State of California—Health and Human Services Agency
California Department of Public Health

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Director & State Health Officer

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IMPORTANT CHANGE IN BabyBIG® PRESCRIBING INFORMATION

Dear Healthcare Provider:

The California Department of Public Health (CDPH) would like to inform you of important changes regarding its public service orphan drug BabyBIG® [Botulism Immune Globulin Intravenous (Human)].

The BabyBIG® prescribing information has been updated with the following changes to the dosing and administration instructions:

- The recommended total dosage of BabyBIG® is now **1.0** mL/kg (**50** mg/kg), given as a single intravenous infusion as soon as the clinical diagnosis of infant botulism is made.
- At the recommended rates, infusion of the indicated dose should take **67.5** minutes total elapsed time.

This dosage change is based on recent potency determinations of the activity of the neutralizing antibodies against botulinum neurotoxins type A and B in the product. The Clinical Pharmacology section of the prescribing information and the carton labeling have been revised to indicate that the titer of antibodies against type B botulinum toxin is at least **4.0** IU/mL. The current dose ensures that patients will receive at least the minimum proven effective dose for anti-type B toxin activity.

BabyBIG® is indicated for the treatment of infant botulism caused by toxin types A or B in patients less than one year of age. Based on clinical experience with other IGIV products, BabyBIG® is not recommended for patients with a prior history of severe reaction to other human immunoglobulin preparations or with selective immunoglobulin A deficiency. Subsequent administration of blood products containing immunoglobulin A should be avoided following administration of BabyBIG®. Patient renal function should be assessed prior to and following administration. In patients predisposed to renal failure, BabyBIG® should be administered at the minimum concentration available and at the minimum rate of infusion practicable. As with all IGIV administrations, anaphylaxis, hypersensitivity and aseptic meningitis syndrome should be monitored for following administration. Also, as with other plasma-derived products, transmission of blood-borne viral agents is a possibility.

CDPH remains committed to providing you with the most current product information available for the management of your patients. Please refer to the enclosed package insert for full prescribing information. As always, we request that any serious adverse events be immediately reported to CDPH at (510) 231-7600 (24/7/365).

Sincerely,

Stephen S. Arnon, M.D.
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