DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1502]

Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket for comment on the Agency's blood donor deferral recommendations for reducing the risk of human immunodeficiency virus (HIV) transmission as described in the document entitled ''Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry'' dated December 2015. Interested persons are invited to submit comments, supported by scientific evidence such as data from research, regarding potential blood donor deferral policy options to reduce the risk of HIV transmission, including the feasibility of moving from the existing time-based deferrals related to risk behaviors to alternate deferral options, such as the use of individual risk assessments. Additionally, comments are invited regarding the design of potential studies to evaluate the feasibility and effectiveness of such alternative deferral options. FDA will take the comments received into account as it continues to reevaluate and update blood donor deferral policies as new scientific information becomes available.

DATES: Submit either electronic or written comments by November 25, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, 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–2016–N–1502 for ''Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Establishment of Public Docket; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jonathan McKnight, 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: In the **Federal Register** of December 23, 2015 (80 FR 79913), FDA announced the availability of the guidance entitled ''Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry'' dated December 2015 (December 2015 guidance) *http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM446580.pdf.*

The December 2015 guidance updates blood donor deferral recommendations to reflect the most current scientific evidence. The recommendations also help ensure continued safety of the blood supply by reducing the risk of HIV transmission by blood and blood products. As part of the updated blood donor deferral recommendations in the December 2015 guidance, FDA changed the recommendation for an indefinite deferral period for men who have sex with men (MSM) to a deferral period of 12 months since the last sexual contact with another man. The updated recommendations better align the deferral period for MSM with the

deferral period for other men and women at increased risk for HIV infection, such as those who had a recent blood transfusion or who have been accidentally exposed to the blood of another individual through a needle stick. In reviewing the Agency's recommendations to reduce the risk of HIV transmission through blood and blood products, FDA rigorously examined several alternative options, including individual risk assessment. Ultimately, FDA concluded that the 12-month deferral period is supported by the best available scientific evidence, at this point in time, relevant to the U.S. population.

As described in the December 2015 guidance, throughout the process of comprehensively updating blood donor deferral policies, FDA has worked with other government Agencies, considered input from external advisory committees, reviewed comments from stakeholders to the draft guidance of the same title (80 FR 27973, May 15, 2015), and carefully examined the most recent available scientific evidence. FDA also has implemented a nationally representative transfusion-transmissible infections monitoring system for the U.S. blood supply with assistance from the National Heart, Lung, and Blood Institute at the National Institutes of Health. This system provides critical information to help inform future actions that FDA may take on blood donor policies.

When FDA issued the December 2015 guidance, it noted that while the December 2015 guidance represents FDA's current thinking on the subject, FDA was committed to continuing to reevaluate and update blood donor deferral policies as new scientific information becomes available. FDA also noted that, because the process must be data-driven, FDA could not specify a time for when future policy changes might occur.

As part of the effort to continue to assess its donor deferral policies, FDA is opening this docket to provide a mechanism for the public to submit additional information regarding potential blood donor deferral policy options. Specifically, we invite interested persons to submit to the docket comments supported by scientific evidence regarding possible revisions to FDA's blood donor deferral policies to reduce the risk of HIV transmission by blood and blood products. FDA requests that commenters provide scientific evidence, such as data from research, to support any suggestions. Additionally, comments are invited regarding the design of potential studies to evaluate the feasibility or effectiveness of such alternative deferral policy options.

FDA recognizes that many stakeholders have expressed the desire to move from a time-based deferral period to a deferral policy based on individual risk assessment. An individual risk assessment would involve asking potential donors a series of questions designed to defer donors with high risk behaviors. In particular, we invite commenters to address the following and provide supporting scientific evidence such as data from research:

1. What questions would most effectively identify individuals at risk of transmitting HIV through blood donation?
2. Are there specific questions that could be asked that might best capture the recent risk of a donor acquiring HIV infection, such as within the 2 to 4 weeks immediately preceding blood donation?
3. How specific can the questions be regarding sexual practices while remaining understandable and acceptable to all blood donors? For example, could questions about specific sexual behaviors be asked if they helped to identify which donors should be at least temporarily deferred because of risk factors? To the extent the questions are explicit about sexual practices, how willing will donors be to answer such questions accurately?
4. Under what circumstances would a short deferral period for high risk behavior be appropriate? For each short deferral period identified, please specify the duration of the deferral and provide the scientific rationale.
5. What changes might be necessary within blood collection establishments to assure that accurate, individual HIV risk assessments are performed?
6. How best to design a potential study to evaluate the feasibility and effectiveness of alternative deferral options such as individual risk assessment?

FDA will consider comments and supporting scientific data received as it continues to reevaluate and update blood donor deferral policies as new scientific information becomes available.

Dated: July 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0007]

Prescription Drug User Fee Rates for Fiscal Year 2017

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2017. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2012 (PDUFA V), authorizes FDA to collect user fees for certain applications for the review of human drug and biological products, on establishments where the products are made, and on such products. This notice establishes the fee rates for FY 2017.

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

Sections 735 and 736 of the FD&C Act (21 U.S.C. 379g and 379h, respectively) establish three different kinds of user fees. Fees are assessed on the following: (1) Certain types of applications and supplements for the review of human drug and biological products; (2) certain establishments where such products are made; and (3) certain products (section 736(a) of the FD&C Act). When certain conditions are met, FDA may waive or reduce fees (section 736(d) of the FD&C Act).

For FY 2013 through FY 2017, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA V. The base revenue amount for FY 2013, which became the base amount for the remaining four FYs of PDUFA V, is $718,669,000, as published in the **Federal Register** of August 1, 2012 (77 FR 45639). The FY 2013 base revenue amount is further adjusted each year after FY 2013 for inflation and workload. For FY 2017, fee revenue and fees may be further adjusted by the final year adjustment. In addition, for FY 2017, excess collections are offset as required by the FD&C Act. Fees for applications, establishments, and products are to be established each year