DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0007]

Fee for Using a Tropical Disease Priority Review Voucher in Fiscal Year 2015

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) 2015. 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 tropical disease 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 submitted to FDA with applications using a tropical disease 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 tropical disease priority review fee rate for FY 2015.

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 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 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) of the FD&C Act), shall receive a priority review voucher upon approval of the tropical disease product application. 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 of the Public Health Service Act (42 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 after the filing date.

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 a draft guidance on its Web site about how this tropical disease priority review voucher program operates (available at: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

This notice establishes the tropical disease priority review fee rate for FY 2015 as $2,562,000 and outlines FDA's process for implementing the collection of the priority review user fees. This rate is effective on October 1, 2014, and will remain in effect through September 30, 2015, 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 2015

Under section 524(c)(2) of the FD&C Act, the amount of the tropical disease priority review user fee 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. 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 provides 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 after the filing date. Normally, an application for a Center for Drug Evaluation and Research product will qualify for a priority review if FDA determines that the product, if approved, provides a safe and effective therapy where no satisfactory alternative therapy exists or is 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 product will qualify for a priority review if FDA determines that the product, if approved, is a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious or life-threatening disease. FDA committed to review and act on 90 percent of the applications granted priority review status no later than 6 months after the filing date. 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 filing. 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 in the review of a human drug application subject to a priority review in the previous FY. FDA is setting fees for FY 2015, and the previous fiscal year is FY 2014. However, the FY 2014 submission cohort has not been closed out yet, and the cost data for FY 2014 are not complete. The latest year for which FDA has complete cost data is FY 2013. 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 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 2013, the latest year for which standard cost data are available, show a

standard cost (rounded to the nearest thousand dollars) of $5,122,000 for a NME NDA and $4,090,000 for a BLA. Based on these standard costs, the total cost to review the 53 applications in these two categories in FY 2013 (31 NME NDAs with clinical data and 22 BLAs) was $248,762,000. (Note: These numbers exclude the President's Emergency Plan for AIDS Relief NDAs; no investigational new drug review costs are included in this amount.) Twenty of these applications (12 NDAs and 8 BLAs) received priority review, which would mean that the remaining 33 received standard reviews. Because a priority review compresses a review 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. 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 midpoint of this range. Using FY 2013 figures, the costs of a priority and standard review are estimated using the following formula:

$(20\ \alpha \times 1.67) + (33\ \alpha) = \$248{,}762{,}000$

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 NME NDAs and BLAs is calculated to be $3,746,000 (rounded to the nearest thousand dollars) and the cost of a priority review for NME NDAs and BLAs is 1.67 times that amount, or $6,256,000 (rounded to the nearest thousand dollars). The difference between these two cost estimates, or $2,510,000, represents the incremental cost of conducting a priority review rather than a standard review.

For FY 2015 fee, FDA will need to adjust the FY 2013 incremental cost by the average amount by which FDA's average costs increased in the 3 years prior to FY 2014, to adjust the FY 2013 amount for cost increases in FY 2014. That adjustment, published in the **Federal Register** on August 1, 2014 (see 79 FR 44807 at 44809), setting FY 2015 PDUFA fees, is 2.0813 percent for the most recent year, not compounded. Increasing the FY 2013 incremental priority review cost of $2,510,000 by 2.0813 percent results in an estimated cost of $2,562,000 (rounded to the nearest thousand dollars). This is the priority review user fee amount for FY 2015 that must be submitted with a priority review voucher in FY 2015, in addition to any PDUFA fee that is required for such an application.

III. Priority Review Fee Schedule for FY 2015

The fee rate for FY 2015 is set out in table 1:

TABLE 1—TROPICAL DISEASE PRIORITY REVIEW SCHEDULE FOR FY 2015

Fee category	Fee rate for FY 2015
Application submitted with a priority review voucher in addition to the normal PDUFA Fee	$2,562,000

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 a human drug 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. In addition, 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 on or after October 1, 2014, 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 FDA 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, Account Number: 75060099, Routing Number: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., Silver Spring, MD 20993–0002.

Dated: August 22, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1167]

Draft Guidance for Industry on Controlled Correspondence Related to Generic Drug Development; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Controlled