November 9, 2011

Hervé Marion, DVM
VICH Secretariat
c/o International Federation for Animal Health
Rue Defacqz, 1 - 1000
Brussels
Belgium

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

HEADQUARTERS
501 FRONT STREET
NORFOLK, VA 23510
TEL 757-622-PETA
FAX 757-622-0457

Sent via email to sec@vichsec.org

Dear Dr. Marion,

On behalf of PETA's more than three million members and supporters who are concerned about promoting reliable and relevant toxicity testing strategies that protect human health while reducing, and ultimately eliminating, the use of animals in laboratory experiments, we would like to make note of several issues that should be addressed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) at the November 15—17 Steering Committee meeting. We request that you ensure that VICH commits to the development of a harmonized guideline that enables the use of serological and *in vitro* rabies vaccine potency tests, and that the Steering Committee keep us apprised of the development of draft guidelines for *in vitro* extraneous agent testing of avian viral vaccines target animal batch safety testing (TABST).

Serological and *in vitro* rabies vaccine batch potency testing guideline

Regulatory authorities and industry representatives recently convened during an October 2011 ICCVAM workshop to establish a path toward the validation, regulatory acceptance and implementation of serological and *in vitro* replacements for the *in vivo* challenge-based veterinary rabies vaccine batch potency test (NIH test). At the workshop's conclusion, participants agreed that the first priority in moving away from the NIH test is the international agreement on a harmonized approach toward the serological replacement assay. Once agreed-upon serological guidance is validated and implemented internationally, manufacturers and regulators would subsequently correlate an *in vitro* antigen quantification assay with the established serological replacement to eliminate the use of animals for this purpose. Considering the support this proposal received at the workshop, we urge the VICH Steering Committee to commit to the development of guidance that will incorporate a serological potency test as well as a path forward for the eventual implementation of an *in vitro* potency test.

Extraneous Agents testing guideline

Following the VICH Conference 4 in June 2010, the Biologics Quality Monitoring Expert Working Group (BQM EWG) announced its plans to resume work on a draft guideline for EA testing and tentatively scheduled a working group meeting for November of that year, but unfortunately this meeting was postponed. In our September 2010 correspondence, you noted that the Biologicals Quality Monitoring Expert Working Group (BQM EWG) would be

convening a meeting between the end of 2010 and early 2011 to review how to proceed with drafting a harmonised guideline for extraneous agents testing. According the VICH website, the most recent BQM EWG meeting was held in September of this year. Has the BQM EWG begun work on this guideline, and was it discussed at the September 2011 meeting? We see no indication of such work on the VICH website, although it is our understanding that draft guidelines are not announced until they have reached the second step of development, at which point they are submitted to the Steering Committee for review.

Mycoplasma testing guideline

You mentioned in our previous correspondence that the BQM EWG would be meeting in 2010-2011 to finalize the draft guideline on the testing for the detection on mycoplasma contamination (GL 34). Was this guideline addressed at the September BQM EWG meeting? At present, the VICH website indicates that GL 34 has remained at step 3 since September 2007 and, as such, is still awaiting approval for consultation by the Steering Committee. We ask that the Steering Committee address this issue and update us on the progress of this guideline's development.

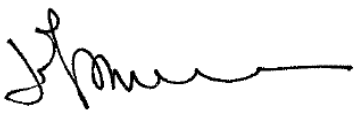
Target Animal Batch Safety Testing (TABST) guideline

Following the September 2011 BQM EWG meeting, VICH updated its website to indicate that the TABST guideline (GL 50) had reached its second step of development and that a draft had been submitted to the Secretariat. We urge the Steering Committee to consider this draft at the upcoming meeting and advance it toward public consultation.

We request that you bring these issues to the attention of the Steering Committee at this month's meeting and, ultimately, to the attention of the members of the BQM EWG prior to their next meeting. I look forward to hearing that VICH will be actively pursuing the development of serological and *in vitro* guidelines for veterinary rabies vaccine batch potency testing, in addition to furthering the development of non-animal guidelines for mycoplasma contamination tests and tests for extraneous agents in avian viral vaccines.

We ask that the Steering Committee consider the current proposed draft of the TABST harmonization guideline and that it be released as soon as possible for public comment. Once the Steering Committee has met, I would appreciate your contacting me directly at (310) 437-8003 or via email at JeffreyB@peta.org regarding these important matters.

Sincerely,



Jeffrey Brown
Research Associate
Regulatory Testing Division