adequate consideration in preparation of the final 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ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug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 The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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: Gene Therapy Clinical Trials—Observing Participants for Delayed Adverse Events'' dated August 2005. This draft guidance provides to sponsors of gene therapy studies recommendations on: (1) Methods to assess the risk of gene-therapy-related delayed adverse events following exposure to gene therapy products, (2) guidance for determining the likelihood that long-term followup observations on study participants will provide scientifically meaningful information, and (3) specific advice regarding the duration and design of long-term followup observations.

This draft guidance, when finalized, will supplement the recommendations in the ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors'' (Retroviral Vector guidance), dated October 2000, for study participant long-term followup. However, the recommendations in the Retroviral Vector guidance regarding the length of followup will be superseded by this Gene Therapy Clinical Trials guidance.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).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. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 information collection provisions in this guidance for the investigational new drug application (IND) regulations (21 CFR part 312) have been approved under OMB control number 0910–0014; and the good laboratory practice (GLP) regulations (21 CFR part 58) have been approved under OMB control number 0910–0119.

III. 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.

IV. 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 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–16629 Filed 8–22–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Proposed Collection; Comment Request; Prior Disclosure Regulations

AGENCY: Bureau of Customs and Border Protection (CBP), U.S. Department of Homeland Security (DHS).

ACTION: Notice and request for comments.

SUMMARY: The Department of the Homeland Security, as part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the Prior Disclosure Regulations. This proposed information collection was previously published in the **Federal Register** (70 FR 35280–35281) on June 17, 2005, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments should be received on or before September 22, 2005, to be assured of consideration.

ADDRESSES: Direct all written comments to the Bureau of Customs and Border Protection, Information Services Branch Attn.: Tracey Denning, 1300 Pennsylvania Avenue NW., Room 3.2C, Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to U.S. Customs Service, Attn.: Tracey Denning, 1300 Pennsylvania Avenue NW., Room 3.2C, Washington, DC 20229, Tel. (202) 344–1429.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3506(c)(2)(A)). The comments should address the accuracy of the burden estimates and ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology, as well as other relevant aspects of the information collection. The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting

comments concerning the following information collection:

Title: Prior Disclosure Regulations.

OMB Number: 1651–0074.

Form Number: N/A.

Abstract: This collection of information is required to implement a provision of the Customs Modernization portion of the North American Free Trade Implementation Act concerning prior disclosure by a person of a violation of law committed by that person involving the entry or introduction or attempted entry or introduction of merchandise into the United States by fraud, gross negligence or negligence, pursuant to 19 U.S.C. 1592(c)(4), as amended.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 3,500.

Estimated Time per Respondent: 60 minutes.

Estimated Total Annual Burden Hours: 3,500.

Estimated Annualized Cost to the Public: N/A.

Dated: August 16, 2005.

Tracey Denning,

Agency Clearance Officer, Information Services Branch.

[FR Doc. 05–16719 Filed 8–22–05; 8:45 am]

BILLING CODE 9110–06–P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Proposed Collection; Comment Request Vessel Entrance or Clearance Statement Form

AGENCY: Bureau of Customs and Border Protection (CBP), Department of Homeland Security (DHS).

ACTION: Notice and request for comments.

SUMMARY: The Department of Homeland Security, as part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning Vessel Entrance of Clearance Statement. This proposed information collection was previously published in the **Federal Register** (70 FR 35280–35281) on June 17, 2005, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)).

DATES: Written comments should be received on or before September 22, 2005, to be assured of consideration.

ADDRESSES: Direct all written comments to Customs and Border Protection, Information Services Group, Attn.: Tracey Denning, 1300 Pennsylvania Avenue, NW., Room 3.2C, Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to U.S. Customs Service, Attn.: Tracey Denning, 1300 Pennsylvania Avenue, NW., Room 3.2C, Washington, DC 20229, Tel. (202) 344–1429.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3505(c)(2)). The comments should address: (1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) estimates of capital or start-up costs and costs of operations, maintenance, and purchase of services to provide information. The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

Title: Vessel Entrance or Clearance Statement Form.

OMB Number: 1651–0019.

Form Number: CBP Form 1300.

Abstract: This form is used by a master of a vessel to attest to the truthfulness of all other forms associated with the manifest.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Businesses, Individuals, Institutions.

Estimated Number of Respondents: 12,000.

Estimated Time per Respondent: 5 minutes.

Estimated Total Annual Burden Hours: 21,991.

Estimated Total Annualized Cost on the Public: N/A.

Dated: August 16, 2005.

Tracey Denning,

Agency Clearance Officer, Information Services Group.

[FR Doc. 05–16723 Filed 8–22–05; 8:45 am]

BILLING CODE 9110–06–P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Agency Information Collection Activities: Entry and Manifest of Merchandise Free of Duty

AGENCY: Bureau of Customs and Border Protection, Department of Homeland Security.

ACTION: Proposed collection; comments requested.

SUMMARY: The Bureau of Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995: Entry and Manifest of Merchandise Free of Duty. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (70 FR 35284) on June 17, 2005, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before September 22, 2005.

ADDRESSES: Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated