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may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance.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 A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.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Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.regulations.gov*.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:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section 741(d) of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
741(d)—Minor Use or Minor Species Fee Waiver & Reduction Requests	9	1	9	2	18
Request for Reconsideration; CVM AGDUFA Waiver Officer[2]	1	1	1	1	1
Request for Review; CVM AGDUFA Appeals Officer	1	1	1	1	1
Request for Review; FDA User Fee Appeals Officer	1	1	1	1	1
Total					21

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] CVM means Center for Veterinary Medicine.

Appeals for reconsideration or review of AGDUFA user fee waiver decisions will be very rare. Waivers are granted only for user fees involving minor use or minor species as defined by the Minor Use and Minor Species Act of 2008 (MUMS). Decisions on waivers of user fees based on minor species do not allow for agency discretion as ''minor species'' is defined specifically in the MUMS statute. As to minor use in a major species, FDA, under MUMS, determines that a new animal drug is for minor use in a major species at the time that the pioneer new animal drug application is submitted. This determination carries over to the abbreviated (generic) new animal drug application. Therefore, we do not anticipate that there will be more than one request for review or reconsideration for either the ''minor use'' or ''minor species'' waivers or reductions under AGDUFA per year.

Fee Waiver or Reduction Requests: For those who, after reading the guidance, decide to apply for a waiver or reduction of one or more of the fees they were assessed, the time to complete the information required for their waiver application, based on the guidance provided, is estimated to be 2 hours or less.

Based on FDA's database system, there are an estimated 50 sponsors of products subject to AGDUFA. However, not all sponsors will have submissions in a given year. CVM estimates nine waiver requests that include minor use or minor species. The estimated hours per response are based on past FDA experience with the various waiver requests in CVM. The hours per response listed in table 1 of this document are based on the average of these estimates.

Dated: March 19, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–6724 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–0664]

Joint Meeting of the Pediatric Advisory Committee and the Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Advisory Committee and Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on Monday, April 27, 2009, from 8 a.m. to 6 p.m.

Addresses: Washington DC North/Gaithersburg Hilton, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Carlos Peña, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane (for express delivery, rm. 14B–08), Rockville, MD 20857, 301–827–3340, or by e-mail: *carlos.peña@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On Monday, April 27, 2009, the Pediatric Advisory Committee and the Oncologic Drugs Advisory Committee will meet to discuss the scientific and ethical issues involved in obtaining and using brain biopsy specimens to evaluate gene expression patterns in children with diffuse pontine gliomas.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2009 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 13, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief