Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by eliminating the next most likely entrant in the market for cosmetic botulinum toxins. The proposed Consent Agreement would remedy the alleged loss of potential competition that would result from the merger in this market.

Botulinum toxin is an increasingly popular, non-surgical treatment for wrinkles caused by repetitive muscle movement, such as the ''worry lines'' that appear on the forehead when a person frowns. Botulinum toxin is uniquely effective in temporarily eliminating these ''dynamic wrinkles'' because it is the only product that can paralyze the underlying muscles associated with these wrinkles. Although there are many products and procedures that can be used to treat facial wrinkles, such as dermal fillers, topical creams, lasers, chemical peels, and surgery, botulinum toxin therapy is sufficiently differentiated from these other products and procedures that they are not close economic substitutes.

Allergan is the dominant supplier of cosmetic botulinum toxin in the United States. Allergan's Botox® is the only botulinum toxin type A approved by the U.S. Food and Drug Administration (''FDA'') for the treatment of facial wrinkles. In 2002, Ipsen granted Inamed the exclusive rights to develop and distribute a botulinum toxin type A product for facial cosmetic indications in the United States. Tentatively branded Reloxin®, Inamed's cosmetic botulinum toxin product is currently in Phase III clinical trials and is expected to be the first serious challenger to Botox® in the United States. Other firms' cosmetic botulinum toxin development programs lag well behind Inamed's Reloxin® program.

Entry into the market for cosmetic botulinum toxin would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Developing and obtaining FDA approval for manufacture and sale of cosmetic botulinum toxin takes at least two years due to substantial regulatory and technological barriers.

According to the Commission's complaint, the proposed acquisition likely would cause significant anticompetitive harm to consumers in the U.S. market for cosmetic botulinum toxin by eliminating potential competition between Allergan and Inamed. The entry of Reloxin®, which is expected to be the second botulinum toxin product to receive FDA approval for the treatment of facial wrinkles, would increase competition and likely reduce prices to consumers. Accordingly, allowing Allergan to control both Botox® and Reloxin® would likely force customers to pay higher prices for cosmetic botulinum toxin.

The proposed Consent Agreement contains several provisions designed to ensure the successful and timely entry of Reloxin® by requiring that: (1) Allergan and Inamed divest the Reloxin® development and distribution rights, including the ongoing clinical trials and certain intellectual property, back to Ipsen; (2) Allergan and Inamed take steps to ensure that confidential business information relating to Reloxin® will not be obtained or used by Allergan; and (3) Ipsen and/or its future marketing partner have the opportunity to enter into employment contracts with certain key individuals who have experience relating to Reloxin®.

The Commission has appointed Charles A. Riepenhoff, Jr. of KPMG LLG as Interim Monitor to oversee the transfer of confidential business information back to Ipsen and to ensure compliance with all of the provisions of the proposed consent order. Mr. Riepenhoff has over thirty-four years of experience in the health care industry. To ensure that the Commission remains informed about the status of the proposed assets and transfers of assets, the proposed Consent Agreement requires Allergan and Inamed to file reports with the Commission periodically until the divestitures and transfers are accomplished.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the Consent Agreement or to modify its terms in any way.

By direction of the Commission, with Commissioner Rosch recused.

Donald S. Clark,

Secretary.

[FR Doc. E6–3550 Filed 3–13–06; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Occupational Safety and Health Education, PAR–05–107, and Research Center and Occupational Safety and Health Training Projects Grants, PAR–05–126

Correction: This notice was published in the **Federal Register** on March 1, 2006, Volume 71, Number 40, page 10538. The titles for the Special Emphasis Panel meetings have been changed.

Titles: Program Announcement for Research (PAR) 05–107, Occupational Safety and Health Education and Research Centers, and Program Announcement for Research (PAR) 05–126, Occupational Safety and Health Training Project Grants.

FOR MORE INFORMATION CONTACT: Charles N. Rafferty, PhD, Designated Federal Official, National Institute for Occupational Safety and Health, CDC, 1600 Clifton Road, NE., Mailstop E–74, Atlanta, GA 30333, Telephone Number (404) 498–2582.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: March 8, 2006.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E6–3564 Filed 3–13–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0260] (formerly Docket No. 02D–0260)

Guidance for Industry on Prescription Drug Marketing Act—Donation of Prescription Drug Samples to Free Clinics; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

availability of a guidance for industry entitled ''Prescription Drug Marketing Act—Donation of Prescription Drug Samples to Free Clinics.'' The guidance provides information for free clinics that receive donated prescription drug samples from licensed practitioners or other charitable institutions. The guidance discusses concerns that have been expressed by certain individuals regarding regulatory requirements for drug sample donations. The guidance announces that FDA, after reviewing an independent study report analyzing the potential effects of the regulations on free clinics, has decided to propose revisions to those regulations. In the interim, FDA intends to exercise its enforcement discretion and does not intend to object if a free clinic fails to comply with certain regulatory requirements for drug sample donations.

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. 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: Meredith S. Francis, Office of Regulatory Policy (HFD–7), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Prescription Drug Marketing Act—Donation of Prescription Drug Samples to Free Clinics.'' Section 203.39 (21 CFR 203.39) of the agency's regulations sets forth requirements for donation of prescription drug samples to charitable institutions. ''Charitable institution'' or ''charitable organization'' is defined in § 203.3(f) as ''a nonprofit hospital, health care entity, organization, institution, foundation, association, or corporation that has been granted an exemption under section 501(c)(3) of the Internal Revenue Code of 1954, as amended.'' Under § 203.39, a charitable institution may receive drug samples donated by a licensed practitioner or another charitable institution for dispensing to its patients, or may donate a drug sample to another charitable institution for dispensing to its patients, provided certain requirements are met. These requirements include, among other things, that a drug sample donated to a charitable institution must be inspected by a licensed practitioner or registered pharmacist, and that drug sample receipt and distribution records be maintained by the institution and retained for a minimum of 3 years.

In the **Federal Register** of June 27, 2002 (67 FR 43330), FDA announced the availability of a draft guidance entitled ''Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics.'' The draft guidance announced that FDA, in the exercise of its enforcement discretion, did not intend to object if a free clinic failed to comply with the requirements in § 203.39. The draft guidance defined the term ''free clinic,'' which is not otherwise defined in the Federal Food, Drug, and Cosmetic Act or regulations, as a charitable institution or organization, under § 203.3(f), that actually provides health care services and relies in whole or part on drug donations and volunteer help to achieve its goals. Thus, charitable institutions that receive donated drug samples but do not provide health care services, or that provide health care services but do not rely at least in part on drug donations and volunteer help to provide those services, would not be considered free clinics. According to the draft guidance, FDA intended to exercise enforcement discretion while the agency studied the potential impact of the regulation on the ability of free clinics to receive and distribute prescription drug samples. Interested persons were given the opportunity to submit comments on the draft guidance by September 25, 2002.

Since issuing the draft guidance, FDA has received a completed study report from Eastern Research Group (ERG) analyzing the burden imposed on free clinics by the requirements in § 203.39 and the potential regulatory alternatives. According to the ERG study report, implementing § 203.39 as written could impose a significant financial burden on free clinics. Based in part on the study report's conclusions, FDA is announcing today that it intends to exercise enforcement discretion while the agency proposes revisions to § 203.39 as applied to free clinics. Specifically, as FDA works to propose regulatory revisions, the agency does not intend to object if a free clinic fails to comply with certain parts of the regulation. The guidance clarifies that the agency's exercise of enforcement discretion with regard to certain requirements of § 203.39 will not extend to fraud or other illegal conduct involving drug samples, and that the agency could, at its discretion, initiate enforcement action for violations of any and all applicable statutory and regulatory provisions implicated by fraudulent or illegal activity. We note also that neither this notice, nor its corresponding guidance, affects or alters any requirements imposed by the U.S. Drug Enforcement Administration (DEA) on any free clinic, person, or other entity with regard to controlled substances donated to those entities. All DEA requirements relating to controlled substances remain fully in effect.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). It represents 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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. 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 either *http://www.fda.gov/cder/guidance/index.htm* or *http:www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–3532 Filed 3–13–06; 8:45 am]

BILLING CODE 4160–01–S