




DEPARTMENT OF HEALTH AND HUMAN SERVICES
U.S. Food & Drug Administration, Forensic Chemistry Center, 6751 Steger Dr., Cincinnati, OH 45237 (513) 679-2700

Case Summary

Date August 29, 2005
From Timothy Y. Yi, Lead Analyst, Organic Branch, Forensic Chemistry Center (HFR-CER501)
Subject Result of Analysis, FACTS #310992 and #310993
To Deborah B. Nixon, CSO
NWJ-DO, ORA/FDA
Thru R. Duane Satzger, Ph.D., Director Organic Branch 
Forensic Chemistry Center (HFR-CER501)

I. Description of Samples Received for Analysis

FACTS Sample Numbers 310992 and 310993 were received by FCC via FedEx shipment on January 4, 2005. The sample number 310992 consisted of one glass vial with gray rubber stopper. The glass vial was commercially labeled in part "BOTULINUM NEUROTOXIN TYPE A ... 500 IU (mouse LD50's) 5.0ng ... TOXIN RESEARCH INTERNATIONAL", and contained a small amount of clear, free-flowing liquid. The sample number 310993 consisted of twenty five translucent plastic vials with green flip-off caps with the exception of one vial. Each plastic vial was commercially labeled in part "0.9% SODIUM CHLORIDE INJ., USP FOR USE AS A STERILE DILUENT.... ABBOTT LABORATORIES" and contained free-flowing liquid.

II. Analytical Tests Performed on Samples

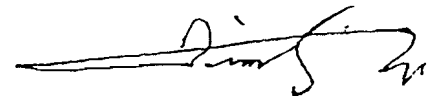
Enzyme-Linked Immunosorbent Assay (ELISA) was used to screen for the presence of botulinum neurotoxin type A (BoNT/A) in the contents of the glass vial from sample number 310992. Subsequently, ELISA was used to determine the presence and amount of purified BoNT/A. Hemagglutinin 33 of BoNT/A complex (Hn 33A) analysis has not been performed which can be used to discriminate between complex and purified form of BoNT/A. No analyses were performed on the samples labeled to contain sodium chloride (#310993).

III. Results of Analyses

The contents of the glass vial (#310992) tested positive for BoNT/A, and the amount of BoNT/A was 518 pg/ml measured as the purified form.

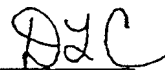
IV. Sample Retention/Disposition Information

This evidence will be kept in FCC custody until directives are received from your office for disposition. Please contact me at (513) 679-2700 x200 if there are questions.




Timothy Y. Yi, Chemist

David L. Craft, Ph. D
Team leader



cc Susan J. Leeds, Special agent, Miami Field Office, OCI/FDA

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