meets the requirements of the regulations promulgated by the Secretary to authorize the use of such a health claim. Section 101.82 (21 CFR 101.82) of FDA's regulations authorizes a health claim for food labels about soy protein and the risk of coronary heart disease. To bear the soy protein/coronary heart disease health claim, foods must contain at least 6.25 grams of soy protein per reference amount customarily consumed. Analytical methods for measuring total protein can be used to quantify the amount of soy protein in foods that contain soy as the sole source of protein. However, at the present time there is no validated analytical methodology available to quantify the amount of soy protein in foods that contain other sources of protein. For these latter foods, FDA must rely on information known only to the manufacturer to assess compliance with the requirement that the food contain the qualifying amount of soy protein. Thus, FDA requires manufacturers to have and keep records to substantiate the amount of soy protein in a food that bears the health claim and contains sources of protein other than soy, and to make such records available to appropriate regulatory officials upon written request. The information collected includes nutrient data bases or analyses, recipes or formulations, purchase orders for ingredients, or any other information that reasonably substantiates the ratio of soy protein to total protein.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
101.82(c)(2)(ii)(B)	25	1	25	1	25

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Based upon its experience with the use of health claims, FDA estimates that only about 25 firms would be likely to market products bearing a soy protein/coronary heart disease health claim and that only, perhaps, one of each firm's products might contain nonsoy sources of protein along with soy protein. The records required to be retained by § 101.82(c)(2)(ii)(B) are the records, e.g., the formulation or recipe, that a manufacturer has and maintains as a normal course of its doing business. Thus, the burden to the food manufacturer is that involved in assembling and providing the records to appropriate regulatory officials for review or copying.

Dated: August 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–16658 Filed 8–22–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0469]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Adverse Experience Reporting for Licensed Biological Products; and General Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Adverse Experience Reporting for Licensed Biological Products; and General Records'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 20, 2005 (70 FR 20571), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0308. The approval expires on July 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: August 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–16659 Filed 8–22–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0310]

Draft Guidance for Industry on Gene Therapy Clinical Trials—Observing Participants for Delayed Adverse Events; 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: Gene Therapy Clinical Trials—Observing Participants for Delayed Adverse Events,'' dated August 2005. The draft guidance provides sponsors of gene therapy studies with recommendations regarding collection of data on delayed adverse events in participants who have been exposed to gene therapy products. When finalized, this guidance 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.

DATES: Submit written or electronic comments on the draft guidance by November 21, 2005, to ensure their

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