Dated: September 4, 2012.

Armando Zamora,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0007]

Fee for Using a Priority Review Voucher in Fiscal Year 2013

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) 2013. The Federal Food, Drug, and Cosmetic Act (the 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 approval of drug or biological products when those applications use a priority review voucher awarded by the Secretary of Health and Human Services. These vouchers are awarded to the sponsors of certain tropical disease product applications, submitted after September 27, 2007, upon FDA approval of such applications. The amount of the fee to be submitted to FDA with applications using a priority review voucher is determined each FY based on the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous FY. This notice establishes the priority review fee rate for FY 2013.

FOR FURTHER INFORMATION CONTACT: David Miller, Office of Financial Management (HFA–100), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–796–7103.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1102 of FDAAA (Pub. L. 110–85) added new 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 certain tropical diseases by offering additional incentives for obtaining FDA approval of such products. Under section 524, the sponsor of an eligible human drug application submitted after September 27, 2007, for a qualified tropical disease (as defined in section 524(a)(3)), shall receive a priority review voucher upon approval of the tropical disease product application. The recipient of a 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 of the Public Health Service Act (21 U.S.C. 262), or transfer (including by sale) the voucher to another party that may then use it. A priority review is a review conducted with a Prescription Drug User Fee Act (PDUFA) goal date of 6 months.

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 has published a draft guidance on its Web site about how this priority review voucher program will operate (available at: *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080599.pdf*).

This notice establishes the priority review fee rate for FY 2013 as $3,559,000 and outlines FDA's process for implementing the collection of the priority review user fees. This rate is effective on October 1, 2012, and will remain in effect through September 30, 2013, for applications submitted with a 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. Priority Review User Fee for FY 2013

Under section 524(c)(2) of the FD&C Act, the amount of the priority review user fee is to be determined each FY based on the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous FY. The priority review voucher fee is intended to cover the incremental costs for FDA to do a priority review on a product that would otherwise get a standard review. The formula used in past years to calculate the priority review user fee was based on the full average cost of a priority review. After reviewing more recent data and experience with the program, FDA has revised the formula to better approximate the current and ongoing incremental FDA resource costs for a priority review. The new formula will provide the Agency with the added resources to conduct a priority review while still ensuring a robust priority review voucher program that is consistent with the Agency's public health goal of encouraging the development of new drug and biological products.

A priority review is a review conducted with a PDUFA goal date of 6 months. Normally, an application for a Center for Drug Evaluation and Research (CDER) product will qualify for a priority review if FDA determines that the product, if approved, would provide safe and effective therapy where no satisfactory alternative therapy exists or would be a significant improvement compared to marketed products, including non-drug products and/or therapies, in the treatment, diagnosis, or prevention of a disease. A Center for Biologics Evaluation and Research (CBER) product will qualify for a priority review if FDA determines that the product, if approved, would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious or life-threatening disease. FDA has committed to a goal to review and act on 90 percent of the applications that have been granted priority review status no later than 6 months after receipt. An application that does not receive a priority designation will receive a standard review. Under the goals identified in the letters referenced in section 101(b) of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), FDA commits to reviewing and acting on 90 percent of standard applications within 10 months of the date of receipt. A priority review involves a more intensive level of effort and a higher level of resources than a standard review.

Section 524 of the FD&C Act specifies that the fee amount should be based on the average cost incurred by the Agency for a priority review in the previous FY. 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 and kept. FDA started by using 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 does publish each year are: (1) New drug applications (NDAs) for a new molecular entity (NME) with clinical data and (2) biologics license applications (BLAs).

The worksheets for standard costs for FY 2011, the latest year for which standard cost data are available, show a standard cost (rounded to the nearest thousand dollars) of $5,092,000 for a new molecular entity NDA and $11,203,000 for a BLA. Based on these standard costs, the total cost to review the 46 applications in these two categories in FY 2011 (10 BLAs and 36 NDAs with clinical data) was $295,342,000. (**Note:** no investigational new drug (IND) review costs are included in this amount.) Records acquired from CDER and CBER by the Office of Policy and Planning (OPP), Economics Staff, indicate that a total of 16 of these applications (12 NDAs [excluding the President's Emergency Plan for AIDS Relief NDAs] and 4 BLAs) received priority review, which would mean that the remaining 30 received standard reviews. Because a priority review compresses a review that ordinarily takes 10 months into 6 months, OPP 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. In the article ''Developing Drugs for Developing Countries,'' published in *Health Affairs,* Volume 25, Number 2, in 2006, the comparison of historical average review times by David B. Ridley, Henry G. Grabowski, and Jeffrey L. Moe supports a priority review multiplier in the range of 1.48 to 2.35. The multiplier derived by FDA falls well below the mid-point of this range. Using FY 2011 figures, the costs of a priority and standard review are estimated using the following formula:

$$(16\,\alpha * 1.67) + (30\,\alpha) = \$295{,}342{,}000$$

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 NMEs is calculated to be $5,207,000 (rounded to the nearest thousand dollars) and the cost of a priority review for NMEs is 1.67 times that amount, or $8,696,000 (rounded to the nearest thousand dollars). The difference between these two cost estimates, or $3,489,000, represents the incremental cost of conducting a priority review rather than a standard review.

Section 524 of the FD&C Act specifies that the fee amount should be based on the average cost incurred by the Agency for a priority review in the previous FY. FDA is setting fees for FY 2013, and the previous fiscal year is FY 2012. However, the FY 2012 submission cohort has not been closed out yet, and the cost data for FY 2012 are not complete. The latest year for which FDA has complete cost data is FY 2011. Accordingly, FDA will adjust the FY 2011 incremental cost figure above by the average amount by which FDA's average salary and benefit costs increased in the 3 years prior to FY 2012, to adjust the FY 2011 amount for cost increases in FY 2012. That figure, published in the **Federal Register** notice on August 1, 2012 setting PDUFA fees for FY 2013, is 2.01 percent. Increasing the FY 2011 incremental priority review cost figure of $3,489,000 by 2.01 percent results in an estimated cost of $3,559,000 (rounded to the nearest thousand dollars). This is the priority review user fee amount for FY 2013 that must be submitted with a priority review voucher in FY 2013, in addition to any PDUFA fee that is required for such an application.

III. Priority Review Fee Schedule for FY 2013

The fee rate for FY 2013 is set out in Table 1 of this document:

TABLE 1—PRIORITY REVIEW SCHEDULE FOR FY 2013

Fee category	Fee rate for FY 2013
Applications Submitted With a Priority Review Voucher in Addition to the Normal PDUFA Fee	$3,559,000

IV. Implementation of Priority Review Fee

Under section 524(c)(4)(A) of the FD&C Act, the priority review user fee is due upon submission of the application for which the priority review voucher is used. Section 524(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. FDA may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section of the FD&C Act, and FDA may not collect priority review voucher fees prior to a relevant appropriation for fees for that FY. Beginning with FDA's appropriation for FY 2009, the annual appropriation language states specifically that ''priority review user fees authorized by 21 U.S.C. 360n (section 524 of the FD&C Act) may be credited to this account, to remain available until expended.'' (Pub. L. 111–8, Section 5, Division A, Title VI).

The priority review fee established in the new fee schedule must be paid for any application that is received after September 30, 2012, and submitted with a priority review voucher. This fee must be paid in addition to any other fee due under PDUFA. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. The user fee identification (ID) number should be included on the check, followed by the words ''Priority Review.'' Payments can be 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.) The FDA post office box number (P.O. Box 979107) must be written on the check. The tax identification number of the Food and Drug Administration is 53–0196965.

Wire transfer payments may also be used. 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 fee and include it with your payment to ensure that your fee is fully paid. The account information is as follows: New York Federal Reserve Bank, U.S. Dept. of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 1350 Piccard Dr., Rockville, MD 20850.

Dated: August 30, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Food and Drug Administration/ American Glaucoma Society Workshop on the Validity, Reliability, and Usability of Glaucoma Imaging Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a