

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 04-61717-CIV-COHN

UNITED STATES OF AMERICA

Plaintiff,

vs.

DR. CHAD LIVDAHL, N.D., DR. ZARAH
KARIM, N.D., TOXIN RESEARCH
INTERNATIONAL, INC., POWDERZ,
INC., THE COSMETIC PHARMACY,
INC., and Z SPA, INC.,

Defendants.

**DECLARATION OF FDA SPECIAL AGENT LUIS PEREZ, IN SUPPORT OF THE
UNITED STATES'S MOTION FOR PRELIMINARY INJUNCTION**

I, Luis Perez, hereby declare and state as follows:

1. I am employed as a Special Agent with the United States Food and Drug Administration (FDA), Office of Criminal Investigations (OCI) in Plantation, Florida. I have been in my current position since October 2000. I was previously employed for approximately 4 years as a Special Agent with the Department of Defense, United States Army Criminal Investigation Division.
2. On December 19, 2004, I contacted by telephone Shannon Alderman, a former employee of Toxin Research Institute (TRI) located in Tucson, Arizona. Ms. Alderman advised me that she worked at TRI from approximately mid-October 2003 through mid-December 2003. Ms. Alderman advised me that in October 2003, TRI hired her to videotape a three

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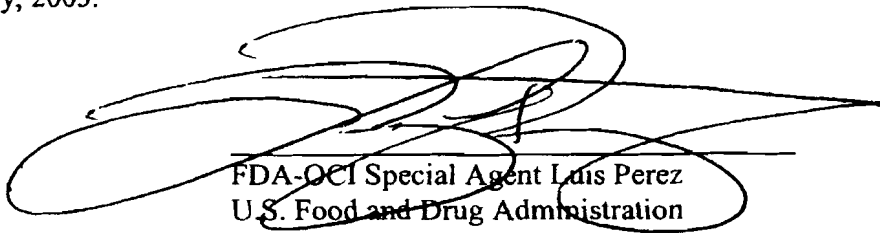
day TRI and Powderz Inc. sponsored conference held at the El Conquistador Resort located in Tucson, Arizona.

3. Ms. Alderman stated that she took approximately 12 MiniDigital videotape (MiniDV) recordings of the conference. After editing the videos, she provided them to Livdahl. Ms. Alderman stated that approximately 30 to 50 Dermatologist and/or Spa owners attended the three-day conference.
4. Ms. Alderman's responsibilities also included answering the telephones at TRI. Ms. Alderman stated that TRI provided her with a script to read to customers who called TRI. The script instructed her to tell customers that TRI sold a "very stable reconstituted form of Botulinum Type A."
5. Ms. Alderman stated that Livdahl purchased customer lists to promote TRI and Powderz, Inc.'s products. TRI and Powderz promoted their products and seminars through mass e-mailing, faxing, and mailing to prospective customers. Ms. Alderman informed me that Powderz, Inc., sold raw-grade pharmaceuticals for medical compounding and that TRI sold toxins like Botulinum Neurotoxin Type A to doctors and spas around the nation.
6. Ms. Alderman informed me that Livdahl told her that all of the Botulinum Neurotoxin Type A vials were purchased from a company in California. Ms. Alderman stated that Livdahl told her that the California company did not know that TRI was selling the Botulinum Neurotoxin Type A vials to doctors, but that the company thought it was being used for research purposes only.

7. Your affiant asked Ms. Alderman about an email dated December 10, 2003 sent by "clivdahl1@comcast.net" to <Shannon@powderz.com> which made reference to FDA's Center for Drug Evaluation and Research (CDER) (Attached as Exhibit 1). Ms. Alderman stated that she received this email from Livdahl after she informed him about a telephone call that she had received from a doctor in Vermont who had received information from TRI/Powderz. The doctor asked whether TRI/Powderz had a license to sell the generic versions of botox and other types of products that they had advertised. When Ms. Alderman told the doctor that TRI/Powderz did not have a generic license, the doctor refused to purchase TRI/Powderz's products. Ms. Alderman informed Livdahl about the doctor's questions regarding TRI/Powderz's generic licensing. In response, Livdahl asked her to research how TRI/Powderz could obtain a generic license from the FDA. Ms. Alderman stated that she called the FDA to find out how to apply for a generic license and conducted her own research via the Internet. She learned that in order to obtain a license to sell generic drugs a company must demonstrate to the FDA that the product is safe. Ms. Alderman informed me that she relayed all of the information that she learned about the generic licensing requirements to Livdahl.
8. Ms. Alderman informed me that a few days after she provided Livdahl with the information about the generic licensing requirements she was fired.

Pursuant to Title 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this 7th day of January, 2005.



FDA-OCI Special Agent Luis Perez
U.S. Food and Drug Administration

From: "clvdahl" <clvdahl1@comcast.net>
To: <Shannon@powderz.com>
Cc:
Sent: Wed, 10 Dec 2003 03:17:38 -0700
Subject: oder

Hi Shannon:

When on the phone with CDER, please question if we can apply for a generic even though our product does not have the same units as botox (we have 500 per vial and botox has 100), but each unit is equivalent and we will be submitting studies to demonstrate that 1 unit of their is equal to 1 unit of ours.

I hope this makes sense... We should know if this is going to be ok before we initiate the process...

Here is what the CDER states:

FDA works with pharmaceutical companies to assure that all drugs marketed in the United States meet specifications for identity, strength, quality, purity, and potency. Before approving a generic drug product, CDER requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug.

CDER bases evaluations of substitutability or "therapeutic equivalence" for generic drugs on scientific evaluations. By law, generic drug products must contain the identical amounts of the same active drug ingredient as the brand name product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand name product. FDA considers drug products to be substitutable if they meet the criteria of therapeutic equivalence, even though the generic drug may differ in certain other characteristics (e.g., shape, flavor, or preservatives).

We will be at a new accountant's in the morning, feel free to call if you need anything.

Thanks, CHad

GOVERNMENT EXHIBIT
CASE NO. 04-61717- COHN
EXHIBIT NO. 1