further rounding upwards to the nearest 50 hours).

3. Estimated Cost Burden

The cost per participant should be negligible. Participation is voluntary, and will not require any start-up, capital, or labor expenditures by study participants. As with the initial study, participants will not pay for their credit reports or credit scores.

William Blumenthal,

General Counsel.

[FR Doc. E6–17507 Filed 10–18–06; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: OS–0990–0304; 30 day notice]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection 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: Regular Clearance, Extension of a currently approved collection.

Title of Information Collection: National Outcomes Performance Assessment of the Collaborative Initiative to Help End Chronic Homelessness.

Form/OMB No.: OS–0990–0304.

Use: The goals of this 3-year program for persons experiencing chronic homelessness include: (1) Increase the effectiveness of integrated systems of care for chronically homeless persons by providing comprehensive services and treatment and linking them to housing; (2) create additional permanent housing for chronically homeless persons; (3) increase the use of underused mainstream resources that pay for services and treatment for chronically homeless persons (*e.g.*, Medicaid, TANF, Food Stamps, block grants, state-funded children's health insurance programs); (4) replicate service, treatment, and housing models known to be effective based on sound evidence; and, (5) support the development of infrastructures that sustain the housing, services, treatments, and inter-organizational partnerships beyond the 3-year Initiative.

Frequency: Reporting, on occasion, quarterly, annually.

Affected Public: Individuals or Households.

Annual Number of Respondents: 723.

Total Annual Responses: 1857.

Average Burden per Response: .9.

Total Annual Hours: 1857.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access the HHS Web site address at *http://www.hhs.gov/ocio/infocollect/pending/* or e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be received within 30 days of this notice directly to the Desk Officer at the address below: OMB Desk Officer: John Kraemer, OMB Human Resources and Housing Branch, Attention: (OMB #0990–0304), New Executive Office Building, Room 10235, Washington DC 20503.

Dated: October 11, 2006.

Alice Bettencourt,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. E6–17424 Filed 10–18–06; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001D–0220 (Formally Docket No. 01D–0220)]

Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments; 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: Biological Product Deviation Reporting for Blood and Plasma Establishments,'' dated October 2006. The guidance provides blood and plasma establishments, including licensed blood establishments, unlicensed registered blood establishments, and transfusion services, with the FDA's current thinking related to the biological product deviation reporting requirements. The guidance document will assist blood and plasma establishments in determining when a report is required, who submits the report, what information to submit in the report, the timeframe for reporting, and how to submit the report. The guidance finalizes the draft guidance document under the same title dated August 2001.

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, suite 200N, 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 CBER 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: Joseph L. Okrasinski, Jr., 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 document entitled ''Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments'' dated October 2006. The guidance is intended to provide

assistance to blood and plasma establishments in the reporting of any event associated with the manufacturing, to include testing, processing, packing, labeling, or storage, or with the holding or distribution, of blood or blood components that may effect the safety, purity, or potency of a distributed product as required under §§ 600.14 and 606.171 (21 CFR 600.14 and 606.171). The guidance provides additional information regarding the regulations in § 606.171 by describing who must report, what must be included in the report, when the establishment must report, and how to report either electronically or by mail using Form FDA–3486, a standardized reporting format. Examples of reportable and non-reportable events concerning donor suitability, product collection, component preparation, testing, labeling, quality control and distribution are discussed. The guidance also contains a Biological Product Deviation Reporting Flow Chart to aid the blood or plasma establishment in determining if an event is reportable.

In the **Federal Register** of August 13, 2001 (66 FR 42546) FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. Editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated August 2001.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the 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

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information under § 606.171 and 21 CFR 606.100 were approved under OMB control number 0910–0116. The collection of information under § 600.14 was approved under OMB control number 0910–0139. The collections of information under 21 CFR 820.90 and 820.100 were approved under OMB control number 0910–0458. The collections of information under 21 CFR 211.192 and 211.198 were approved under OMB control number 0910–0139.

III. 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.

IV. 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: October 10, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–17378 Filed 10–18–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001D–0221 (Formally Docket No. 01D–0221)]

Guidance for Industry: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components; 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: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components,'' dated October 2006. The guidance document provides licensed manufacturers of biological products other than blood and blood components with the FDA's current thinking related to the biological product deviation reporting requirements. The guidance document will assist the licensed manufacturers of biological products other than blood and blood components in determining when a report is required, who submits the report, what information to submit in the report, the timeframe for reporting, and how to submit the report. This guidance finalizes the draft guidance document of the same title dated August 2001.

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, suite 200N, 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 CBER 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: Joseph L. Okrasinski, Jr., 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 document entitled ''Guidance for Industry: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components,'' dated October 2006. The guidance is intended to provide assistance to licensed manufacturers of biological products other than blood and blood components in the reporting of any event associated with the manufacturing, to include testing, processing, packing, labeling, or storage, or with the holding or distribution of a licensed biological product which may affect the safety, purity, or potency of a distributed licensed product as required under § 600.14 (21 CFR 600.14). The guidance provides additional information regarding the regulations in § 600.14, which describe who must report, what must be included in the report, when the licensed manufacturer must report, and provides that the licensed