Important Changes in BabyBIG® Lot 8 Dosage and Administration Information

FDA is issuing this notification to provide important information regarding the dosage and administration changes for BabyBIG® Lot 8 [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.

Summary of changes for Lot 8 Dosage and Administration :

- The new recommended dose for BabyBIG® Lot 8 is **0.4 mL/kg** (20 mg/kg), administered as a single intravenous (IV) infusion as soon as the clinical diagnosis of infant botulism is made. This recommendation supersedes the dose recommended in the Prescribing Information which was 1.0 mL/kg (50 mg/kg).

- 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, compared to historical levels. The increased antibody titers, along with efforts to maintain an adequate supply of Lot 8, support the new dosing adjustment.

- Use the sterile, disposable 0.2-micron filter provided with the shipment for administration. The 0.2-micron filter replaces the 18-micron filter that was supplied with previous lots of BabyBIG®.

- The filter change is supported by comprehensive filtration studies using the new disposable filter for BabyBIG®.

New Dosage and Administration Information Summary

The new recommended dose for BabyBIG® Lot 8 is 0.4 mL/kg (20 mg/kg).

A new sterile 0.2-micron filter is supplied for infusion of BabyBIG®.

Changes to the dosing and in-line filter ensure effective BabyBIG® activity, safety, and continuous supply. FDA does not object to the dosage reduction for Lot 8 and implementation of the new disposable filter.

Contact Information:

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