and easy to obtain from *http://www.dnb.com/US/duns_update/.*

FOR FURTHER INFORMATION CONTACT: U.S. Department of Health and Human Services, Administration on Aging, Office of Evaluation, Washington, DC 20201, telephone: (202) 357–0145.

Dated: June 30, 2003.

Josefina G. Carbonell,

Assistant Secretary for Aging.

[FR Doc. 03–16839 Filed 7–2–03; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–10091]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (CMS)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection; *Title of Information Collection:* UPIN (UPIN Physician Identification Number) Participating Directory/Accepting New Patients Indicator; *Form No.:* CMS–10091 (OMB# 0938–NEW); *Use:* In November of 2000, CMS launched the Participating Physicians Directory on *http://www.medicare.gov.* This particular directory was created to provide beneficiaries with the names, addresses, and specialties of Medicare participating physicians who have agreed to accept assignment on all Medicare claims and covered services. CMS is adding information from already existing sources; in addition, CMS wants to collect a new data element ''Accepting New Patients Indicator'' which is essential to a beneficiary's search for a physician; *Frequency:* On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 109,800; *Total Annual Responses:* 10,980; *Total Annual Hours:* 915.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at *http://cms.hhs.gov/regulations/pra/default.asp,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Dawn Willinghan, Room: C5–14–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: June 26, 2003.

Dawn Willinghan,

CMS Reports Clearance Officer, Division of Regulations Development and Issuances, Office of Strategic Operations and Strategic Affairs.

[FR Doc. 03–16815 Filed 7–2–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0286]

Agency Information Collection Activities: Proposed Collection; Comment Request; User Fee Cover Sheet; Form FDA 3397

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 on Form FDA 3397, User Fee Cover Sheet that must be submitted along with certain drug and biologic product applications and supplements.

DATES: Submit written or electronic comments on the collection of information by September 2, 2003.

ADDRESSES: Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* Submit written comments 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: JonnaLynn P. Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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 comment on: (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.

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