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FDA APPROVES BOTOX TO TREAT FROWN LINES

FDA today announced the approval of Botulinum Toxin Type A (Botox Cosmetic) to temporarily improve the appearance of moderate to severe frown lines between the eyebrows (glabellar lines), a medical condition that is not serious. The product's manufacturer, Allergan, Inc., Irvine, California, is now allowed to market Botulinum Toxin Type A for this new indication.

Botulinum Toxin Type A is a protein produced by the bacterium *Clostridium botulinum*. When used in medical settings as an injectable form of sterile, purified botulinum toxin, small doses of the toxin are injected into the affected muscles and block the release of the chemical acetylcholine that would otherwise signal the muscle to contract. The toxin thus paralyzes or weakens the injected muscle.

Botox was first approved in December 1989, to treat two eye muscle disorders (blepharospasm and strabismus) and in December 2000 to treat cervical dystonia, a neurological movement disorder causing severe neck and shoulder contractions.

In placebo-controlled, multicenter, randomized clinical trials involving a total of 405 patients with moderate to severe glabellar lines who were injected with Botox Cosmetic, data from both the investigators' and the patients' ratings of the improvement of the frown lines were evaluated. After 30 days, the great majority of investigators and patients rated frown lines as improved or nonexistent. Very few patients in the placebo group saw similar improvement.

In these studies, the severity of the glabellar lines was reduced somewhat for up to 120 days for those patients who received Botox Cosmetic. Most of the patients in the study were female, and the majority was under 50 years old. It is recommended that Botox Cosmetic be injected no more frequently than once every three months, and the lowest effective dose should be used.

Because Botox Cosmetic is a prescription drug, it must be used carefully under medical supervision.