.'' Some CDER-led combination products feature a device constituent part with electronics and/or software that may be used as a platform across multiple products. An application for such a combination product may necessitate review by multiple centers, offices, and divisions within FDA. In addition, because the device constituent part may be used as a platform in multiple CDER-led combination products, the same device information may be applicable to and used to support multiple CDER submissions. For such combination products, a Type V DMF can be an efficient mechanism to provide information regarding the device constituent part when the same information is applicable to several CDER applications, and additional measures to ensure consistency are needed.

Further, because of rapid advances in technology, the device constituent part of these types of combination products could be modified frequently. Knowledge of these modifications is important in determining whether they have any impact on the safety and effectiveness of the combination product or its indications for use. Amendments to the Type V DMF provide a regulatory pathway for the DMF holder to report device modifications and for FDA to be notified of and to review device modifications.

Once FDA reviews the Type V DMF device information for one CDER application, its review may be applicable to other CDER applications if the device information remains unchanged and is pertinent to products in other CDER applications that also incorporate the DMF by reference. FDA's ability to use previously completed scientific reviews for a DMF can contribute to an efficient FDA review process and help ensure consistency across CDER applications referencing the same information.

This draft guidance applies to Type V DMF submissions as described above for CDER-led combination products. Specifically, the information in this draft guidance may be appropriate for device constituent parts with electronics and/or software that meet the statutory definition of a device and perform functions such as the following:

- Facilitate drug delivery in a manner that may include patient input or analysis (*e.g.,* an electromechanically driven pen injector with software that allows input of patient or dosing information or that analyzes dosing or device use information).
- Provide information that is used in making a decision regarding treatment, therapy, or drug delivery.
- Interface with other devices or systems to provide patient use or other information to the user or health care provider (*e.g.,* physiological parameters).
- Control or drive the features of the user interface.

This draft guidance addresses process and general content expectations for Type V DMFs for such device constituent parts. It does not address FDA premarket review standards or expectations for such constituent parts or the combination products that include them. This draft guidance is also not intended to suggest that a Type V DMF should be submitted to CDER if the sponsor has rights of reference to a device master file located in another center containing the same information.

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 ''Type V DMFs for CDER-Led Combination Products Using Device Constituent Parts With Electronics or Software.'' 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. Paperwork Reduction Act of 1995

This draft 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 21 CFR 314.420 have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov*.

Dated: October 22, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23585 Filed 10–28–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Nurse Anesthetist Traineeship (NAT) Program Specific Data Forms, OMB Control No. 0915–0374—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR have been provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than November 29, 2019.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Nurse Anesthetist Traineeship (NAT) Program Specific Data Forms, OMB Control No. 0915–0374—Revision.

Abstract: HRSA provides advanced education nursing training grants to educational institutions to increase the numbers of Certified Registered Nurse Anesthetists through the NAT Program. The NAT Program is authorized by Section 811 of the Public Health Service (PHS) Act (42 U.S.C. 296j). The NAT Tables request information on program participants such as the number of enrollees/trainees, number of enrollees/trainees supported, number of graduates, number of graduates supported, number of projected enrollees/trainees, degree program (Master's and Doctoral), and the distribution of Nurse Anesthetists who practice in underserved, rural, and/or public health practice settings.