Generic Name:
Pentavalent (ABCDE) botulinum toxoid
Trade Name:
No trade name
Company:
CDC
Notes:

In today's *MMWR*, CDC announced that on November 30 it will stop providing the investigational pentavalent (ABCDE) botulinum toxoid (PBT) for vaccination to workers at risk for occupational exposure to botulinum serotypes. The agency cited evidence of declining immunogenicity, decreased product potency, increased occurrence of injection site-related adverse reactions, and the age of the product in explaining its decision. For recent vaccinees who need to complete the primary series, the investigational new drug application will remain in effect through May 31, 2012.

CDC summarized data showing that protective antibody levels against all toxin serotypes decline rapidly and that revaccination was required at 6 months, after the initial primary series of 0, 2, and 12 weeks, and that an annual booster was also needed to obtain adequate protection. Those data prompted a change in the initial primary series in 2004 to include vaccinations at 0, 2, and 12 weeks, and 6 months as the the new primary series with a required annual booster to acheive a robust enough immune response.

As a result of this modified schedule, moderate local skin reactions rose from 12.4% in 2005 to 31.0% by 2010. No increase in severe local reactions was observed.

Once this investigational product is discontinued, no replacement botulism vaccine will be available in the U.S. A recombinant botulism vaccine is being developed by the Department of Defense Chemical Biological Medical Systems Joint Project Management Office.

Medication Monitor Categories:
Product Withdrawals