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FDA Puts A Stricter Warning Label On Botox

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Recent studies show that the effect of Botox can spread throughout the body, resulting to difficulty in breathing, swallowing, and even death.

Acting on the evidence, the US Food and Drug Administration advised Botox product manufacturers to put stricter label warnings on the anti-wrinkle drug.

Botox is based from botulinum toxin, a protein associated with botulism—a disease that can result to paralysis and death. The toxin was approved by the FDA in 1989 to alleviate crossed eyes and eye twitching, in 2000 to treat abnormal pain or neck twitches and in 2002 it was approved to eliminate frown lines.

In 2005, the Journal of American Academy of Dermatology alerted the FDA of 29 deaths due to non-cosmetic applications of Botox. And last January, Public Citizen - a non-profit public-interest group - called for stricter regulations on Botox, citing numerous adverse reactions of the cosmetic drug.

The FDA approved the data and noted that the severe cases were obtained from unapproved applications, for instance: using Botox to treat children's limb spasms associated with cerebral palsy. The regulator agreed to review the safety of the product.

Recently, the FDA came to a decision and found that the drug can lead to adverse reactions and deaths. The new warning label will note "the risk of adverse events when the effects of the toxin spread beyond the site where it is injected" said the FDA in their Web site. They will also brief doctors and patients about the risks of the treatment.