U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, D.C. 20590

DEC 11 2009

Mr. Philip Perotti
QA Sr. Manager
Revance Therapeutics, Inc.
7555 Gateway Blvd
Newark, CA 94560

Ref. No. 09-0259

Dear Mr. Perotti:

This responds to your letter requesting clarification of the packaging requirements for toxic substances under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you ask whether any regulatory exceptions apply to shipments of Botulinum Toxin A, a Division 6.1 Packing Group I hazardous material, in quantities of 0.5 mg per shipment. Your questions are paraphrased and answered as follows:

Q1. Do the HMR provide any packaging exceptions for hazardous materials described as "UN3462, Toxins, extracted from living sources, solid, n.o.s., 6.1, PG I"?

A1. No. Packaging exceptions for a hazardous material are specified, if any, in a section or sections identified in Column (8A) of the § 172.101 Hazardous Materials Table (HMT). There is no section referenced in Column (8A) of the HMT entry for "UN3462, Toxins, extracted from living sources, solid, n.o.s., 6.1, PG I."

Q2. Special provision 141 is referenced in Column (7) of the HMT entry for UN3462. How does this special provision impact the proper description or packaging of Botulinum Toxin A?

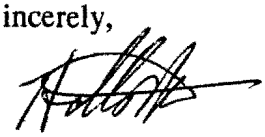
A2. Under § 172.102(c)(1) Special provision 141, if your material also meets the criteria for a Division 6.2 infectious substance, it must be described as UN2900 or UN2814, as appropriate, and packaged in accordance with requirements in § 173.196.

Q3. If Botulinum Toxin A does not meet the definition of an infectious substance, is it eligible for the small quantity exceptions under § 173.4?

A3. Yes, if all the conditions specified in § 173.4 are met.

I trust this satisfies your inquiry. Please contact us if we can be of further assistance.

Sincerely,



Hattie L. Mitchell
Chief, Regulatory Review and Reinvention
Office of Hazardous Materials Standards

Stevens

§173.153
Exceptions
09-0259

Revance THERAPEUTICS

7555 Gateway Blvd.
Newark, CA 94560

p 510.742.3400 f 510.742.3401

www.revance.com

Thursday, October 22, 2009

U.S. Department of Transportation
PHMSA Office of Hazardous Materials Standards
ATTN-PHH-10
East Building
1200 New Jersey Avenue, SE
Washington, DC 20590-0001

Dear Sir or Madam,

Revance intends to manufacture Botulinum Toxin A for commercial sale as a medicine in the future much like commercial Botox® is today; I wish to understand how I can alleviate our current DOT shipping requirement for ID# UN3462; Hazard Class 6.1; Packaging Group I; Provision 141 – we will be shipping commercial scale quantities of our product in the 2011 timeframe and wish to understand what our options are per DOT regulations. We do not intend to ship anymore at one time than the 0.5mg quantities regulated by the CDC APHIS form 2 and the paint-can style packaging is not feasible.

I am referring to CFR 173.153(c)(2) but I do not understand the text in the General section 173.153(a) that states the material is only eligible if it is referenced in the 172.101 Table of the subchapter……I cannot locate anything to this affect.

Can you please help? What is the process of exemption for UN3462 per 173.153?

The DOT operators I get on the phone when I call a DOT helpline are not knowledgeable whatsoever in this regard and do not know where to direct me. I get no response from any email address I have attempted to contact from the website. I have spoken to Mr. William Clark, an FAA Security and Hazardous Materials Special Agent out of the Burlingame, California office on the phone and he has directed me to write this letter and follow-up by phone.

I intend to attempt to contact someone at 1-800-467-4922 after sufficient time has been given to receive and read this letter. If you wish, you can contact me directly by phone or by email.

Regards,

Philip Perotti | QA Sr. Manager

Revance Therapeutics, Inc.
7555 Gateway Blvd | Newark, CA 94560
T 510-742-3448 | F 510-742-3401
pperotti@revance.com | www.revance.com