TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 U.S.C. section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
21 U.S.C. 379aa–1(b)(1)—serious adverse event reports for dietary supplements	230	12	2,760	2	5,520
21 U.S.C. 379aa–1(c)(2)—followup reports of new medical information	58	12	696	1	696
Total					6,216

[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 annual decrease of 219 hours for reporting. We attribute this adjustment to a decrease in the number of reports we received over the last few years.

This estimate is based on our experience with similar adverse event reporting programs and the number of serious adverse event reports and followup reports received in the past 3 years. All dietary supplement manufacturers, packers, or distributors are subject to serious adverse event mandatory reporting.

In the past 3 years, we received an average of 2,760 initial serious adverse event reports. We also estimated an average number of firms filing reports to be 230. Finally, we estimate that it will take respondents an average of 2 hours per report to collect information about a serious adverse event associated with a dietary supplement and report the information to us on Form FDA 3500A. Thus, the estimated burden associated with submitting initial dietary supplement serious adverse event reports is 5,520 hours (2,760 responses × 2 hours) as shown in row 1 of table 1.

If a respondent that has submitted a serious adverse event report receives new information related to the serious adverse event within 1 year of submitting the initial report, the respondent must provide the new information to us in a followup report. We estimate that around 25 percent of serious adverse event reports related to dietary supplements will have a followup report submitted, resulting in approximately 696 followup reports submitted annually. Dividing the annual number of reports among the 230 firms reporting results in approximately 12 reports for 58 respondents. We estimate that each followup report will require an hour to assemble and submit, including the time needed to copy and attach the initial serious adverse event report as recommended in the guidance. Thus, the estimated burden for followup reports of new information is 696 hours (696 responses × 1 hour) as shown in row 2 of table 1.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 U.S.C. section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
21 U.S.C. 379aa–1(e)(1))—dietary supplement adverse events records.	1,815	72	130,680	0.5 (30 minutes)	65,340

[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 annual increase of 2,440 hours for recordkeeping. We attribute this adjustment to an increase in the number of reports we received over the last few years.

All dietary supplement manufacturers, packers, or distributors are subject to serious adverse event recordkeeping. We estimate that there are 1,815 such respondents. Estimating that each recordkeeper will keep approximately 72 records per year results in an annual burden of 130,680 records. Estimating that assembling and filing these records, including any necessary photocopying, will take approximately 30 minutes, or 0.5 hour, per record, results in an annual burden of 65,340 hours (130,680 records × 0.5 hour).

Once the documents pertaining to an adverse event report have been assembled and filed in accordance with the safety reporting portal, we expect the records retention burden to be minimal, as we believe most establishments would normally keep this kind of record for at least several years after receiving the report, as a matter of usual and customary business practice.

Dated: September 19, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20766 Filed 9–24–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3103]

Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications; Draft Guidance for Industry and Review 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 draft guidance for industry and review staff entitled ''Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications.'' This draft guidance describes the fundamental values and

operational principles that serve as the foundation for the review process. It also clarifies the roles and responsibilities of review staff and identifies ways in which applicants may support a robust and efficient review process. This draft guidance revises the guidance for review staff and industry entitled ''Good Review Management Principles and Practices for PDUFA Products'' issued April 2005.

DATES: Submit either electronic or written comments on the draft guidance by December 24, 2018 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–2018–D–3103 for ''Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications.'' 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, or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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: Pinakini Patel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6367, Silver Spring, MD 20993–0002, 301–796–7475; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and review staff entitled ''Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications.'' This draft guidance describes good review management principles and practices (GRMPs) for the review of a new drug application (NDA), biologics license application (BLA), or an efficacy supplement/supplement with clinical data. This guidance applies to *human drug applications* (as defined in section 735(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379g(1))) and *biosimilar biological product applications* (section 744G(4) of the FD&C Act (21 U.S.C. 379j–51(4))). This guidance also discusses the roles and responsibilities of review staff in managing the review process and identifies ways in which applicants may support an efficient and robust review process.

