

Important Change in BabyBIG® Lot 7 Dosage Information

FDA is issuing this notification to provide important information regarding the dosage for BabyBIG® [Botulism Immune Globulin Intravenous (Human), BIG-IV], manufactured and distributed by the California Department of Public Health (CDPH). BabyBIG® is the only FDA-approved human plasma-derived antitoxin for the treatment of infant botulism caused by toxin types A or B in patients less than one year of age.

Changes to the production of BabyBIG® using recombinant botulinum vaccine for serotypes A and B (rBV A/B) as the source plasma booster immunogen resulted in increased antibody titers against type A and type B botulinum neurotoxins. The increased titers, combined with the need to extend the availability of Lot 7, support the reduction of Lot 7 dose from 1.0 mL/kg (50 mg/kg) to **0.4 mL/kg** (20 mg/kg). FDA does not object to this change.

The new total dosage represents a 60% reduction from the previous dosage and ensures that patients will continue to receive an effective dose for anti-type A and anti-type B antitoxin activity, while maintaining continuous supply of BabyBIG®.

New Dosage Information

The current dosage for this lot of BabyBIG® is **0.4 mL/kg** (20 mg/kg), changed from the prior dose of 1.0 mL/kg (50 mg/kg).

Contact Information:

If you have questions about this letter, contact the California Department of Public Health at (510) 231-7600 (24/7/365), or the Office of Therapeutic Products/CBER at OTPRPMS@fda.hhs.gov.