domestic FDF facility fee, we divide the $174,586,000 by the total number of facilities (675) which results in a domestic FDF facility fee of $258,646. The foreign FDF facility fee is $15,000 more than the domestic FDF facility fee, or $273,646.

VII. API Facility Fee

Under GDUFA, the annual API facility fee is owed by each person that owns a facility which produces, or which is pending review to produce, one or more active pharmaceutical ingredients identified, or intended to be identified, in at least one generic drug submission that is pending or approved or in a Type II active pharmaceutical ingredient drug master file referenced in such generic drug submission. These fees are due no later than the first business day on or after October 1 of each such year. Section 744B(b)(2)(D) of the FD&C Act specifies that the API facility fee will make up 14 percent of $323,011,000 in fee revenue, which is $45,221,000 (rounded down to the nearest thousand dollars).

In order to calculate the API fee, FDA used data submitted by generic drug facilities through the self-identification process mandated in the GDUFA statute and specified in a Notice of Requirement published on October 2, 2012. The total number of API facilities identified through self-identification was 789. Of the total facilities identified as API facilities, there were 101 domestic facilities and 688 foreign facilities. The foreign facility differential is $15,000. In order to calculate the fee for domestic facilities, we must first subtract the fee revenue that will result from the foreign facility fee differential. We take the foreign facility differential ($15,000) and multiply it by the number of foreign facilities (688) to determine the total fees that will result from the foreign facility differential. As a result of that calculation, the foreign fee differential will make up $10,320,000 of the total API fee revenue. Subtracting the foreign facility differential fee revenue ($10,320,000) from the total API facility target revenue ($45,221,000) results in a remaining balance of $34,901,000. To determine the domestic API facility fee, we divide the $34,901,000 by the total number of facilities (789) which gives us a domestic API facility fee of $44,234. The foreign API facility fee is $15,000 more than the domestic API facility fee, or $59,234.

VIII. Fee Schedule for FY 2017

The fee rates for FY 2017 are set out in Table 4.

TABLE 4—FEE SCHEDULE FOR FY 2017

Fee category	Fee rates for FY 2017
Applications:	
Abbreviated New Drug Application (ANDA)	$70,480
Prior Approval Supplement (PAS) to an ANDA	35,240
Drug Master File (DMF)	51,140
Facilities:	
Active Pharmaceutical Ingredient (API)—Domestic	44,234
API—Foreign	59,234
Finished Dosage Form (FDF)—Domestic	258,646
FDF—Foreign	273,646

IX. Fee Payment Options and Procedures

The new fee rates are effective October 1, 2016. To pay the ANDA, PAS, DMF, API facility, and FDF facility fee, you must complete a Generic Drug User Fee Cover Sheet, available at *http://www.fda.gov/gdufa,* and generate a user fee identification (ID) number. Payment must be made in U.S. currency drawn on a U.S. bank by electronic check, check, bank draft, U.S. postal money order, or wire transfer. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay.* Once you search for your invoice, click ''Pay Now'' to be redirected to *Pay.gov*. Note that electronic payment options are based on the balance due. Payment by credit card is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be drawn on U.S. bank accounts as well as U.S. credit cards.

FDA has partnered with the U.S. Department of the Treasury to utilize *Pay.gov*, a Web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA Web site after completing the Generic Drug User Fee Cover Sheet and generating the user fee ID number.

Please include the user fee ID number on your check, bank draft, or postal money order and make payable to the order of the Food and Drug Administration. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000. If checks are to be sent by a courier that requests a street address, the courier can deliver checks to: U.S. Bank, Attention: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (**Note:** This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery contact the U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery). Please make sure that the FDA post office box number (P.O. Box 979108) is written on the check, bank draft, or postal money order.

If paying by wire transfer, please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the wire transfer fee and include it with your payment to ensure that your fee is fully paid. The account information is as follows: U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, account number: 75060099, routing number: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993–0002. The tax identification number of FDA is 53–0196965.

Dated: July 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17801 Filed 7–26–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2153]

Use of Real-World Evidence to Support Regulatory Decisionmaking for Medical Devices; 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 ''Use of Real-World Evidence to Support Regulatory Decisionmaking for Medical Devices.'' FDA is issuing this draft guidance to clarify how we evaluate real-world data (RWD) to determine whether it may be sufficiently relevant and reliable to generate the types of real-world evidence that can be used in regulatory decisionmaking for medical devices. This guidance also clarifies when an

investigational device exemption (IDE) may be needed to prospectively collect and use RWD for purposes of determining the safety and effectiveness of a device. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 25, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2153 for ''Use of Real-World Evidence to Support Regulatory Decisionmaking for Medical Devices.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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 ''Use of Real-World Evidence to Support Regulatory Decisionmaking for Medical 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-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Benjamin Eloff, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2254, Silver Spring, MD 20993–0002, 301–796–8528.

SUPPLEMENTARY INFORMATION:

I. Background

To protect and promote the public health, FDA needs to understand and evaluate the available evidence related to regulated products. For medical devices, available evidence is traditionally comprised of non-clinical and in some cases, clinical studies conducted and provided to FDA by the device manufacturer or sponsor. However, FDA recognizes that a wealth of data covering medical device experience exists and is routinely collected in the course of treatment and management of patients. Under certain circumstances, these RWD may be of sufficient quality to help inform or augment FDA's understanding of the benefit-risk profile of devices at various points in their life cycle, and could potentially be used to aid FDA in regulatory decisionmaking.

This document describes the characteristics and sources of RWD that may be sufficient for use in making various regulatory decisions. Because of its nature, the quality (*i.e.,* relevance and reliability) of RWD can vary greatly across sources. Likewise, there are many types of regulatory decisions with varying levels of evidentiary needs. FDA's evidentiary standards for regulatory decisionmaking are not changing; FDA will evaluate whether the available RWD is of sufficient relevance and reliability to address the specific regulatory decision being considered.

This guidance does not affect any federal, state or local laws or regulations or foreign laws or regulations that may otherwise be applicable to the use or collection of real-world evidence and that provide protections for human subjects or patient privacy. When finalized, this guidance should be used to complement, but not supersede, other device-specific and good clinical practice guidance documents.

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 ''Use of Real-World Evidence to Support Regulatory Decisionmaking for Medical Devices.'' 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.

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 *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Use of Real-World Evidence to Support Regulatory Decisionmaking for Medical Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500012 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 and guidance. 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 part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E (premarket approval) have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H (humanitarian device exemption) have been approved under OMB control number 0910–0332; the collections of information in 21 CFR part 812 (investigational device exemption) have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 822 (postmarket surveillance) have been approved under OMB control number 0910–0449; the collections of information in 21 CFR part 50.23 (exception from general requirements for informed consent) have been approved under OMB control number 0910–0586; the collections of information in 21 CFR part 54 (financial disclosure by clinical investigators) have been approved under OMB control number 0910–0396; the collections of information in 21 CFR part 56.115 (IRB records) have been approved under OMB control number 0910–0130; and the collections of information in 21 CFR parts 50 (informed consent) and 56 (IRBs) have been approved under OMB control number 0910–0755. The collections of information in the guidance ''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.

Dated: July 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17750 Filed 7–26–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1439]

Adaptive Designs for Medical Device Clinical Studies; 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 ''Adaptive Designs for Medical Device Clinical Studies.'' This guidance provides sponsors and FDA staff with guidance on how to plan and implement adaptive designs for clinical studies when used in medical device development programs. An adaptive design for a medical device clinical study is defined as a clinical trial design that allows for prospectively planned modifications based on accumulating study data without undermining the trial's integrity and validity. Adaptive designs, when properly implemented, can reduce resource requirements and/or increase the chance of study success.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–1439 for ''Adaptive Designs for Medical Device Clinical Studies.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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