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.''

agencies explain their new enforcement policies before that date.

B. Revisions to the Joint FDA–CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes

On April 14, 2004, FDA and CBP (we) announced the availability of a joint plan entitled ''Joint FDA–CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes.'' The joint plan describes the process by which FDA and CBP intend to increase integration and examine whether we could amend the timeframe requirements in FDA's prior notice IFR to have the same advanced notice timeframes for arrivals by land via road or rail or arrival via air that are currently in CBP's advance electronic information rule (69 FR 19765). Due to the revisions in the CPG described previously that extend the transition period of the prior notice IFR to November 1, 2004, certain dates outlined in the joint FDA–CBP are revised as follows:

- We intend to implement the plan in November 2004.
- From November 1, 2004, to January 3, 2005, we plan to assess existing procedures and staffing needed to receive, review, and respond to the prior notices submitted in accordance with the prior notice IFR (i.e., 2 hours before arrival by land by road; 4 hours before arrival by air or by land by rail; and 8 hours before arrival by water).
- From January 4, 2005, to February 3, 2005, we intend to identify what changes to work practices and staffing would be necessary to determine if FDA could continue to receive, review, and respond to all prior notice submissions with reduced timeframes (e.g., 1 hour or 30 minutes before arrival by land by road; 2 hours before arrival by land by rail; and by ''wheels up'' for flights originating in North and Central America, South America (north of the Equator only), the Caribbean, and Bermuda; otherwise 4 hours before arrival by air).
- From February 4, 2005, to May 3, 2005, we plan to implement necessary changes and make appropriate adjustments to ensure we could receive, review, and respond to all prior notice submissions with reduced timeframes.
- In June 2005, we intend to issue a prior notice final rule that responds to the comments we received on the prior notice IFR, including this revised joint plan, during the two open comment periods.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the revised CPG. 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 revised CPG 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

An electronic version of the revised CPG is available on the Internet at *http://www.fda.gov/ora* under ''Compliance Reference.'' An electronic version of the revised joint plan is available on the Internet at *http://www.fda.gov/oc/bioterrorism/bioact.html*.

Dated: August 11, 2004.

John Marzilli,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 04–18742 Filed 8–12–04; 10:56 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: (301) 496–7057; fax: (301) 402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Multivariate Profiling of Complex Biological Regulatory Pathways

Kevin Gardner *et al.* (NCI)

U.S. Patent Application No. 10/822,140 filed 12 Apr 2004 (DHHS Reference No. E–127–2003/0–US–02)

Licensing Contact: Cristina Thalhammer-Reyero; (301) 435–4507; *thalhamc@mail.nih.gov.*

This invention is in the general area of methods for high-throughput profiling of transcriptional targets. More particularly, it can be described as systems and methods for generating and analyzing multi-factorial biological response profiles, using a transcriptional approach that profiles the activation of multiple transcriptional targets against combinatorial arrays of signal transducing agents and therapeutic drugs. Cellular behavior in response to changes in its environment is controlled through extracellular events that are biochemically ''transduced'' at the cell membrane, and through a series of molecular signaling pathways converge in the nucleus to influence the combination of transcription factor binding sites that control the activation of targeted genes. Most of those promoter or regulatory regions of gene loci have a modular structure that is bound by two or more different transcriptional factors in a highly cooperative fashion. Accordingly, it is the nature of the surrounding regulatory elements or ''promoter context'' that combine to determine how genes are transcriptionally regulated. Currently there are very few techniques that provide a clear picture of the level of signal integration that must occur at these transcriptional targets.

The technology is further described in *Targeting Combinatorial Transcriptional Complex Assembly at Specific Modules within the Interleukin-2 Promoter* by the *Immunosuppressant SB203580* by James L. Smith, Irene Collins, G. V. R. Chandramouli, Wayne G. Butscher, Elena Zaitseva, Wendy J. Freebern, Cynthia M. Haggerty, Victoria Doseeva, and Kevin Gardner. J. Biol. Chem., Oct 2003; 278: 41034—41046).

Resonant Structure for Spatial and Spectral-Spatial Imaging of Free Radical Spin Probes Using Radiofrequency Time Domain Electron Paramagnetic Resonance Spectroscopy

Nallathamb Devasahayam *et al.* (NCI)

U.S. Patent 6,573,720 issued 03 Jun 2003 (DHHS Reference No. E–166–1997/0–US–07); European, Japanese, Canadian and Australian rights are also pending