DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Biologics Evaluation and Reseai
1401 Rockville Pike
Rockville MD 20852-1448

VIA FACSIMILE AND USPS

September 5, 2002

Mr. Peter A. Kresel
Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92623-9534

Dear Mr. Kresel:

Through routine monitoring and surveillance the Advertising and Promotional Labeling Branch (APLB) of FDA's Center for Biologics Evaluation and Research has identified promotional materials for your product, BOTOX® COSMETIC Botulinum Toxin Type A, that are in violation of the Food, Drug and Cosmetic Act and its implementing regulations. APLB has reviewed several direct-to-consumer (DTC) promotional and broadcast (15 and 30 second air-time) pieces and has concluded that these materials contain misleading statements about BOTOX® Cosmetic. Copies of all referenced materials are enclosed.

Misleading statements:

"It seems like everybody is talking about Botox® Cosmetic, the highly effective, non-surgical procedure that can dramatically reduce your toughest wrinkle within 7 days." This statement is prominently presented at the beginning of the Patient Brochure (Tab A) and is misleading because it does not emphasize that this is a temporary procedure. In addition, the term "toughest wrinkle" does not adequately specify the approved indication for use and misleadingly suggests that Botox Cosmetic is for use in all tough wrinkles. Please immediately cease distribution of these, and similarly worded, materials and revise these statements to clearly emphasize the temporary duration of this product and to appropriately identify the approved indication for use, e.g. "those tough lines between your eyebrows."

"Is BOTOX® Cosmetic right for you? If doing all you can to look your best is important to you, Botox® Cosmetic may be for you." These statements in the Patient Brochure (Tab A) are misleading because they fail to state that the product is indicated for patients from 18 to 65 years of age. It is not until several pages later in the brochure that the approved age range is presented to the reader. Please revise this, and all similar presentations, at the time of your next printing to accurately and clearly define the approved population when discussing "Is BOTOX® Cosmetic ...right for you?"

The dilution table on the physician page of your website, www.botoxcosmetic.net, (Tab B) listing the amount of diluents to be added to the lyophilized vial of BOTOX® Cosmetic and the resulting dose in units per 0.1mL is misleading. The chart promotes four other dilutions and doses that are not approved for the glabellar lines indication for BOTOX® Cosmetic, which could confuse the physician and/or promote off-label use. Please immediately revise this chart to only include the approved dilution scheme. In addition, please revise the statement, "Recommended dose is 4 units at each of the 5 injection sites," to "recommended dose is 4.0 units per 0.1 mL at each of the 5 injection sites for a total treatment dose of 20 units in 0.5mL."

"So you can frown, smile, or look surprised—without the furrows, creases, and wrinkles." This and similar quotes were identified in your Patient Brochure, Quick Reference Guide, and Patient Education Video (Tabs A, C, and D). These statements do not adequately identify the approved indication for use and are misleading to the reader. Please revise this, and similar, statements to appropriately identify the approved indication for use, e.g. "...so you can frown, ..., and wrinkles between your eyebrows."

Violative Reminder Advertisements:

The "WOW" DTC television (TV) reminder advertisements (ads), transcripts in Tab E, are in violation of 21 CFR 202.1(e)(2)(i), regarding reminder advertisements. These ads, which 1) focus attention on complexion and image, 2) make repeated references to age, and 3) make the statement, "Ask your dermatologist or plastic surgeon about BOTOX Cosmetic" include the indication for use of the product. These examples strongly suggest that the product is intended to treat the signs of aging or glabellar lines.

Allergan should immediately stop all broadcasts of these ads and all other promotional activities for Botox Cosmetic that contain the same or similar presentations until such time that you have revised these, and all other relevant, pieces to comply with the applicable regulations and have submitted them to FDA.

This is not intended to be an all-inclusive list of deficiencies associated with your promotion of the above product. It is your responsibility to ensure that all materials distributed within the United States are in conformance with each requirement of the Act and applicable regulations.

You should respond in writing within ten days of the date of this letter. Your response should include a statement confirming that the requested items were immediately discontinued, of your intent to comply with each recommendation above, a list of all similarly violative materials, and a description of the method for discontinuation and the discontinuation date.

Your response should be directed by facsimile, to 301-827-3528, or in writing to Mr. Glenn N. Byrd, Chief, APLB, at the address listed on the following page. Should you

have any questions or concerns involving this matter, please contact Ms. Maryann Gallagher, Regulatory Review Officer at 301-827-3028.

Center for Biologics Evaluation and Research
Office of Compliance and Biologics Quality
Division of Case Management
Advertising and Promotional Labeling Branch, HFM-602
1401 Rockville Pike, 200S
Rockville, MD 20852-1448

Sincerely,

Kathleen M Lewis

for Mary A. Malarkey
Director, Division of Case Management
Office of Compliance and Biologics Quality
Center for Biologics Evaluation
and Research

Enclosures

cc: Mr. David Garbe