clinical data) was $224,352,000. (Note: no investigational new drug (IND) review costs are included in this amount.) A total of 18 of these applications (12 NDAs [excluding the President's Emergency Plan for Aids Relief NDAs] and 6 BLAs) received priority review, which would mean that the remaining 36 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 2012 figures, the costs of a priority and standard review are estimated using the following formula: $(18\ \alpha \times 1.67) + (36\ \alpha) = \$224{,}352{,}000$ 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 $3,396,000 (rounded to the nearest thousand dollars) and the cost of a priority review for NMEs is 1.67 times that amount, or $5,671,000 (rounded to the nearest thousand dollars). The difference between these two cost estimates, or $2,275,000, 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 2014, and the previous fiscal year is FY 2013. However, the FY 2013 submission cohort has not been closed out yet, and the cost data for FY 2013 are not complete. The latest year for which FDA has complete cost data is FY 2012, so that must be adjusted for inflation in order to estimate the FY 2013 cost. Accordingly, FDA will adjust the FY 2012 incremental cost figure by the average amount by which FDA's average costs increased in the 3 years prior to FY 2013, to adjust the FY 2012 amount for cost increases in FY 2013. That figure, published in the **Federal Register** notice on August 2, 2013 (see 78 FR 46980 at 46982), setting PDUFA fees for FY 2014, is 2.20 percent. Increasing the FY 2012 incremental priority review cost figure of $2,275,000 by 2.20 percent results in an estimated cost of $2,325,000 (rounded to the nearest thousand dollars). This is the priority review user fee amount for FY 2014 that must be submitted with a priority review voucher in FY 2014, in addition to any PDUFA fee that is required for such an application.

III. Priority Review Fee Schedule for FY 2014

The fee rate for FY 2014 is set out in Table 1 of this document:

TABLE 1—PRIORITY REVIEW SCHEDULE FOR FY 2014

Fee category	Fee rate for FY 2014
Applications Submitted with a Priority Review Voucher in Addition to the Normal PDUFA Fee	$2,325,000

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, 2013, 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, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 1350 Piccard Dr., Rockville, MD 20850.

Dated: August 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–21542 Filed 9–4–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0350]

Guidance for Tobacco Retailers on Tobacco Retailer Training Programs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for tobacco retailers entitled ''Tobacco Retailer Training Programs.'' The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) does not require retailers to implement retailer training programs. However, the Tobacco Control Act does provide for lower civil money penalties for violations of sale and distribution, including youth access, advertising, and promotion restrictions issued under the Federal Food, Drug, and Cosmetic Act

(the FD&C Act), as amended by the Tobacco Control Act, for retailers who have implemented a training program that complies with standards developed by FDA for such programs. FDA intends to issue regulations establishing standards for approved retailer training programs. In the interim, this guidance document is intended to assist tobacco retailers who wish to implement training programs for employees.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beth Buckler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 1–877–287–1373, *beth.buckler@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for tobacco retailers entitled ''Tobacco Retailer Training Programs.'' This guidance document is intended to assist tobacco retailers who wish to implement training programs for employees.

On June 22, 2009, the President signed the Tobacco Control Act (Pub. L. 111–31; 123 Stat. 1776) into law. The Tobacco Control Act grants FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Among its many provisions, section 906(d) of the FD&C Act (21 U.S.C. 387f(d)), as amended by the Tobacco Control Act, states that ''[t]he Secretary may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health.''

In accordance with section 102 of the Tobacco Control Act (21 U.S.C. 387a-1), FDA re-issued its 1996 final regulation restricting the sale and distribution of cigarettes and smokeless tobacco products (75 FR 13225, March 19, 2010). The regulation is deemed to be issued under chapter 9 of the FD&C Act, as amended by the Tobacco Control Act (section 102(a)(1)(A) of the Tobacco Control Act). The regulation contains provisions designed to limit young people's access to cigarettes and smokeless tobacco products, as well as restrictions on advertising and promotion of such products, to curb the appeal of these products to minors (part 1140 (21 CFR part 1140)).

Section 103(q)(2) of the Tobacco Control Act (21 U.S.C. 333 note) includes two schedules for assessing the maximum civil money penalties against retailers for violations of restrictions issued under section 906(d) of the FD&C Act, as amended by the Tobacco Control Act, pertaining to the sale and distribution, including youth access, and advertising and promotion of tobacco products. Under each schedule, violators are subject to increasing penalties for multiple violations within prescribed time periods. For the first three violations in a 24-month period, retailers with an approved training program are subject to lower penalties than retailers without such programs. Section 103(q)(2)(B) defines ''approved training program'' as a training program that complies with standards developed by FDA for such programs.

FDA intends to issue regulations establishing standards for approved retailer training programs. In the interim, however, FDA is issuing this guidance to provide recommendations on elements the Agency believes should be included in a retailer training program. Until FDA issues these regulations, the Agency intends to use the lower maximum civil money penalties schedule for all retailers who violate the regulations restricting the sale and distribution of cigarettes and smokeless tobacco products (part 1140), whether or not they have implemented a training program. However, FDA may consider further reducing the civil money penalty for retailers who have implemented a training program.

In the **Federal Register** of July 16, 2010 (75 FR 41498), FDA announced the availability of a draft guidance entitled ''Tobacco Retailer Training Programs.'' The Agency considered received comments as it finalized this guidance. In addition, editorial changes were made to improve clarity.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on tobacco retailer training programs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov*. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0745.

V. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm*.

Dated: August 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Allergenic Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.