misleading; (5) developing a sound science base for dietary supplement regulation through enhanced research and analytical capabilities and collaboration with governmental and external partners; and (6) expanding outreach to stakeholders.

The strategy now being announced describes a series of specific, integrated steps that will bring CFSAN closer to achieving each of its longer-term goals for DSHEA implementation and enforcement under the 10-year plan. This strategy also is consistent with the ''Dietary Supplement Enforcement Report'' announced in December 2002 (*http://www.fda.gov/oc/mcclellan/chbn.html*), and it incorporates and is in furtherance of CFSAN's 2004 Program Priorities, announced in May 2004 (*http://www.cfsan.fda.gov/~dms/cfsan404.html*). We are making this strategy available to maximize the sharing of information among the agency, consumers, and stakeholders about implementation of DSHEA.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this strategy. 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 brackets in the heading of this document. The strategy and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

Person with access to the Internet may obtain the document at *http://www.cfsan.fda.gov/~dms/ds-stra3.html*.

Dated: October 22, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–24870 Filed 11–4–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004D–0465]**

### Draft Guidance for Food and Drug Administration Review Staff and Sponsors: Content and Review of Chemistry, Manufacturing, and Control Information for Human Gene Therapy Investigational New Drug Applications; 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 FDA Review Staff and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs)'' dated November 2004. The draft guidance document, when finalized, is intended to provide guidance to FDA review staff and sponsors of human gene therapy products on IND submissions, and on the information FDA CMC reviewers record and assess as part of the review of an original IND.

**DATES:** Submit written or electronic comments on the draft guidance by February 7, 2005, to ensure their adequate consideration in preparation of the final document. 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, suite 200N, 1401 Rockville Pike, 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 the CBER Voice Information System 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:** Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for FDA Review Staff and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs)'' dated November, 2004. The document provides guidance to help sponsors and reviewers to assess, given the phase of the investigation, whether an IND provides sufficient information to allow the reviewer to evaluate the proper identification (identity testing), quality, purity, and strength (potency) of the investigational product (21 CFR 312.23(a)(7)(i)). The draft guidance document is intended to help ensure that all applicable regulatory requirements are reviewed for the appropriate stage of product development.

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 the agency'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 document 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 written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except 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 document at either *http:/*

*/www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: November 1, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–24879 Filed 11–8–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2003D–0554]**

### Compliance Policy Guide Regarding Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a revised Compliance Policy Guide (CPG) entitled ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' The CPG provides written guidance to FDA's and Customs and Border Protection's (CBP's) staff on enforcement of section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulations, which require prior notice for food imported or offered for import into the United States. The CPG has been revised to provide additional guidance to FDA and CBP staff regarding prior notice submissions that do not provide information about the identity of the manufacturing facility of food no longer in its natural state, articles of food imported or offered for import by express courier, prior notice submission time frames, and lastly, gift packs purchased or otherwise acquired by an individual and imported or offered for import for nonbusiness purposes.

**DATES:** This guidance is final and effective on November 8, 2004. However, you may submit written or electronic comments at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Domenic Veneziano, Office of Regulatory Affairs (HFC–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 703–621–7809.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is announcing the availability of revised CPG section 110.310 entitled ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' This revised guidance is issued with CBP concurrence and explains to FDA and CBP staff the new FDA and CBP policies on enforcement of section 307 of the Bioterrorism Act and its implementing regulations, which require prior notice to FDA of all food imported or offered for import into the United States (68 FR 58974, October 10, 2003 (codified at 21 CFR part 1, subpart I, 1.276 through 1.285)). The original CPG was published December 2003, and was revised June 2004 to include additional guidance regarding food imported or offered for import for noncommercial purposes with a noncommercial shipper. In August 2004, the CPG was revised to provide additional guidance regarding food imported or offered for import for quality assurance, research or analysis purposes only, not for human or animal consumption and not for resale. We (FDA) also revised the CPG in August to extend until November 1, 2004,[1] our enforcement discretion policy concerning certain violations related to the registration number of the manufacturing facility and the shipper, the airway bill number or bill of lading number, and the name and address of the ultimate consignee.

*A. Identity of the Manufacturer*

FDA is revising the CPG to provide additional guidance regarding prior notice submissions that do not provide information to identify the manufacturing facility of an article of food (i.e., the specific facility that manufactured the food). This information is required for food that is no longer in its natural state. FDA and CBP intend to exercise broad enforcement discretion when this information is required but is not provided, under the following circumstances:

(1) If, after a good faith effort, the person submitting prior notice does not know the registration number of the facility that manufactured the food and the facility is required to be registered, that person instead provides the name and full address of the facility that manufactured the food.

(2) If, after a good faith effort, the person submitting prior notice does not know either the registration number or the name and full address of the facility that manufactured the food, that person instead provides the name and full address of the headquarters of the facility that manufactured the food.

(3) If, after a good faith effort, the person submitting prior notice does not know either the information described in (1) about the facility that manufactured the food, or in (2) about the headquarters of the facility that manufactured the food, that person instead provides the name and full address of the invoicing firm.

FDA is taking these steps to provide additional flexibility in filing prior notice to various kinds of importers while the final prior notice rule is under development. However, if the facility that manufactured the food is a foreign facility that is required to be registered and either its registration number is not provided or the name and address of a different facility (i.e., the manufacturing facility's headquarters or the invoicing firm) is provided, then it will be more difficult and/or may take more time for FDA and CBP to verify the identity of the manufacturing facility and its registration status and to determine whether the article of food is subject to being held under section 801(l) of the Federal Food, Drug, and Cosmetic Act (the act). As a result, if an article of food is imported or offered for import with the manufacturer's name and full address, or the name and address of the manufacturing facility's headquarters or the invoicing firm, instead of the manufacturer's name and registration number, and if FDA has concerns that the food may pose a serious health threat, then the food may be delayed at the port of arrival until the verification is completed. Moreover, as with other types of prior notice violations, FDA may consider the failure to provide required information about the manufacturer as a factor in determining whether and where to examine the article of food. Under all circumstances,

[1] This date was extended to November 7, 2004.