4. *Type of Information Collection Request:* Extension of a currently approved information collection; *Title of Information Collection:* Intermediate Care Facility for the Mentally Retarded or Persons with Related Conditions ICF/MR Survey Report Form and Supporting Regulations at 42 CFR 442.30, 483.410, 483.420, 483.440, 483.50, and 483.460; *Use:* The survey forms are needed to ensure provider compliance. In order to participate in the Medicaid program as an ICF/MR, providers must meet Federal standards. The survey report form is used to record providers' level of compliance with the individual standard requirements and report it to the Federal government; *Form Number:* CMS–3070G–I (OMB#: 0938–0062); *Frequency:* Recordkeeping and Reporting—Annually; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 6,428; *Total Annual Responses:* 6,428; *Total Annual Hours:* 19,284.

5. *Type of Information Collection Request:* Extension of a currently approved information collection; *Title of Information Collection:* Reconciliation of State Invoice and Prior Quarter Adjustment Statement; *Use:* Section 1927 of the Social Security Act requires drug labelers to enter into and have in effect a rebate agreement with CMS for States to receive funding for drugs dispensed to Medicaid recipients. Drug manufacturers must complete and submit to States the CMS–304 form to explain any rebate payment adjustments for the current quarter, and complete and submit the CMS–304A form to States to explain rebate payment adjustments to any prior quarters. Both forms are used to reconcile drug rebate payments made by manufacturers with the States' invoices of rebates due; *Form Number:* CMS–304/304A (OMB#: 0938–0676); *Frequency:* Recordkeeping and Reporting—Quarterly; *Affected Public:* Business or other for-profit; *Number of Respondents:* 550; *Total Annual Responses:* 3,740; *Total Annual Hours:* 139,480.

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://www.cms.hhs.gov/PaperworkReductionActof1995*, 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.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on October 13, 2006.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—A, Attention: Melissa Musotto, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: August 3, 2006.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E6–13189 Filed 8–11–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1997D–0318] (formerly Docket No. 97D–0318)

Draft Guidance for Industry on an Amendment Involving Donor Deferral for Transfusion in France Since 1980 to ''Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Amendment (Donor Deferral for Transfusion in France Since 1980) to 'Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products,''' dated August 2006. The draft guidance document, when finalized, is intended to amend FDA's ''Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products'' dated January 2002. This draft guidance, which is a level I guidance document, would add to the January 2002 guidance a donor deferral recommendation for donors who have received a transfusion of blood or blood components in France since 1980. After we review comments received on this draft guidance, we intend to incorporate this donor deferral recommendation and reissue the revised January 2002 guidance as a level II guidance document for immediate implementation.

DATES: Submit written or electronic comments on the draft guidance by October 13, 2006 to ensure their adequate consideration in preparation of the revisions to the 2002 guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft 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 draft 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 draft guidance document.

Submit written comments on the draft 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: Brenda R. Friend, 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 draft document entitled ''Guidance for Industry: Amendment (Donor Deferral for Transfusion in France Since 1980) to 'Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products''' dated August 2006 (Draft Guidance). The Draft Guidance is intended to amend FDA's ''Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products'' (CJD/vCJD Guidance), dated January 2002, by adding a donor deferral recommendation for donors who have received a transfusion of blood or blood components in France since 1980. After we review comments received on this Draft Guidance, we intend to

incorporate this donor deferral recommendation and reissue the revised CJD/vCJD Guidance as a level II guidance document in accordance with § 10.115(g)(4)(i) (21 CFR 10.115(g)(4)(i)).

Since the original publication of the CJD/vCJD Guidance, we have learned of additional information warranting revision to the CJD/vCJD Guidance to address a possible increased risk of vCJD transmission from individuals who have received a transfusion of blood or blood components in France. This revision is based on:

- The likelihood of exposure to the Bovine Spongiform Encephalopathy (BSE) agent in that country and
- The recent documentation of three presumptive cases of transfusion-transmitted vCJD infection in the United Kingdom (U.K.).

Because an unknown but possibly significant number of blood donors might have already been infected in France during peak significant years of the BSE outbreak in Europe, FDA believes that it would be a prudent preventive measure to indefinitely defer all donors (including Source Plasma donors) who received transfusions of blood or blood components in France since 1980.

The Draft Guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The Draft Guidance, when finalized, will represent 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. Comments

The Draft Guidance is being distributed for comment purposes only and is not intended for implementation at this time. 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.

III. 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.fda.gov/ohrms/dockets/default.htm*.

Dated: August 1, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–13234 Filed 8–11–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0362]

Guidance for Industry on Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin G (IgG) Antibodies; 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: Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin G (IgG) Antibodies,'' dated August 2006. The guidance document is intended to assist Source Plasma manufacturers in submitting to FDA the appropriate information when implementing an IgG antibody collection program or when adding a new IgG antibody collection to an existing program. This guidance finalizes the draft guidance entitled ''Guidance for Industry: Recommendations for Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin (IgG) Antibodies,'' dated October 2005, and supersedes the draft reviewers' guide entitled ''Disease Associated Antibody Collection Program,'' dated October 1, 1995.

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 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: Brenda R. Friend, 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: Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin G (IgG) Antibodies'' dated August 2006. The document supersedes the draft reviewers' guide, ''Disease Associated Antibody Collection Program,'' dated October 1, 1995. The document provides guidance to Source Plasma manufacturers in submitting the appropriate information to FDA when implementing an IgG antibody collection program or when adding a new IgG antibody collection to an existing program. The guidance identifies changes in collection programs that must be documented as minor changes in an annual report to FDA under § 601.12(d)(21 CFR 601.12(d)). These collection programs include disease-associated IgG antibodies and other existing IgG antibodies. The guidance also identifies labeling changes to be submitted as a supplement for changes being effected under § 601.12(f)(2)(i)(E). The guidance neither includes recommendations related to implementing Immunoglobulin M antibody collection programs, nor does it include recommendations for donors who do not meet all donor suitability requirements under 21 CFR 640.63.

In the **Federal Register** of October 20, 2005 (70 FR 61135), FDA announced the availability of the draft guidance entitled ''Guidance for Industry: Recommendations for Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin (IgG) Antibodies'' dated October 2005. FDA received one comment on the draft guidance. However, this comment related to the guidance process itself, not to the draft guidance. No changes other than editorial for clarification