

VIII. Procedures for Paying the FY 2018 Fees

A. Application Fees and Payment Instructions

The appropriate application fee established in the new fee schedule must be paid for an animal drug application or supplement subject to fees under ADUFA III that is submitted on or after October 1, 2017. The payment must be made in U.S. currency by one of the following methods: Wire transfer, electronically, check, bank draft, or U.S. postal money order made payable to the Food and Drug Administration. 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> or the *Pay.gov* payment option is available to you after you submit a cover sheet. (Note: only full payments are accepted. No partial payments can be made online.) Once you search for and find your invoice, select "Pay Now" to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available only for balances that are less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

When paying by check, bank draft, or U.S. postal money order, please write your application's unique Payment Identification Number (PIN), beginning with the letters AD, on the upper right-hand corner of your completed Animal Drug User Fee Cover Sheet. Also write the FDA post office box number (P.O. Box 979033) on the enclosed check, bank draft, or money order. Mail the payment and a copy of the completed Animal Drug User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197-9000. When paying by wire transfer, the invoice number needs to be included; without the invoice number, the payment may not be applied. If the payment amount is not applied, the invoice amount would be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full.

Use the following account information when sending a payment by wire transfer: U.S. Department of Treasury, TREAS NYC, 33 Liberty St.,

New York, NY 10045, FDA Deposit Account Number: 75060099, U.S. Department of Treasury routing/transit number: 021030004, SWIFT Number: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993-0002.

To send a check by a courier such as Federal Express, the courier must deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery contact U.S. Bank at 314-418-4013. This telephone number is only for questions about courier delivery.)

It is important that the fee arrives at the bank at least a day or two before the application arrives at FDA's CVM. FDA records the official application receipt date as the later of the following: The date the application was received by FDA's CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Treasury notifies FDA of receipt of an electronic or wire transfer payment. U.S. Bank and the U.S. Treasury are required to notify FDA within 1 working day, using the PIN described previously.

The tax identification number of FDA is 53-0196965. (Note: In no case should the payment for the fee be submitted to FDA with the application.)

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log on to the ADUFA Web site at <http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm> and, under Tools and Resources, click "The Animal Drug User Fee Cover Sheet" and then select "Create ADUFA User Fee Cover Sheet." For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two—Create an Animal Drug User Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Drug User Fee Cover Sheet. One cover sheet is needed for each animal drug application or supplement. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be

able to print a copy of your cover sheet showing your unique PIN.

Step Three—Send the payment for your application as described in section VIII.A.

Step Four—Please submit your application and a copy of the completed Animal Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV-199), 7500 Standish Pl., Rockville, MD 20855.

C. Product, Establishment, and Sponsor Fees

By December 31, 2017, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2018 using this fee schedule. Payment will be due by January 31, 2018. FDA will issue invoices in November 2018 for any products, establishments, and sponsors subject to fees for FY 2018 that qualify for fees after the December 2017 billing.

Dated: July 26, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0689]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; De Novo Classification Process (Evaluation of Automatic Class III Designation)

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 September 1, 2017.

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 oir_submission@omb.eop.gov. All

comments should be identified with the OMB control number 0910-NEW and title “De Novo Classification Process (Evaluation of Automatic Class III Designation).” 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, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, *PRASStaff@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.

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

OMB Control Number 0910-NEW

The draft guidance entitled “De Novo Classification Process (Evaluation of Automatic Class III Designation)” provides guidance on the process for the submission and review of a De Novo classification request (hereafter a “De Novo request”) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(2)), also known as the De Novo classification process. This process provides a pathway to class I or class II classification for medical devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

The proposed collection of information is necessary to satisfy the

previously mentioned statutory requirements for implementing this voluntary submission program.

In the **Federal Register** of August 14, 2014 (79 FR 47651), FDA published a 60-day notice requesting public comment on the proposed collection of information. Seven organizations commented on the draft guidance document. None of the comments were related to the information collection.

