2. Are there new technologies that hold promise for helping to characterize proteins?

3. What factors, including quality attributes, impurity profiles, and changes in the manufacturing process, should be considered when assessing similarity of different protein products?

4. Is it possible to accurately predict safety and efficacy from analytical studies?

C. Immunogenicity

1. How, and to what extent, should immunogenicity be evaluated for a follow-on protein product?

2. Under what circumstances should comparative immunogenicity studies be conducted?

D. Preclinical and Clinical

1. When and how would it be appropriate to streamline or eliminate certain animal or human studies during development of a follow-on protein product?

E. Potency and Surrogates for Efficacy and Safety

1. What factors should be considered regarding bioactivity and potency assays used for comparing two products?

2. What is the role of in vitro and in vivo assays for use as surrogates in establishing safety and efficacy?

F. Terminology

1. Please comment on the appropriateness of this notice's working definition of ''follow-on protein'' as a protein that is intended to be a similar version or copy of an already approved or licensed protein pharmaceutical product.

2. Please comment on this notice's working definition of a ''second-generation protein product'' as a product similar to an already approved or licensed product but which has been deliberately modified to change one or more of the product's characteristics (e.g., to provide more favorable pharmacokinetic parameters or to decrease immunogenicity).

Dated: August 10, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–18627 Filed 8–11–04; 11:15 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0361]

Guidance for Industry: Prior Notice of Imported Food Contingency Plan for System Outages; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a contingency plan that provides guidance on submitting prior notice of imported food during system outages affecting the applicable FDA and Customs and Border Protection (CBP) program systems. Section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and its implementing regulations require prior notice to FDA of all food imported or offered for import into the United States.

DATES: This guidance is final upon the date of publication. 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), Food and Drug Administration, 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

In the **Federal Register** of October 10, 2003 (68 FR 58974), FDA issued an interim final rule (IFR) to implement section 307 of the Bioterrorism Act. The prior notice IFR requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States. The prior notice IFR provides that if a customs broker's or self-filer's system is not working or if the Automated Broker Interface of the Automated Commercial System is not working, prior notice must be submitted through the Prior Notice System Interface (PNSI); and that if PNSI or the Operational and Administrative System for Import Support is not operating, prior notice information must be submitted by e-mail or by fax to FDA.

We stated in the prior notice IFR that FDA does not plan to exempt any specific categories of food articles from prior notice if system(s) are not working, and that FDA and CBP are working together to develop contingency plans for when the applicable FDA and CBP program systems are not working (68 FR 58974 at 58997). FDA with concurrence from CBP is announcing the availability of a contingency plan that provides guidance on submitting prior notice of imported food during system outages affecting the applicable FDA and CBP program systems. The contingency plan identifies seven potential system downtime scenarios that could impact transmission, confirmation, and processing of prior notice submissions and explains recommended submission options for each of the identified scenarios. In any of the scenarios described in the contingency plan, where the alternate submission options include both e-mail and fax (telephonic facsimile) transmissions, e-mail transmission is strongly encouraged as the more efficient means.

FDA is issuing this document as a level 1 guidance consistent with FDA's good guidance practices regulation (§10.115 (21 CFR 10.115)). The contingency plan is being implemented immediately without prior public comment, under §10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. Under section 307 of the Bioterrorism Act, the prior notice requirements were effective December 12, 2003, and FDA and CBP's systems for processing prior notice submissions are up and running, making it urgent that the agencies explain how submitters can fulfill the prior notice requirements in the event of system outages.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance document. Submit two copies of written comments, except that individuals may submit one

copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance 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

Persons with access to the Internet may obtain the document at *http://www.fda.gov/oc/bioterrorism/bioact.html.*

Dated: August 11, 2004.

John Marzilli,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 04–18741 Filed 8–12–04; 10:56 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0554]

Revised Compliance Policy Guide Regarding Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Revised Joint Food and Drug Administration-Customs and Border Protection Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes; 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) Sec. 110.310 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 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 all food imported or offered for import into the United States. This document also describes certain date changes to the Joint Food and Drug Administration-Customs and Border Protection Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes (revised joint plan) that was announced in the **Federal Register** of April 14, 2004 (69 FR 19765).

DATES: The revised CPG and the revised joint plan are final upon the date of publication. However, you may submit written or electronic comments on the revised CPG at any time.

ADDRESSES: Submit written requests for single copies of the revised CPG 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 revised CPG may be sent. Submit written comments on the revised CPG to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

Submit written requests for single copies of the revised joint plan to the Office of Regional Operations (HFC–100), 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 it may be sent.

See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised CPG and the revised joint plan.

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

A. Revisions to the CPG

FDA is announcing the availability of revised CPG Sec. 110.310 entitled ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' This revised CPG 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 1.276 through 1.285)). The original CPG was issued in December 2003 and was revised in June 2004 to include additional guidance regarding food imported or offered for import for noncommercial purposes with a noncommercial shipper. Since the prior notice interim final rule (IFR) became effective in December 2003, FDA and CBP have been reviewing the data quality of prior notice submissions. This review has revealed practical implementation problems with certain data elements, such as registration number, bill of lading number, and ultimate consignee. In part, these problems result from a lack of standardization. The problems also arose due to the practical difficulties faced by submitters in obtaining required information in complex commercial settings. Therefore, the CPG is being revised concerning the following violations:

- The registration number submitted for the manufacturing facility is inaccurate or is invalid;
- The registration number for the shipper is not provided;
- The airway bill number or bill of lading number is not provided or is invalid; and
- The name and address of the ultimate consignee is inaccurate because it contains the name and address of the express consignment operator or consolidator instead of the ultimate consignee.

For the violations listed previously in this document, FDA and CBP should typically consider not taking any regulatory action until November 1, 2004.[1] If, however, the violation reflects a history of repeated conduct of a similar nature by a person who had been notified of such violations, then the action FDA and CBP staff typically should consider taking is assessment of CBP Civil Monetary Penalties.

Another change relates to food imported or offered for import for quality assurance, research or analysis purposes only, not for human or animal consumption and not for resale. If prior notice does not include a required manufacturing facility registration number, FDA and CBP should typically not take any regulatory action.

FDA is issuing this revised CPG as level 1 guidance consistent with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)). The revised CPG Sec. 110.310 is being implemented immediately without prior public comment, under § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. This document revises policies that were due to take effect on August 13, 2004, so it is urgent that the

[1] In the original CPG issued in December 2003, the transition period was to end August 12, 2004; CBP and FDA informally referred to this time period as ''Phase IV.'' The two agencies now will refer to the time period of August 13, 2004, until November 1, 2004, as ''Phase IV (revised)'' and the time period on or after November 1, 2004, as ''Phase V.''