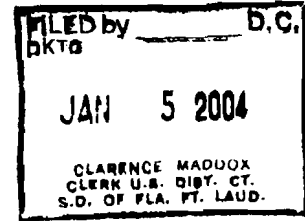


UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

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 REGISTERED NURSE ANITA D'ENTREMONT IN SUPPORT OF
UNITED STATES' MOTION FOR PRELIMINARY INJUNCTION

I, Anira D'Entremont, hereby declare and state as follows:

1. I am a Registered Nurse, employed at Hudson Dermatology, at the office of Dr. Neera Agarwal-Antal, M.D., Board Certified Dermatologist, 1325 Corporate Drive, Suite A, Hudson, Ohio, 44236. I have been so employed since April 29, 2002.
2. In January, 2004, I received an advertisement in the mail from Toxin Research International, Inc., (TRI) for Botulinum Toxin Type A. The advertisement offered, "A Very Stable Clostridium Botulinum Toxin Type A." I did not notice the labeling that stated it was for research purposes only, not for human use. (Exhibit 1).
3. I then called TRI to inquire further about their product. When I called TRI, I spoke to a male representative. I introduced myself, and stated that I was calling on behalf of a dermatologist's office. I explained to the TRI representative that I was unhappy with the

results our office had gotten in using Allergan's BOTOX® COSMETIC in the treatment of wrinkles. I then asked what the recommendations were for storage, shelf life, and reconstitution for TRI's product.

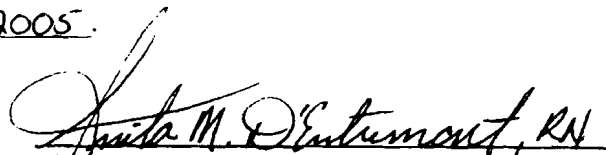
4. The male TRI representative responded to all of my questions. At no time did he inform me that their product was not for human use. He explained that TRI's product was no different than Allergan's product, and that multiple doctors' offices were using TRI's product.
5. I then requested an order form from TRI. TRI sent it to me. Once received, on February 6, 2004, I placed an order for 1 Vial, 500/IU Vial, of TRI's Botulinum Toxin Type A, for \$1,250.00. (Exhibit 2)
6. Approximately two and a half weeks later, TRI's product arrived. When the Botulinum Toxin Type A arrived, I notice that the labeling said it was for research purposes only, and not for human use.
7. On February 24, 2004, I then attempted to contact a representative at TRI. I called and left a message. I explained that I was calling on behalf of a dermatologist's office, and had no use for their product, because we did not conduct research, rather we treated patients. I then requested a refund.
8. In response, I received a fax, dated February 24, 2004. (Exhibit 3). The fax stated that the company was refusing to refund the purchase money. It stated, "We have clearly marked everywhere you look on our product, website and printed material that it is a research product. We must state that for legal purposes to protect ourselves. Our product is simply Botulinum Toxin Type A which is exactly the same as any Botulinum Toxin

Type A that you used in the past.” The fax went on to apologize for any inconvenience, and concluded by stating, “We hope you find some use for our product, and again, we apologize, but all sales are final.”

9. After receiving this fax, I called TRI back. I spoke to a female representative. I again reiterated that I was calling from dermatologist’s office, and had no use for a product whose only function was for research. The TRI representative responded that all sales were final. I then safely disposed of TRI’s product into a sealed biohazard sharps container, and did not administer it to any patients.
10. On December 23, 2004, I received a facsimile at Dr. Agarwal-Antal’s office, from TRI, dated 12/22/04. (Exhibit 4) The facsimile was an advertisement for TRI’s Botulinum Toxin Type A. It also stated, in bold writing, that if the incident [in Florida] had affected our research in a negative manner, that TRI would be obliged to send us one (1) complimentary 500 IU (5ng) vial with our next order. Upon receipt of this facsimile, I immediately notified FDA Special Agent Tina Stasulli Korb, and forwarded a copy of this advertisement to her.