Upon further review of the information collection, it has come to our attention that the 60-day notice did not include an estimated hour burden for requests for withdrawal or estimated operating and maintenance costs for eCopy,¹ printing, and shipping of De Novo submissions. To correct this oversight, we have included these estimates here.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
De Novo request under section 513(f)(2)(i) of the FD&C Act						
CDRH	25	1	25	100	2,500
CBER	1	1	1	100	100
De Novo request under section 513(f)(2)(ii) of the FD&C Act						
CDRH	25	1	25	180	4,500
CBER	1	1	1	180	180
Total De Novo requests	52	7,280	\$6,308
Request for withdrawal	5	1	5	10	50	5
Total	7,330	6,313

¹ There are no capital costs associated with this collection of information.

FDA estimates from past experience with the De Novo classification program that the complete process involved with the program under section 513(f)(2)(i) of the FD&C Act takes approximately 100 hours, and the complete process under section 513(f)(2)(ii) of the FD&C Act takes approximately 180 hours. This includes the time for any supplements or amendments to the original submission. We estimate that requests for withdrawal take approximately 10 minutes. The average burdens per response are based upon estimates by FDA administrative and technical staff who are familiar with the requirements for submission of a De Novo request (and related materials), have consulted

and advised manufacturers on the submissions, and have reviewed the documentation submitted.

Respondents to the information collection are medical device manufacturers seeking to market medical device products that have been classified into class III under section 513(f)(2) of the FD&C Act. It is expected that the number of De Novo requests will reach a steady rate of approximately 52 submissions per year. We expect that we will receive approximately five requests for withdrawal per year.

The operating and maintenance cost for a De Novo submission includes the cost of printing, shipping, and the

eCopy. We estimate the cost burden for a De Novo submission to be \$121.30 (\$90 printing + \$30 shipping + \$1.30 eCopy). The annual cost estimate for De Novo submissions is \$6,308 (rounded) (52 submissions × \$121.30). We estimate the cost for a request for withdrawal to be \$1 (rounded) (\$0.09 printing 1 page + \$0.03 shipping + \$1.30 eCopy). The annual cost estimate for requests for withdrawal is \$5.

The draft guidance also refers to currently approved information collections found in FDA regulations. The collections of information in 21 CFR part 807, subpart E, are approved under OMB control number 0910-0120.

¹ See the eCopy guidance, “eCopy Program for Medical Device Submissions; Guidance for Industry

and Food and Drug Administration Staff,” at <https://www.fda.gov/ucm/groups/fdagov-public/>

[@fdagov-meddev-gen/documents/document/ucm313794.pdf](https://fdagov-meddev-gen/documents/document/ucm313794.pdf).

Dated July 27, 2017.

Anna K. Abram,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0744]

Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases; 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 guidance for industry entitled “Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases.” The purpose of the guidance is to assist sponsors in the development of new antibacterial drugs to treat serious bacterial diseases in patients with an unmet medical need, including patients who have a serious bacterial disease for which effective antibacterial drugs are limited or lacking. This guidance finalizes the draft guidance of the same name issued July 2, 2013.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments 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-2013-D-0744 for “Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases.” 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.

Submit written requests for single copies of this 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 guidance document.

FOR FURTHER INFORMATION CONTACT:

Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6244, Silver Spring, MD 20993-0002, 301-796-1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases.” The purpose of this guidance is to assist sponsors in the development of new antibacterial drugs for the treatment of serious bacterial diseases in patients with an unmet medical need, including patients who have a serious bacterial disease for which effective antibacterial drugs are limited or lacking.

Efforts to develop new antibacterial drugs have diminished in the past few decades. Because bacteria continue to develop resistance to available antibacterial drugs, a situation of unmet medical need has arisen in which patients with serious bacterial diseases have limited or in some cases no alternative antibacterial drugs available for treatment. To foster new antibacterial drug development that will have the potential to keep pace with continued selective pressures of antibacterial resistance, FDA is exploring approaches to help streamline development programs for new