

Dysport the newest wrinkle-stopping drug to hit market

May 13 2009, By Jodi Mailander Farrell

There's a new wrinkle remover on the market. Late last month, the U.S. Food and Drug Administration sanctioned Dysport for cosmetic and therapeutic use. Like Botox, it's an injectable drug derived from a botulinum toxin. It has been sold in Europe at a price cheaper than Botox for several years.

Despite recent FDA warnings that these products could spread beyond the injection site and lead to botulism poisoning, nearly 2.5 million Americans had Botox injections in 2008 for cosmetic reasons. Here's what you need to know before your next dermatologist's visit:

When available: The companies that develop and license Dysport say they plan to make it available in the United States within 60 days.

What is it? Injectable botulinum toxins are purified forms of the bacterial poison that causes botulism, a paralyzing disease that can be fatal. The drugs temporarily reduce or halt <u>muscle activity</u>.

Warnings: A day after approving Dysport, the FDA issued an order that Dysport and Botox must now carry the most stringent kind of warning labels that explain the material has the potential to spread from the injection site to distant parts of the body -- with the risk of serious difficulties, like problems with swallowing or breathing. Requiring a drug to carry a box with bold-face risk information -- a so-called blackbox warning -- is one of the strongest safety actions the FDA can take. It's usually reserved for medications known to have serious or life-



threatening risks, such as antidepressants.

Is it safe? The FDA began its safety review of botulinum-based products after being petitioned by the public advocacy group Public Citizen. The group says there have been 180 serious health problems and 16 deaths connected to the injections. But an FDA official in a press conference last month said the problems have occurred mainly in patients who received overdoses of the drug for unapproved treatments, like limb spasticity in children with cerebral palsy. Botulinum toxins are safe when administered for approved uses at approved doses, the FDA says.

Accepted uses: In the last 20 years, the FDA has approved Botox to treat crossed eyes, eyelid spasms, severe underarm sweating, and cervical dystonia, a neck problem that can cause severe pain and abnormal head position. Under the name Botox Cosmetic, the drug is also approved to treat frown lines. The agency recently approved Dysport for frown lines and cervical dystonia.

More info: Read about the FDA's ongoing safety review at <u>www.fda.gov/cder/drug/earlycom ... niumtoxins200904.htm</u>.

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