This draft guidance revises the guidance for review staff and industry entitled ''Good Review Management Principles and Practices for PDUFA Products'' issued in April 2005. FDA committed to updating the 2005 guidance as part of the Prescription Drug User Fee Act (PDUFA) VI and Biosimilar User Fee Act (BsUFA) II. This draft guidance meets that commitment by reflecting advances in the PDUFA program and implementation of BsUFA. This draft guidance also reflects the evolution of GRMPs to support new regulatory programs such as breakthrough therapy, the Program for Enhanced Review

Transparency and Communication for NME (New Molecular Entity) NDAs and Original BLAs, and risk evaluation and mitigation strategies.

In addition, the draft guidance has been consolidated to focus on the fundamental values and operational principles that serve as the foundation for the GRMPs. Details of the review process are covered in other documents referenced by this guidance. Fundamental values and operational principles should remain relatively constant over time, while processes must be able to adapt and respond to scientific advances in product development and evolving public health needs.

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 GRMPs for NDAs and BLAs. 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. This guidance is not subject to Executive Order 12866.

II. Electronic Access

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

Dated: September 19, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20789 Filed 9–24–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0007]

Fee for Using a Tropical Disease Priority Review Voucher in Fiscal Year 2019

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the fee rates for using a tropical disease priority review voucher for fiscal year (FY) 2019. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Amendments Act of 2007 (FDAAA), authorizes FDA to determine and collect priority review user fees for certain applications for review of drug or biological products when those applications use a tropical disease priority review voucher. These vouchers are awarded to the applicants of certain tropical disease product applications, submitted after September 27, 2007, upon FDA approval of such applications. The amount of the fee submitted to FDA with applications using a tropical disease priority review voucher is determined each fiscal year based on the difference between the average cost incurred by FDA to review a human drug application designated as priority review in the previous fiscal year and the average cost incurred in the review of an application that is not subject to priority review in the previous fiscal year. This notice establishes the tropical disease priority review fee rate for FY 2019.

FOR FURTHER INFORMATION CONTACT: Lola Olajide, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14541B, Silver Spring, MD 20993–0002, 240–402–4244.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1102 of FDAAA (Pub. L. 110–85) added section 524 to the FD&C Act (21 U.S.C. 360n). In section 524, Congress encouraged development of new drug and biological products for prevention and treatment of tropical diseases by offering additional incentives for obtaining FDA approval of such products. Under section 524, the applicant of an eligible human drug application submitted after September 27, 2007, for a tropical disease (as defined in section 524(a)(3) of the FD&C Act) shall receive a priority review voucher upon approval of the tropical disease product application (assuming other criteria are met). The recipient of a tropical disease priority review voucher may either use the voucher with a future submission to FDA under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262), or transfer (including by sale) the voucher to another party. The voucher may be transferred (including by sale) repeatedly until it ultimately is used for a human drug application submitted to FDA under section 505(b)(1) of the FD&C Act or section 351(a) of the Public Health Service Act. A priority review is a review conducted with a Prescription Drug User Fee Act (PDUFA) goal date of 6 months after the receipt or filing date, depending upon the type of application. Information regarding the PDUFA goals is available at: *https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm511438.pdf.*

The applicant that uses a priority review voucher is entitled to a priority review but must pay FDA a priority review user fee in addition to any other fee required by PDUFA. FDA published guidance on its website about how this tropical disease priority review voucher program operates (available at: *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080599.pdf*).

This notice establishes the tropical disease priority review fee rate for FY 2019 as $2,457,140 and outlines FDA's process for implementing the collection of the priority review user fees. This rate is effective on October 1, 2018, and will remain in effect through September 30, 2019, for applications submitted with a tropical disease priority review voucher. The payment of this priority review user fee is required in addition to the payment of any other fee that would normally apply to such an application under PDUFA before FDA will consider the application complete and acceptable for filing.

II. Tropical Disease Priority Review User Fee for FY 2019

FDA interprets section 524(c)(2) of the FD&C Act as requiring that FDA determine the amount of the tropical disease priority review user fee each fiscal year based on the difference between the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous fiscal year and the average cost incurred by FDA in the review of a human drug application that is not subject to priority review in the previous fiscal year.

A priority review is a review conducted with a PDUFA goal date of 6 months after the receipt or filing date, depending on the type of application. Under the PDUFA goals letter, FDA has committed to reviewing and acting on 90 percent of the applications granted priority review status within this expedited timeframe. Normally, an application for a human drug or biological product will qualify for priority review if the product is intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. An application that does not receive a priority designation receives a standard review. Under the