July 29, 2013

Kevin Shea, Administrator
Animal and Plant Health Inspection Service
c/o Regulatory Analysis and Development
Policy and Program Development
Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

HEADQUARTERS
501 FRONT STREET
NORFOLK, VA 23510
TEL 757-622-PETA
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Re: Notice of Request for Revision to and Extension of Approval of an Information Collection; Virus-Serum-Toxin Act and Regulations, Docket APHIS-2013-0011

Dear Mr. Shea,

These comments are submitted on behalf of PETA's more than three million members and supporters who are concerned about the suffering of animals used in laboratory experiments as well as regulatory guidance that includes the use of animal-based testing for biological products. We thank the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) for the opportunity to comment on the revision and extension of approval for information collection regarding the preparation, importation, distribution and sale of veterinary biological products judged "worthless, contaminated, dangerous, or harmful in the treatment of animals." We agree that these information collection activities are necessary to ensuring animal health. **We strongly urge APHIS to ensure that identification of an unsafe product triggers an immediate follow-up inspection of the facility in which the product was produced to ensure that any Animal Welfare Act (AWA) violations that have accompanied the licensure or distribution of unsafe products are identified and corrected**.

While APHIS largely identifies substandard products through the inspection of the products themselves, the information collection activities outlined in this notice make no indication that the production of potentially harmful products raises enough question to prompt concern for the welfare of the animals used by the licensee or permittee. As stated in this notice, 9 CFR 105.3 establishes APHIS' ability to order licensees or permittees to cease production of potentially harmful veterinary biologics. Next outlined in 9 CFR 115.2 and replicating the language from 9 CFR 105.3, APHIS' ability to identify these potentially harmful products is largely via inspections of biological products:

(a) Any biological product, the container of which bears a United States veterinary license number or a United States veterinary permit number or other mark required by these regulations, may be inspected at any time or place. If, as a result of such inspection, it appears that any such product is worthless, contaminated, dangerous, or harmful, the Secretary shall give notice to stop distribution and sale to the manufacturer (licensee) or importer (permittee) and may proceed against such product pursuant to the provisions of part 118 of this subchapter.

While the inspection of these products and the subsequent information collection activities are outlined in both 9 CFR 115.2 and 105.3, inspection of the facilities involved in the production of these potentially harmful products is not stated as a consequence despite clear authority to do so under 9 CFR 115.1:

> (a) Any inspector shall be permitted to enter any establishment where any biological product is prepared, at any hour during the day or night, and shall be permitted to inspect, without previous notification, the entire premises of the establishment, including all buildings, compartments, and other places, all biological products, and organisms and vectors in the establishment, and all materials and equipment, such as chemicals, instruments, apparatus, and the like, and the methods used in the manufacture of, and all records maintained relative to, biological products produced at such establishment.

We commend APHIS for collecting information that assists in tracking veterinary biological products that may cause harm to the animals intended to receive them, and those collection activities should continue. We urge APHIS to consider that the production and distribution of "worthless, contaminated, dangerous, or harmful" veterinary biologics strongly suggests a need for a facility to be inspected for potential AWA violations, such as unsanitary conditions, that may have contributed to the licensee or permittee bringing such a product to market. Considering APHIS' estimation that 220 respondents are required to submit information under 9 CFR 105.3 accounting for such products, we submit that no amount of information collection is complete until the licensees and permittees implicated in such actions are scrutinized in their compliance with APHIS' regulatory requirements under the AWA.

Please do not hesitate to contact me on this important matter. I can be reached by phone at (310) 437-8003 or via email at JeffreyB@peta.org.

Sincerely,

Jeffrey Brown
Research Associate
Regulatory Testing Division