

## Medication Safety Alert

- MEDICATIONS:** Botox® and Botox Cosmetic® (Botulinum toxin Type A), Allergan  
Myobloc® (Botulinum toxin Type B), Solstice Neurosciences
- DOSAGE FORMS:** Botox® (Botulinum toxin Type A) 100 unit Injection  
Botox Cosmetic® (Botulinum toxin Type A) 100 unit Injection  
Myobloc® (Botulinum toxin Type B) 5000 unit/mL Injection
- ISSUE:** A follow-up alert to an ongoing safety review of botulinum toxin products; the FDA will require strengthened warnings on product labeling, a boxed warning, a Risk Evaluation and Mitigation Strategy (REMS), and patient Medication Guide be included with botulinum toxin products.

### The following was posted on the FDA Med Watch Web site on April 30, 2009:

“(The) FDA notified healthcare professionals that, after an ongoing safety review initiated in February 2008, the manufacturers of licensed botulinum toxin products will be required by (the) FDA to strengthen warnings in product labeling and add a boxed warning regarding the risk of adverse events when the effects of the toxin spread beyond the site where it was injected.

(The) FDA will also require that manufacturers develop and implement a Risk Evaluation and Mitigation Strategy [REMS], including a communication plan to provide more information regarding the risk for distant spread of botulinum toxin effects after local injection, as well as information to explain that botulinum toxin products cannot be interchanged. The REMS would also include a Medication Guide that explains the risks to patients, their families, and caregivers. (The) FDA is requiring the manufacturers to submit safety data after multiple administrations of the product in a specified number of children and adults with spasticity to assess the signal of serious risk regarding distant spread of toxin effects.

### Recommendations

(The) FDA’s evaluation of the data continues to support the recommendations made in the [2008 Early Communication](#); that healthcare professionals who use botulinum toxin products should:

- Understand that dosage strength (potency) expressed in “Units” or “U” are different among the botulinum toxin products; clinical doses expressed in units are not interchangeable from one botulinum toxin product to another.
- Be alert to and educate patients and caregivers about potential adverse events due to distant spread of botulinum toxin effects following local injections including: unexpected loss of strength or muscle weakness, hoarseness or trouble talking (dysphonia), trouble saying words clearly (dysarthria), loss of bladder control, trouble breathing, trouble swallowing, double vision, blurred vision and drooping eyelids.
- Understand that these adverse events have been reported as early as several hours and as late as several weeks after treatment.
- Advise patients to seek immediate medical attention if they develop any of these symptoms.

**A complete copy of the accompanying “Ongoing Safety Review Update” dated April 30, 2009 from the FDA may be viewed at:**

[http://www.fda.gov/cder/drug/early\\_comm/botulinium\\_toxins200904.htm](http://www.fda.gov/cder/drug/early_comm/botulinium_toxins200904.htm)