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December 15, 2005

Mr. Douglas Ingram  
Executive Vice President  
Allergan, Inc.  
2525 Dupont Drive  
Irvine, CA 92612-1599

Via facsimile (714-246-6987) and overnight delivery

Dear Mr. Ingram,

It has been a little over a year since we last communicated. As you know, The HSUS went public with its concerns about the lethal testing of Botox Cosmetic® only after our attempts at fruitful collaboration with Allergan were rebuffed. I want to briefly review HSUS' more recent activities on this issue and propose a course of action for Allergan.

After going public with the campaign, we have taken the following key actions:

- We have sued the U.S. Food and Drug Administration for failing to release documents concerning the regulation of Botox Cosmetic, in response to our Freedom of Information Act requests. This suit is pending.
- We have given a presentation on the Botox situation at the Fifth World Congress on Alternatives and Animal Use in the Life Sciences, held in Berlin in August, and have subsequently written up that presentation for the Congress proceedings. Both the oral and written presentations were in conjunction with the Fund for the Replacement of Animals in Medical Experiments (FRAME).
- More recently, we have “nominated” the lethal testing of Botulinum toxin-based products to the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). Our nomination was discussed publicly at the December 12<sup>th</sup> meeting of ICCVAM’s Scientific Advisory Committee on Alternative Toxicological Methods (SACATM), of which I am a member. In response to the nomination, ICCVAM officials are establishing a Biologics Working Group and planning to hold a workshop to address both the current situation and promising 3R alternative methods. Prior to the planned workshop, ICCVAM will be contacting the manufacturers of Botulinum toxin-based products to discuss relevant issues. ICCVAM will be coordinating its activities with its European counterpart, the European Centre for the Validation of Alternative Methods (ECVAM). The SACATM endorsed this activity as a high priority.

The ICCVAM/ECVAM collaborative project on potency testing of Botulinum toxin products provides an excellent opportunity for Allergan to contribute openly towards developing and validating alternative methods. The HSUS would publicly praise Allergan for taking meaningful action in this regard.

I would be happy to discuss these matters with you. My contact information is as before: tel. 301-258-3040; [mstephens@hsus.org](mailto:mstephens@hsus.org). For your information, the lead staff person at ICCVAM on this issue is Dr. William Stokes (919-541-7997; [stokes@niehs.nih.gov](mailto:stokes@niehs.nih.gov)). Allergan consultant and fellow SACATM member, Dr. Sidney Green, participated in the SACATM meeting and can provide further information on the discussion.

I look forward to hearing from you.

Best wishes,



Martin L. Stephens, Ph.D.  
Vice President for Animal Research Issues

P.S. I will be in Irvine for a meeting at the National Academy of Sciences on Jan. 19 and 20. While I hope to hear from you prior to then, I would welcome an opportunity to meet with you to discuss these issues in person. I probably will arrive on the 18<sup>th</sup>, but I am flexible.