



Food and Drug Administration
OFFICE OF CRIMINAL INVESTIGATIONS
MEMORANDUM OF INTERVIEW

[REDACTED]

DOCUMENT NUMBER: 85856

PERSON INTERVIEWED: Karen Crawford

PLACE OF INTERVIEW: 540 Division Street, Campbell, CA

DATE OF INTERVIEW: 12/09/2004

TIME OF INTERVIEW: 7:00 pm

INTERVIEWED BY: SA Susan Leeds and CSO Susan Turcovski

OTHER PERSONS PRESENT: None

KAREN CRAWFORD, President of List Biological Laboratories, Inc. ("List"), Campbell, CA, was interviewed during the execution of a search warrant at the premises of List. After being apprised of the identities of the interviewing agents, CRAWFORD voluntarily provided the following information.

On January 27, 2003, List received an internet inquiry from POWDERZ. They originally wanted 10 micrograms, but then negotiated a five-nanogram vial, which is 500 units. POWDERZ wanted a larger vial. They supplied the vials and enclosures. POWDERZ also wanted List to add albumin to the product. List manufactured three lots of the botulinum due to the capacity of its lyophilizer. These three lots were from the same bulk that was diluted on different dates. For lots 13025D1 and 13025E1, the label was placed on the foam wrapped around the vial. CRAWFORD was under the impression POWDERZ was doing some sort of test kit with the toxin, and the quantity they were ordering would be some type of control.

List was contacted by another firm in southern California interested in a similar arrangement [to the one with POWDERZ]. The name of the firm was [REDACTED] and the contact person was [REDACTED]. When [REDACTED] expressed that it might inject the botulinum in humans or ship it to Saudi Arabia, List notified their contact person at the CIA.

List just moved into this building [located at 540 Division Street, Campbell, CA], and is not manufacturing right now. They have applied to the CDC to transfer their license from the old office location to this new office. CRAWFORD displayed a List price list and explained that all products designated with footnote 1 are Select Agents. For some of these, there are exemptions from the Select Agent requirements at certain levels.

In selling its products, List's first contact with customers usually occurs on the internet. They receive orders from businesses, such as those manufacturing test kits that use List's products as controls. CRAWFORD cited as an example a company that would want to test an anthrax vaccine. Allergan orders botulinum from List to use as a control.

List does not do any research to ensure a customer is using a product as they said they would. In making sales, they use some intuition. They recently received an order from Florida, either earlier that day or the day before, in which they called back and got a home answering machine. CRAWFORD expressed a willingness to work on the company's sales process to ensure product ordered is used as intended.

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The sales representatives for List are: Christina Amaro, Nancy Ferguson, and Debbie Renshaw. The List sales representatives are not given any training regarding questioning customers about their intended use of the products. Debbie Dye of List would know whether the sales representatives maintain the order forms. The computer at the receptionist desk is used to log in sales.

List orders Shiga toxin from Japan. It manufactures all of the other select agents.

Debbie Dye told CRAWFORD that POWDERZ was using the botulinum toxin to do a test kit. The toxin is used as a positive kit. Dye said POWDERZ seemed to understand the toxin, and know what they wanted and the difference between nanograms and micrograms.

CRAWFORD had no direct conversations with POWDERZ. Debbie Dye had most of the interaction with them. Linda Eaton spoke with them regarding CDC standards. The botulinum was custom-manufactured for POWDERZ. They never told Debbie Dye that they were going to inject it into humans.

All manufacturing at List is done at BL3 [Biosafety Level 3, which requires gowning, safety glasses, gloves, hair cover, and mouth and beard cover]. POWDERZ supplied human albumin. The botulinum was shipped to POWDERZ via FedEx. The vials were shipped to POWDERZ with List's own label. The first lot they attached the labels to the vials with scotch tape. The last two lots List attached the labels to the foam wrapped around each vial.

In some cases, List will send vials without labels, depending on the agreement with the client. In those cases, they would label the package.

List does no sterility testing of the botulinum, and the company makes no claim regarding the sterility of the botulinum.

NAME-TITLE *Susan J. Leeds* NAME-TITLE _____
Susan J. Leeds, Special Agent

DATE 7/14/05 DATE _____

APPROVED: *David W. Bourne*
David W. Bourne, SAIC

DATE: 7/15/05



ATTACHMENTS: None