

July 13, 1999

CENTER FOR VETERINARY BIOLOGICS NOTICE 99-17

Subject: International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH): Request for Comments Regarding Proposed Guidelines for Technical Requirements

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

The purpose of this notice is to provide background on methods the Center for Veterinary Biologics (CVB) is using to assist in the development of harmonized international standards for veterinary biologics, to outline the CVB strategy for adopting these harmonized guidelines, and to encourage comments from interested parties on draft guidelines as they are published in the Federal Register.

The International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH) is a unique project that brings together the regulatory authorities of the European Union, Japan, and the United States and representatives from the animal health industry in the three regions to harmonize technical requirements for veterinary products (both drugs and biologics). The VICH initiative is conducted under the auspices of the International Office of Epizootics.

The United States Government is represented in VICH by the Food and Drug Administration (FDA) and the Animal and Plant Health Inspection Service (APHIS). The FDA provides expertise regarding veterinary drugs, while APHIS fills a corresponding role for veterinary biological products. As VICH members, APHIS and FDA participate in efforts to enhance harmonization and have expressed their commitment to seeking scientifically based harmonized technical requirements for the development of veterinary drugs and biological products. One of the goals of harmonization is to identify and reduce the differences in technical requirements for veterinary medicines and biologics among regulatory agencies in different countries, and develop guidelines to clarify uniform requirements. When guidelines apply to veterinary biological products regulated by APHIS under the Virus-Serum-Toxin Act, we will request comments on their provisions through Federal Register publication, so that we may include any relevant public input on the draft in the Agency's comments to the VICH Steering Committee.

VICH guidelines are initiated when the VICH Steering Committee appoints an expert working group to develop recommendations regarding specific technical matters. Draft VICH guidelines will reflect current APHIS thinking on the design and conduct of studies, tests, and procedures for the production and evaluation of veterinary biological products. Once the draft of a guideline has been approved by the Steering Committee, the guideline will be circulated for comment and consultation; in the U.S., this will include the publication of notices in the Federal Register. In accordance with the VICH process, the working group will take comments into consideration in preparing a revised draft guideline, which will then be recommended for adoption by the regulatory bodies of the European Union, Japan, and the United States. As with all VICH documents, the guidelines, once finalized, will not create or confer any rights for or on any person and will not operate to bind APHIS or the public. Further, the VICH guidelines will specifically provide for the use of alternative approaches if those approaches satisfy the requirements of applicable regulatory requirements. Ultimately, APHIS intends to adopt the VICH Steering Committee's final guidance documents, and publish them for use by U.S. veterinary biologics licensees, permittees, and applicants. In addition, APHIS may also use the final guidance documents as the basis for proposed additions or amendments to its regulations in 9 CFR subchapter E (Viruses, Serums, Toxins, and Analogous Products; Organisms and Vectors). Given that we anticipate that the applicable provisions of guidelines will be introduced into APHIS' veterinary biologics regulatory program in the future, we encourage your comments on the draft versions of these guidelines.

Persons with access to the Internet may obtain additional information regarding the VICH from their web page at "<http://www.vich.eudra.org>".

/s/ James E. Tanner
for

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics