on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

User Fee Cover Sheet; Form FDA 3397 (OMB Control Number 0910–0297)—Extension

Under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g and 379h), the Prescription Drug User Fee Act of 1992 (PDUFA) (Public Law 102–571), as amended by the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), and the Prescription Drug User Fee Amendments of 2002 (Public Law 107–188), FDA has the authority to assess and collect user fees for certain drug and biologics license applications and supplements. Under this authority, pharmaceutical companies pay a fee for certain new human drug applications, biologics license applications, or supplements submitted to the agency for review. Because the submission of user fees concurrently with applications and supplements is required, review of an application by FDA cannot begin until the fee is submitted. Form FDA 3397, the user fee cover sheet, is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fee submitted for an application with the actual application by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new drug applications, biologics license applications, and supplemental applications.

Respondents to this collection of information are new drug and biologics manufacturers. Based on FDA's database system for fiscal year (FY) 2002, there are an estimated 225 manufacturers of products subject to PDUFA. However, not all manufacturers will have any submissions and some may have multiple submissions in a given year. The total number of annual responses is based on the average number of submissions received by FDA in FY 2000 through 2002. CDER estimates 2,494 annual responses that include the following submissions: 105 new drug applications; 1,557 chemistry supplements; 670 labeling supplements; and 162 efficacy supplements. CBER estimates 737 annual responses that include the following submissions: 11 biologics license applications; 640 manufacturing (chemistry) supplements; 72 labeling supplements; and 14 efficacy supplements. Based on previous estimates, the rate of submissions is not expected to change significantly in the next few years. The estimated hours per response are based on past FDA experience with the various submissions and range from 5 to 30 minutes. The hours per response are based on the average of these estimates.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3397	225	14.36	3,231	0.30	969

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 24, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–16791 Filed 7–2–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0080]

Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires'' dated July 2003. The guidance document provides guidance to blood and plasma establishments on the recommendations of FDA for implementing self-administered donor questionnaires at the predonation donor screening interview. The guidance document also describes the information to be included in a biologics license application supplement or annual report for the implemented changes. The guidance supersedes section I.A of FDA's memorandum dated April 23, 1992, entitled ''Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products,'' and finalizes the draft guidance of the same title dated April 2002.

DATES: Submit written or electronic comments on agency guidances at any time.

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

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. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Michael D. Anderson, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for industry: Streamlining the Donor Interview Process: Recommendations

for Self-Administered Questionnaires,'' dated July 2003. The guidance is intended to provide recommendations to the blood and plasma establishments on the changes from the current predonation donor screening interview procedure to a self-administered format. The guidance also describes the information to be included in a biologics license application supplement or annual report for the implemented changes. The guidance does not address the informed consent process or specific screening questions, a specific questionnaire, or how to submit changes to the questions on a currently approved questionnaire. The guidance supersedes section I.A of FDA's memorandum dated April 23, 1992, entitled ''Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products,'' and finalizes the draft guidance of the same title dated April 2002.

The 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 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. Comments

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this 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 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.

III. Electronic Access

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

Dated: June 24, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–16790 Filed 7–2–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Bureau of Citizenship and Immigration Services

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: 30-day notice of information collection under review: Application Requirements for the Adjustment of Status under Section 586 of Public Law 106–249; OMB–27.

The Department of Homeland Security, Bureau of Citizenship and Immigration Services (BCIS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously approved by OMB under emergency review proceedings on December 13, 2002 and the agency was granted temporary approval.

The BCIS intends to request an extension of this information collection. Therefore, the purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until August 4, 2003. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Homeland Security Desk Officer, 725 17th Street, NW., Room 10235, Washington, DC 20530.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a currently approved information collection.

(2) *Title of the Form/Collection:* Application Requirements for the Adjustment of Status under Section 586 of Public Law 106–249.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* No Agency Form Number; File No. OMB–27, Bureau of Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. The data is used by the agency to determine an applicant's eligibility for adjustment of status under section 586 of Public Law 106–249.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 5,000 responses at 30 (.05) minutes per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 2,500 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Regulations and Forms Services Division, Bureau of Citizenship and Immigration Services, Department of Homeland Security, Room 4304, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

Dated: June 27, 2003.

Richard A. Sloan,

Department Clearance Officer, Department of Homeland Security, Bureau of Citizenship and Immigration Services.

[FR Doc. 03–16796 Filed 7–2–03; 8:45 am]

BILLING CODE 4410–10–M