

FDA: Pull Botox Ads

LOS ANGELES, Sept. 9, 2002

Print and television ads for the wrinkle-smoothing drug Botox are misleading and should be pulled until they are changed, the U.S. Food and Drug Administration told the drug's maker Allergan Inc.

Irvine, California-based Allergan, however, said it strongly disagrees with the FDA's position.

The regulatory agency said in a Sept. 5 letter posted on its Web site that the ads fail to emphasize that Botox is a temporary fix for wrinkles, suggest incorrectly that it can be used to treat all kinds of wrinkles and do not mention that cosmetic use is approved only for people aged 18 to 65.

The FDA asked the company to stop all broadcast ads and other promotional activities that contain misleading claims.

"We have no plans to pull the ads ... we are very frustrated and disappointed," Allergan spokesperson Christine Cassiano said.

Botox, a purified form of the toxin that causes botulism food poisoning, smoothes out wrinkles by interfering with neurotransmitters and relaxing muscles.

Approved since 1989 for eye muscle disorders, and used for years "off-label" to reduce wrinkles, Botox was officially approved by the FDA in April for temporary improvement in the appearance of moderate to severe brow furrows.

Global sales of Botox totaled \$200.8 million in the first half of the year, with cosmetic use accounting for about 40 percent of the total, according to Allergan.

"Allergan might be using language in its promotional materials that's more aggressive than some, but as far as impact on sales or earnings I don't think this is a big deal at all," said Marc Goodman, an analyst at Morgan Stanley.

He said the company will probably negotiate with the FDA and any interruption in advertising would be short-term.

The FDA said a brochure stating, "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," misleads because it does not state that the effect is temporary.

"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,'" Mary Malarkey, of the FDA's office of compliance and biologics quality, said in the letter.

The FDA also said Allergan was misleading consumers with statements like, "If doing all you can to look your best is important to you, Botox Cosmetic may be for you," because they do not clearly define the age range it is approved for.

The agency singled out for retooling a TV ad that focuses on complexion and image, refers to age and includes the statement, "Ask your dermatologist or plastic surgeon about Botox Cosmetic."

But Cassiano said the FDA reviewed that ad, which she said is a "reminder commercial" that by definition is not required to include the drug's indication, several months ago.

The FDA also warned Allergan that dilution instructions for doctors posted on a company Web site promote several dilutions and doses that are not approved for cosmetic procedures.

The FDA asked the company to respond by Sept. 15 and Cassiano said Allergan is in the process of drafting its response.

The company's shares, down about 25 percent so far this year, closed down 65 cents at \$56.44 on the New York Stock Exchange and were halted after hours.

© MMII Reuters Limited. All Rights Reserved.