ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
CCDF QPR	56	1	60.0	3,360

Estimated Total Annual Burden Hours: 3,360 hours.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2017–20765 Filed 9–27–17; 8:45 am]

BILLING CODE 4184–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0007]

Fee for Using a Rare Pediatric Disease Priority Review Voucher in Fiscal Year 2018

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the fee rate for using a rare pediatric disease priority review voucher for fiscal year (FY) 2018. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to determine and collect rare pediatric disease priority review user fees for certain applications for review of human drug or biological products when those applications use a rare pediatric disease priority review voucher. These vouchers are awarded to the sponsors of rare pediatric disease product applications that meet all of the requirements of this program and that are submitted 90 days or more after July 9, 2012, upon FDA approval of such applications. The amount of the fee for using a rare pediatric disease priority review voucher is determined each FY, 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 FY and the average cost incurred in the review of an application that is not subject to priority review in the previous FY. This notice establishes the rare pediatric disease priority review fee rate for FY 2018 and outlines the payment procedures for such fees.

FOR FURTHER INFORMATION CONTACT: Robert J. Marcarelli, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14202F, Silver Spring, MD 20993–0002, 301–796–7223.

SUPPLEMENTARY INFORMATION:

I. Background

Section 908 of FDASIA (Pub. L. 112–144) added section 529 to the FD&C Act (21 U.S.C. 360ff). In section 529 of the FD&C Act, Congress encouraged development of new human drugs and biological products for prevention and treatment of certain rare pediatric diseases by offering additional incentives for obtaining FDA approval of such products. Under section 529 of the FD&C Act, the sponsor of an eligible human drug application submitted 90 days or more after July 9, 2012, for a rare pediatric disease (as defined in section 529(a)(3)) shall receive a priority review voucher upon approval of the rare pediatric disease product application. The recipient of a rare pediatric disease priority review voucher may either use the voucher for a future human drug application submitted 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(a)), 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 on the type of application. Information regarding PDUFA goals is available at *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm511438.pdf.*

The applicant that uses a rare pediatric disease priority review voucher is entitled to a priority review of its eligible human drug application, but must pay FDA a rare pediatric disease priority review user fee in addition to any user fee required by PDUFA for the application. Information regarding the rare pediatric disease priority review voucher program is available at: *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm375479.htm.*

This notice establishes the rare pediatric disease priority review fee rate for FY 2018 at $2,830,579 and outlines FDA's procedures for payment of rare pediatric disease priority review user fees. This rate is effective on October 1, 2017, and will remain in effect through September 30, 2018.

II. Rare Pediatric Priority Review User Fee for FY 2018

Under section 529(c)(2) of the FD&C Act, the amount of the rare pediatric disease priority review user fee is determined 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 will receive a standard review. Under the PDUFA goals letter, FDA has committed to reviewing and acting on 90 percent of standard applications within 10 months of the receipt or filing date depending on the type of application. A priority review involves a more intensive level of effort and a higher level of resources than a standard review.

FDA is setting a fee for FY 2018, which is to be based on standard cost data from the previous fiscal year, FY 2017. However, the FY 2017 submission cohort has not been closed out yet, thus the cost data for FY 2017 are not complete. The latest year for which FDA has complete cost data is FY 2016. Furthermore, because FDA has never tracked the cost of reviewing applications that get priority review as a separate cost subset, FDA estimated this cost based on other data that the Agency has tracked. FDA uses data that the Agency estimates and publishes on its Web site each year—standard costs for review. FDA does not publish a standard cost for ''the review of a human drug application subject to priority review in the previous fiscal year.'' However, we expect all such applications would contain clinical data. The standard cost application categories with clinical data that FDA publishes each year are: (1) New drug applications (NDAs) for a new molecular entity (NME) with clinical data and (2) biologics license applications (BLAs).

The standard cost worksheets for FY 2016 show standard costs (rounded to the nearest hundred dollars) of $5,929,100 for an NME NDA, and $4,887,100 for a BLA. Based on these standard costs, the total cost to review the 49 applications in these two categories in FY 2016 (27 NME NDAs with clinical data and 22 BLAs) was $267,601,900. (*Note:* These numbers exclude the President's Emergency Plan for AIDS Relief NDAs; no investigational new drug (IND) review costs are included in this amount.) 23 of these applications (14 NDAs and 9 BLAs) received priority review, which would mean that the remaining 26 received standard reviews. Because a priority review compresses a review schedule that ordinarily takes 10 months into 6 months, FDA estimates that a multiplier of 1.67 (10 months divided by 6 months) should be applied to non-priority review costs in estimating the effort and cost of a priority review as compared to a standard review. This multiplier is consistent with published research on this subject which supports a priority review multiplier in the range of 1.48 to 2.35 (Ref. 1). Using FY 2016 figures, the costs of a priority and standard review are estimated using the following formula:

$$(23\ \alpha \times 1.67) + (26\ \alpha) = \$267{,}601{,}900$$

where ''α'' is the cost of a standard review and ''α times 1.67'' is the cost of a priority review. Using this formula, the cost of a standard review for NME NDAs and BLAs is calculated to be $4,154,664 (rounded to the nearest dollar) and the cost of a priority review for NME NDAs and BLAs is 1.67 times that amount, or $6,938,289 (rounded to the nearest dollar). The difference between these two cost estimates, or $2,783,625, represents the incremental cost of conducting a priority review rather than a standard review.