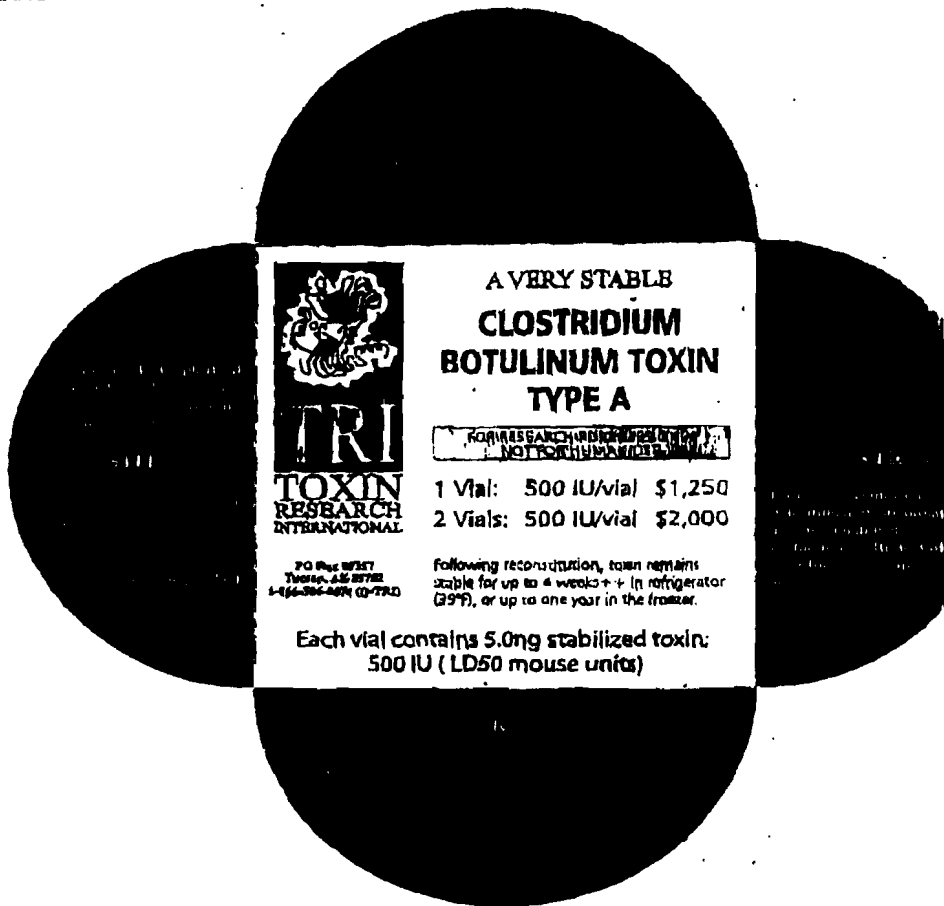
Pursuant to Title 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this 3 day of January, 2005.


Anita D'Entremont
Registered Nurse

Nancy C. Pullen
Commissioner, Appeals
7/25/07

DEC. 14. 2004 4:36PM NEERA AGARWAL ANTAL



**GOVERNMENT
 DONOR**
1

DEC. 14. 2004 4:37PM NEERA AGARWAL ANTAL

NO. 958 P. 4/16

**BOTULINUM
NEUROTOXIN
TYPE A**

with a PURSE and STABILIZED
in applying the Research Field

SPECIALIZING



NO. 10017
Tampa, AZ 05753
1-800-306-0174 (TAN)

SPECIALIZED

ORDER

Amazing Offer!

BOTULINUM TOXIN TYPE A

GUARANTEED
or your money back

DEC. 14. 2004

4:38PM

NEERA AGARWAL ANTAL



**TOXIN
RESEARCH
INTERNATIONAL**

Client Name: HUDSON DERMATOLOGY

Date: 2.6.04

Order Form

Print and use this form when ordering by mail or fax.
Please also include a copy of your credentials.
FOR RESEARCH PURPOSES ONLY

Toxin Research International, Inc.

