

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 BURDEN¹

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.

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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