

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.*

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## 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.*

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## 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