P.O. Box 89357, Tucson, AZ 85752
Tel. 1-866-306-0874 Fax. 520-572-7814

(1 Vial: 500 IU/Vial \$1,250)
(2 Vials: 500 IU/Vial \$2,000)

(MasterCard, Visa, or Check)

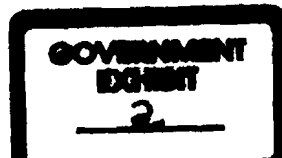
- * Credit Card Number: 4264 2942 2486 6998 Exp. Date: 02/07
- * Name on Card: NEERA P AGARWALANTAL
- * Address Card is Billed to:
1325 CORPORATE DR. STE. A
- * City: HUDSON State: OH Zip: 44236
- * Email: NANTAL@HUDSONDERM.COM
- * Person Ordering: NEERA AGARWAL-ANTAL, MD / ANITA M. DENTREMONTE
- * Ship to Name: HUDSON DERMATOLOGY
- * Address: 1325 CORPORATE DR. STE. A
- * City: HUDSON State: OH Zip: 44236
- * Telephone: (330)650-4200 Fax: (330)650-6900

QUANT.	DESCRIPTION	PRICE	TOTAL
1 VIAL	500 IU/VIAL	1,250.00	1,250.00

-All items are shipped UPS next day on ice.
-Orders received after 12 pm on Thursday, will be sent on the following Monday. Saturday delivery is available upon request.

DEA: BA 5699840

Handwritten notes:
Toxin
MIS
2.6.04 PAGES



DEC. 14. 2004 4:36PM NEERA AGARWAL ANTAL

NO. 958 P. 2/16



TOXIN RESEARCH INTERNATIONAL, INC.

P.O. BOX 89357 TUCSON, ARIZONA 85752 USA

WWW.TOXINRESEARCH.COM

A Very Stable *Clostridium botulinum* Toxin Type A

Facsimile Transmittal Sheet

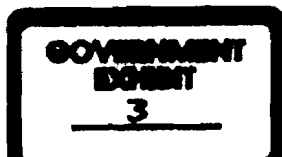
To: Anita	From: Toxin Research International
Company: Dr. Antall	Date: Feb. 24, 2004
Fax Number: 330-650-6900	Pages Including Cover: 3
Phone Number: 330-650-4200	Telephone Number: 1-866-306-0874
RE: Botulinum Toxin A	Fax Number: 1-520-572-7814

Hi there,

We received a call from you today about wanting to return our product due to you not noticing that our product is NOT meant for human use. I spoke to the company manager and accounting department and according to our Company returns policy (which I have attached and it is also on our website we do not make returns based on these conditions). We have clearly marked everywhere you look on our product, website and printed material that it is a research product. We must state that for legal purposes to protect ourselves. Our product is simply Botulinum Toxin Type A which is exactly the same as any Botulinum Toxin Type A that you used in the past. Sorry for any inconvenience it was surely not intended. We hope you find some use for our product, and again we apologize but all sales are final.

Best Regards

Susan.



FOR IMMEDIATE RELEASE 12/22/04 7:00 PM EST



**TOXIN
RESEARCH**
For Research Purposes
Not for Human Use

TOXIN RESEARCH INTERNATIONAL, INC.

P.O. BOX 83357 TUCSON, ARIZONA 85752 USA

WWW.TOXINRESEARCH.COM

Clostridium botulinum toxin type A

December 22, 2004

Dear Sir/Madam:

I am sure that you are all aware of the unfortunate events that have occurred in Florida in recent weeks.

Toxin Research International, Inc. (TRI) would officially like to inform you that it had no involvement in this incident.

The FDA, in fulfilling its duties, evidently felt obligated to investigate TRI. Contrary to the inaccurate statements made by the media, TRI is, and always has, cooperated to its fullest extent with the FDA and its investigation.

We wish to extend to you our deepest apologies for any inconvenience that this may have caused to you and your research as we are aware that product inconsistency and delays during a project may result in invalid outcomes.

Please inform us, in writing if this incident has affected your research in a negative manner. If so, we would be obliged to send you one (1) complimentary 500IU (5ng) vial with your next order.

We look forward to restoring your complete confidence in our product and our company.

We wish you a Happy Holiday Season and a wonderful New Year!

Sincerely,

Dr. Chad Livdahl – CEO
T.R.I.

