

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA

CASE NO. \_\_\_\_\_

04 - 61777 CIV-COHN MAGISTRATE JUDGE SNOW

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.

**MEMORANDUM OF LAW IN SUPPORT OF UNITED STATES EMERGENCY  
MOTION FOR TEMPORARY RESTRAINING ORDER,  
PRELIMINARY AND PERMANENT INJUNCTION**

**I. Introduction:**

Plaintiff, the United States of America, by and through the undersigned Assistant United States Attorney, files this memorandum of law in support of its motion for a temporary restraining order, preliminary and permanent injunction pursuant to 21 U.S.C. § 332(a), and 18 U.S.C. § 1345. This lawsuit seeks to enjoin the defendants, Dr. Chad Livdahl, N.D., individually, Dr. Zarah Karim, N.D., individually, Toxin Research International, Inc., Powderz Inc., and The Cosmetic Pharmacy, Inc., from continuing to violate the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 331(a), by causing the introduction or delivery for introduction into interstate commerce of a drug, as defined in 21 U.S.C. § 321(g)(1), which is

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The principals of TRI (as well as Powderz and The Cosmetic Pharmacy), defendants Chad Livdahl and Zarah Karim, specifically told FDA investigators that their product was sent only to individuals conducted in non-human research, and thus they did not have to register an IND (Investigational New Drug) or an NDA (new Drug Application) with the FDA. (Affidavit, ¶ 13). However, the overwhelming evidence is that defendants intended to, and did market and distribute their product in interstate commerce as a drug; i.e. an article intended to affect the structure and/or function of the body of man. 21 U.S.C. § 321(g)(1)(C).<sup>3</sup>

When FDA Consumer Safety Officer ("CSO") Randall Johnson conducted his investigation of TRI in October 2004, Dr. Karim did not respond to CSO Johnson's question regarding whether the physicians purchasing the product were performing their research on humans, animals, or tissue cultures. (Affidavit, ¶14).<sup>4</sup> According to the Establishment

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<sup>3</sup>The Interstate Commerce prong of the FDCA, (much like the other elements of the FDCA), is clearly satisfied. "Interstate commerce" is defined as "commerce between any State or Territory and any place outside thereof." 21 U.S.C. § 321(b)(1). Thomas P. Toia, an employee of Advanced Integrated Medical Center, Inc., ("Advanced Integrated"), 1655 E. Oakland Park Boulevard, Fort Lauderdale, Florida, 33334, since September 2003, whose father was the owner of the center, was responsible for ordering medical supplies for the clinic, including, at the direction of doctors, drugs. He stated that on two to four occasions, he ordered vials of Botulinum Toxin Type A from TRI for Advanced Integrated by telephone, and received such orders through an interstate carrier, UPS. (Affidavit, ¶ 18). Additionally, FDA investigators executing the federal search warrant on TRI found copies of five (5) invoices in the FDA search of TRI, dated December 1 and 2, 2004, and completed order forms for TRI's Botulinum Neurotoxin Type A reflecting sales to: Dr. Robert West at the Almos Heights Skin Clinic in San Antonio, Texas; Dr. Martha Gonzalez, Physician and Surgeon, Ventura California; Dr. Kreg Jensen, Physician and Surgeon, Oren Utah; and Dr. Herbert Smyczek, Newark, New Jersey. (Affidavit, ¶ 17g.). Also, Dr. Martin Blau, from New York and Dr. Herve Gentile from Texas, stated they purchased the product from TRI. (Affidavit, ¶¶ 20, 21).

<sup>4</sup>According to the EIR, FDA initiated the inspection upon receiving a complaint from a cosmetic surgeon in Tennessee, who advised the FDA he had been receiving literature from TRI which the doctor believed to be in furtherance of a fraudulent business scheme involving the sale of Botox. (Affidavit, ¶ 13).