For the FY 2018 fee, FDA will need to adjust the FY 2016 incremental cost by the average amount by which FDA's average costs increased in the 3 years prior to FY 2017, to adjust the FY 2016 amount for cost increases in FY 2017. That adjustment, published in the **Federal Register** on September 14, 2017 (82 FR 43244), setting the FY 2018 PDUFA fee, is 1.6868 percent for the most recent year, not compounded. Increasing the FY 2016 incremental priority review cost of $2,783,625 by 1.6868 percent (or 0.016868) results in an estimated cost of $2,830,579 (rounded to the nearest dollar). This is the rare pediatric disease priority review user fee amount for FY 2018 that must be submitted with a priority review voucher for a human drug application in FY 2018, in addition to any PDUFA fee that is required for such an application.

III. Fee Schedule for FY 2018

The fee rate for FY 2018 is set out in Table 1:

TABLE 1—RARE PEDIATRIC DISEASE PRIORITY REVIEW SCHEDULE FOR FY 2018

Fee category	Fee rate for FY 2018
Application submitted with a rare pediatric disease priority review voucher in addition to the normal PDUFA fee	$2,830,579

IV. Implementation of Rare Pediatric Disease Priority Review User Fee

Under section 529(c)(4)(A) of the FD&C Act, the priority review user fee is due (*i.e.* the obligation to pay the fee is incurred) when a sponsor notifies FDA of its intent to use the voucher. Section 529(c)(4)(B) of the FD&C Act specifies that the application will be considered incomplete if the priority review user fee and all other applicable user fees are not paid in accordance with FDA payment procedures. In addition, section 529(c)(4)(C) specifies that FDA may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section of the FD&C Act. Beginning with FDA's appropriation for FY 2015, the annual appropriation language states specifically that ''priority review user fees authorized by 21 U.S.C. 360n [*i.e.,* section 524 of the FD&C Act] and 360ff [*i.e.,* section 529 of the FD&C Act] shall be credited to this account, to remain available until expended.'' (Pub. L. 113–235, Section 5, Division A, Title VI).

The rare pediatric disease priority review fee established in the new fee schedule must be paid for any application that is received on or after October 1, 2017. In order to comply with this requirement, the sponsor must notify FDA 90 days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application.

Upon receipt of this notification, FDA will issue an invoice to the sponsor who has incurred a rare pediatric disease priority review voucher fee. The invoice will include instructions on how to pay the fee via wire transfer or check.

As noted in section II, if a sponsor uses a rare pediatric disease priority review voucher for a human drug application, the sponsor would incur the rare pediatric disease priority review voucher fee in addition to any PDUFA fee that is required for the application. The sponsor would need to follow

FDA's normal procedures for timely payment of the PDUFA fee for the human drug application.

Payment must be made in U.S. currency by electronic check, check, bank draft, wire transfer, credit card, or U.S. postal money order payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (*Note:* Only full payments are accepted. No partial payments can be made online). Once you search for your invoice, select ''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 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.

If paying with a paper check the invoice number should be included on the check, followed by the words ''Rare Pediatric Disease Priority Review.'' All paper checks must be in U.S. currency from a U.S. bank made payable and mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000.

If checks are sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979107, 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). The FDA post office box number (P.O. Box 979107) must be written on the check. If needed, FDA's tax identification number is 53–0196965.

If paying by wire transfer, please reference your invoice number when completing your transfer. 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. The account information is as follows: U.S. Dept. 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.

V. Reference

The following reference is on display in the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Ridley, D.B., H.G. Grabowski, and J.L. Moe, ''Developing Drugs for Developing Countries,'' *Health Affairs,* vol. 25, no. 2, pp. 313–324, 2006.

Dated: September 22, 2017.

Anna K. Abram,

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

[FR Doc. 2017–20798 Filed 9–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1119]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 October 30, 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 *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0037. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@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.

I. Background

Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers 21 CFR 108.25 and 108.35, and Parts 113 and 114

OMB Control Number 0910–0037—Extension

Section 402 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342) deems a food to be adulterated, in part, if the food bears or contains any poisonous or deleterious substance that may render it injurious to health. Section 301(a) of the FD&C Act (21 U.S.C. 331(a)) prohibits the introduction or delivery for introduction into interstate commerce of adulterated food. Under section 404 of the FD&C Act (21 U.S.C. 344), our regulations require registration of food processing establishments, filing of process or other data, and maintenance of processing and production records for acidified foods and thermally processed low-acid foods in hermetically sealed containers. These requirements are intended to ensure safe manufacturing, processing, and packing procedures, and to permit us to verify that these procedures are being followed. Improperly processed low-acid foods present life-threatening hazards if contaminated with foodborne microorganisms, especially *Clostridium botulinum.* The spores of *C. botulinum* need to be destroyed or inhibited to avoid production of the deadly toxin that causes botulism. This is accomplished with good manufacturing procedures, which must include the use of adequate heat processes or other means of preservation.

To protect the public health, our regulations require that each firm that manufactures, processes, or packs acidified foods or thermally processed low-acid foods in hermetically sealed containers for introduction into interstate commerce register the establishment with us using Form FDA 2541 (§§ 108.25(c)(1) and 108.35(c)(2) (21 CFR 108.25(c)(1) and 108.35(c)(2)). In addition to registering the plant, each firm is required to provide data on the processes used to produce these foods, using Forms FDA 2541d, FDA 2541e,