DATES: Submit a written or electronic request for participation in this program by April 27, 2009. You should include the following information in your request: contact name, contact phone number, e-mail address, name of the establishment, address, and license number (if applicable).

ADDRESSES: If you are interested in participating in this program, you should submit a request to participate in the program to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic requests to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Lore Fields, Center for Biologics Evaluation and Research (HFM–375), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6143, Fax: 301–827–3534, or e-mail: *lore.fields@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

CBER regulates certain biological products, including blood and blood products, and is committed to advancing the public health through innovative activities that help ensure the safety, effectiveness and timely delivery of these products to patients. Further, CBER seeks to continuously enhance and update review efficiency and quality, and the quality of its regulatory efforts and interactions, by providing CBER staff and industry with improved processes. In support of this goal, CBER has participated in the FDA development of a computer-assisted automated BLA/BLS submission program called eSubmitter to improve the process for providing certain regulatory submissions to FDA. The eSubmitter will include programs to submit applications for licensure, supplements to an approved license, and amendments to pending applications or supplements.

II. The eSubmitter Pilot Evaluation Program Expectations

The eSubmitter pilot evaluation program is expected to last approximately 6 months. During this period of time, participants will complete BLA/BLS regulatory submissions using the eSubmitter template developed at CBER for use by Source Plasma establishments. The eSubmitter was developed using the same review criteria for applications for these products as currently used in the BLA/BLS review process at CBER. During the BLA/BLS submission process, the participants will enter the requested information into the eSubmitter tool and attach requested documents as an Adobe document (pdf format). This information will be saved onto a CD–ROM and mailed to CBER for review. Paper copies of submissions will not be required. CBER will review the information provided on the CD–ROM and the attachments according to current managed review procedures.

During the BLA/BLS submission process, CBER staff will be available to answer any questions or concerns that may arise. As each submission is completed, the users will be asked to comment on the eSubmitter program. These discussions will assist CBER in the final development and release of this electronic tool for use by industry.

III. Requests for Participation

Requests to participate in the eSubmitter pilot are to be identified with the docket number found in brackets in the heading of this document. Once requests for participation are received, FDA will contact interested establishments to discuss the pilot program.

Dated: March 20, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–6687 Filed 3–25–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0137]

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 and Human Cells, Tissues, and Cellular and Tissue-Based Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''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 and Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' dated March 2009. The draft guidance document notifies establishments that manufacture Whole Blood and blood components intended for use in transfusion, and establishments that make eligibility determinations for donors of HCT/Ps about FDA approval of a biologics license application for an enzyme-linked immunosorbent assay (ELISA) test system for the detection of antibodies to *Trypanosoma cruzi* (*T. cruzi*). The draft guidance also notifies establishments that make donor eligibility determinations for HCT/P donors that FDA has determined *T. cruzi* to be a relevant communicable disease under current regulations. In addition, the guidance provides recommendations for using a licensed test for antibodies to *T. cruzi* to test individual human donors, including donors of Whole Blood and blood components for transfusion and HCT/P donors (living and cadaveric (non-heart beating)), for antibodies to *T. cruzi* in plasma and serum samples. The guidance document does not apply to Source Plasma.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by June 24, 2009. Submit written comments on the information collection burden by May 26, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''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 and Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' dated March 2009. The draft guidance document notifies establishments that manufacture Whole Blood and blood components intended for use in transfusion, and establishments that make eligibility determinations for donors of HCT/Ps about FDA approval of a biologics license application for an ELISA test system for the detection of antibodies to *T. cruzi*. The test is intended for use as a donor screening test 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, and HCT/P donors.

In addition, FDA is providing establishments that manufacture Whole Blood and blood components intended for use in transfusion with recommendations for unit and donor management, labeling of Whole Blood and blood components, and procedures for reporting implementation of a licensed *T. cruzi* test at their facilities or contract testing laboratories, as required for blood establishments under title 21 of the Code of Federal Regulations (CFR) § 601.12 (21 CFR 601.12). FDA is notifying establishments that make donor eligibility determinations for HCT/P donors, that it has determined *T. cruzi* to be a relevant communicable disease under 21 CFR 1271.3(r)(2), and is providing them with recommendations for screening and antibody testing of HCT/P donors.

The guidance document applies to Whole Blood and blood components intended for transfusion and donors of HCT/Ps. The guidance document does not apply to Source Plasma. The recommendations made in the guidance with respect to HCT/Ps are in addition to recommendations made in the document entitled ''Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' dated August 2007.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The draft guidance document contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). Under the PRA, Federal agencies must obtain approval from 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 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 comment 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 on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 and Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)

The draft guidance would implement the FDA approved donor screening ELISA test system for the detection of antibodies to *T. cruzi*. The use of the donor screening test is 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 use in transfusion. The draft guidance recommends establishments that manufacture Whole Blood and blood components intended for use in transfusion to 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 3 calendar days after a donor tests repeatedly reactive by a licensed test for *T. cruzi* antibody. The draft guidance also recommends that 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 geographical risk for exposure in an endemic area, or medical diagnostic testing of the donor, the establishment notify consignees of all previously distributed blood and blood components collected during the lookback period and, if blood or blood components were transfused, encourage consignees to notify the recipient's physician of record of a possible increased risk of *T. cruzi* infection.

Description of Respondents: The reporting recommendations described in the draft guidance affect establishments that manufacture Whole Blood and blood components intended for use in transfusion.

Burden Estimate: We believe that the information collection provisions for consignee notification and consignees to notify the recipient's physician in the draft guidance do not create a new burden for respondents and are part of usual and customary business practice. 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 this licensed assay. We believe these establishments have already developed standard operating procedures for notifying consignees and the consignees to notify the recipient's physician.

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in § 601.12 have been approved under OMB control no. 0910–0338; the collections of information in 21 CFR 606.100, 606.121, 606.122, 606.160(b)(ix), 606.170(b), and 630.6 have been approved under OMB control no. 0910–0116; the collections of information in 21 CFR 606.171 have been approved under OMB control no. 0910–0458.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. We recognize that recent

scientific information obtained from screening of donors may affect the recommendations for implementation in the guidance. In particular, we welcome comments on potential strategies for selective donor testing for *T. cruzi* infection. Also, we recognize that lookback studies conducted using the licensed ELISA test suggest that the risk of transmission of this agent by transfusion of a seropositive unit in the United States may be much lower than previously thought, and we welcome comments in that regard. Additionally, we encourage you to submit comments to the docket regarding the value of performing recipient notification on prior collections from a donor who is repeatedly reactive on a currently licensed *T. cruzi* antibody test, and a prior collection had a licensed test result with a signal to cutoff ratio greater than 0.75 (i.e., a grey zone result), but for whom there may not be additional information indicating risk of infection.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.regulations.gov*.

Dated: March 20, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–6684 Filed 3–25–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0149]

Agency Emergency Processing Under Office of Management and Budget Review; Guidance for Industry: Animal Generic Drug User Fees and Fee Waivers and Reductions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns the burden hours required to implement the new statutory requirements for the user fees and fee waivers reductions provisions of the Animal Generic Drug User Fee Act of 2008 (AGDUFA) (Federal Food, Drug, and Cosmetic Act (the act)).

DATES: Fax written comments on the collection of information provisions by March 31, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title ''Guidance for Industry: Animal Generic Drug Fees and Fee Waivers Reduction; Emergency Request.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA–710); Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857, 301–796–3793.

SUPPLEMENTARY INFORMATION: FDA is requesting emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). Section 741(d) of the act (21 U.S.C. 379k(d)), as amended by AGDUFA, authorizes FDA to collect user fees for certain: (1) Abbreviated applications for generic new animal drugs, (2) new animal drug products, and (3) sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions of new animal drugs. However, AGDUFA also provides FDA with the authorization to grant a waiver from or a reduction of those fees in certain circumstances. To provide guidance, FDA has developed the guidance entitled ''Animal Generic Drug User Fees and Fee Waivers and Reductions,'' which is crucial to firms understanding whether they might qualify for the waiver or reduction, and if so, how to apply for it.

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: Animal Generic Drug User Fees and Fee Waivers and Reductions (Section 741(d) of the Federal Food, Drug, and Cosmetic Act); Emergency Request

AGDUFA requires FDA to collect user fees for certain: (1) Abbreviated applications for a generic new animal drug, (2) generic new animal drug products, and (3) sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. AGDUFA also contains a specific provision under which a fee waiver or reduction may be requested for any or all of these fees. The type of fee waiver and reduction requests to be submitted is: Minor Use or Minor Species. FDA seeks OMB approval for this summary of information required for a fee waiver or reduction request.

Respondents to the proposed collection of information will likely be private industry. Requests for a waiver or reduction may be submitted by a person paying any of the generic new animal drug user fees assessed—application fees, product fees, or sponsor fees.

FDA estimates the burden of this collection of information as follows: