administrative supplement requests, change of organization requests, and change of grantee/training institution requests submitted September 25, 2013 and beyond. Multi-project applications that are transitioning to electronic submission beginning with the September 25, 2013 due dates (see the NIH Guide Notice *NOT–OD–13–075*) will also use FORMS–C packages.

Exceptions

The programs noted below will move to FORMS–C application packages as follows:

- Individual Research Career Development Award Programs (Ks), Institutional Training and Career Development Programs (Ts and Ds) and Individual National Research Service Awards (Fs) applicants will be required to use FORMS–C packages for due dates on or after January 25, 2014.
- Small Business programs (SBIR/STTR) applicants will transition to FORMS–C packages later in 2014, so that anticipated form changes relating to the Small Business Authorization Act can be incorporated.

Instructions

- If presented with more than one forms package, applicants should download and use the most recent set of forms to complete their submission.
- Verify you have the correct application package by checking the Competition ID field for FORMS–C. The Competition ID field can be found when downloading the application package from Grants.gov, in the application header information of the downloaded package or in FOA summary information for multi-project applications.
- Learn more about choosing the correct forms packages at: *http://grants.nih.gov/grants/ElectronicReceipt/files/right_forms.pdf.*
- All applicants should carefully read their FOA and the appropriate ''C Series'' Application Guide for program-specific instructions before completing their application.

Inquiries

Please direct all inquiries to: Technical Information Management Section, Procurement and Grants Office, Centers for Disease Control and Prevention, Telephone: 770–488–2700, Email: *pgotim@cdc.gov.*

Dated: July 26, 2013.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–18608 Filed 8–1–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0536]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Medical Device User Fee Cover Sheet, Form FDA 3601

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Device User Fee Cover Sheet, Form FDA 3601'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On February 8, 2013, the Agency submitted a proposed collection of information entitled ''Medical Device User Fee Cover Sheet, Form FDA 3601'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0511. The approval expires on April 30, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: July 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–18638 Filed 8–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0868]

Agency Information Collection Activities; Proposed Collection; Comment Request; Draft Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Whole Blood and Blood Components for Transfusion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments concerning establishment notification of a consignee and consignee notification of a recipient's physician of record regarding a possible increased risk of *Trypanosoma cruzi (T. cruzi)* infection.

DATES: Submit either electronic or written comments on the collection of information by October 1, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests

or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry: Use of Serological Tests To Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components for Transfusion—(OMB Control Number 0910–0681)—Extension

The guidance implements the donor screening recommendations for the FDA-approved serological test systems for the detection of antibodies to *T. cruzi.* The use of the donor screening tests are to reduce the risk of transmission of *T. cruzi* infection by detecting antibodies to *T. cruzi* in plasma and serum samples from individual human donors, including donors of Whole Blood and Blood Components intended for transfusion. The guidance recommends that establishments that manufacture Whole Blood and Blood Components intended for transfusion should notify consignees of all previously collected in-date blood and blood components to quarantine and return the blood components to establishments or to destroy them within three calendar days after a donor tests repeatedly reactive by a licensed test for *T. cruzi* antibody. When establishments identify a donor who is repeatedly reactive by a licensed test for *T. cruzi* antibodies and for whom there is additional information indicating risk of *T. cruzi* infection, such as testing positive on a licensed supplemental test (when such test is available) or until such test is available, information that the donor or donor's mother resided in an area endemic for Chagas disease (Mexico, Central and South America) or as a result of other medical diagnostic testing of the donor indicating *T. cruzi* infection, we recommend that the establishment notify consignees of all previously distributed blood and blood components collected during the ''lookback'' period and, if blood and blood components were transfused, encourage consignees to notify the recipient's physician of record of a possible increased risk of *T. cruzi* infection.

Respondents to this information collection are establishments that manufacture Whole Blood and Blood Components intended for transfusion. We believe that the information collection provisions in the guidance for establishments to notify consignees and for consignees to notify the recipient's physician of record do not create a new burden for respondents and are part of usual and customary business practices. Since the end of January 2007, a number of blood centers representing a large proportion of U.S. blood collections have been testing donors using a licensed assay. We believe these establishments have already developed standard operating procedures for notifying consignees and the consignees to notify the recipient's physician of record.

The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 606.100, 606.121, 606.122, 606.160(b)(ix), 606.170(b), 610.40, and 630.6 have been approved under OMB control number 0910–0116; the collections of information in 21 CFR 606.171 have been approved under OMB control number 0910–0458.

Dated: July 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–18573 Filed 8–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0007]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2014

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates and payment procedures for fiscal year (FY) 2014 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Animal Drug User Fee Amendments of 2013, which was signed by the President on June 13, 2013 (ADUFA III), authorizes FDA to collect user fees for certain animal drug applications and supplements, for certain animal drug products, for certain establishments where such products are made, and for certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2014.

FOR FURTHER INFORMATION CONTACT: Visit FDA's Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm* or contact Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7529 Standish Pl., Rockville, MD 20855, 240–276–9718. For general questions, you may also email the Center for Veterinary Medicine (CVM) at: *cvmadufa@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 740 of the FD&C Act (21 U.S.C. 379j–12) establishes four different types of user fees: (1) Fees for certain types of animal drug applications and supplements; (2) annual fees for certain animal drug products; (3) annual fees for certain establishments where such products are made; and (4) annual fees for certain sponsors of animal drug applications and/or investigational animal drug submissions (21 U.S.C. 379j–12(a)). When certain conditions are met, FDA will waive or reduce fees (21 U.S.C. 379j–12(d)).

For FY 2014 through FY 2018, the FD&C Act establishes aggregate yearly base revenue amounts for each fiscal year (21 U.S.C. 379j–12(b)(1)). Base revenue amounts established for years after FY 2014 are subject to adjustment