



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 31 2003

Mr. Alexander S. Mathews
President and CEO
Animal Health Institute
1325 G Street NW
Suite 700
Washington, D.C. 20005-3104

Re: Docket No. 93P-0337

Dear Mr. Mathews:

This is the final response from the Food and Drug Administration (FDA) to the Animal Health Institute's Citizen Petition filed September 14, 1993 (Docket #93P-0337). The petition was addressed to both the FDA and the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA). FDA issued an interim response to the petition on March 14, 1994. Despite the amount of time that has elapsed since the initial Citizen Petition was filed, the issues you raised are still pertinent.

Your petition asks that FDA (and APHIS) publish for notice and comment as a proposal any agreed changes to the memorandum of understanding (MOU) dated May 7, 1982 between the USDA and FDA. The MOU concerns the jurisdiction over animal health products between the two agencies. Your petition further requests that FDA amend 21 C.F.R. § 510.4, regarding products subject to the Virus, Serum and Toxin Act (VSTA) by adopting substitute language that was appended to the petition. Finally, the petition asks that APHIS amend the definition of "biological products," contained in 9 C.F.R. § 101.2. APHIS published a final rule amending the definition of "biological products," on June 9, 1997 (62 FR 31326). FDA reviewed and concurred in the APHIS definition. Thus, this latter request was granted by APHIS.

We agree that certain portions of the 1982 MOU do not reflect the revisions to 9 C.F.R. § 101.2. We are working with APHIS to produce a revised MOU. However, at the present time we do not plan to publish a revised MOU for public comment, and therefore we deny your request. We will, however, publish a copy of the MOU in the Federal Register in accordance with FDA regulation 21 C.F.R. § 20.108(c) and agency practice.

We also deny your request with respect to revision of the regulation 21 C.F.R. § 510.4. The regulation states that an animal drug produced and distributed in full conformance with the VSTA and regulations issued under the VSTA shall not be deemed to be subject to Section 512 of the Federal Food, Drug, and Cosmetic Act (FFDCA). You proposed that the regulation be amended to state that an animal drug product intended to be used as an animal biological product, and subject to the VSTA and regulations issued under the VSTA, shall not be deemed to be subject to the FFDCA.

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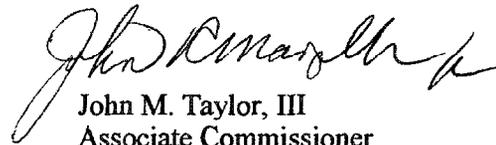
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Your petition states that there may have been some justification for the wording in 21 C.F.R. § 510.4 before the 1985 amendments to the VSTA, but that the amendments gave APHIS comprehensive authority to regulate animal biologics and the enforcement tools to do so effectively. We agree that the 1985 VSTA amendments addressed the VSTA's limitations with respect to intrastate manufacturers, inspectional authority and enforcement remedies. However, the FFDCA definition of "drug" continues to include animal biological products. This has been confirmed by case law both before and after the VSTA amendments. Congress had opportunities to change the definition of "drug" in 1938 (passage of the FFDCA), 1968 (amendment of section 902(c) of the FFDCA as part of the Animal Drug Amendments) and 1985 (amendments to VSTA), but did not do so.

Your petition contends that section 902(c) of the FFDCA means animal biologics "are not covered by the FDC Act." That section states that nothing in the FFDCA is to be construed as in any way "affecting, modifying, repealing or superseding" the provisions of the VSTA. However, Congress did not use exempting language when it adopted section 902(c), as it did in section 902(b) with regard to meats and meat food products. Thus section 902(c) does not exempt from the FFDCA products subject to the VSTA. FDA would not take any action with respect to an animal biologic that would affect, modify, repeal, or supersede the VSTA, but "animal biologics may be subject to regulation by the FDA, under appropriate circumstances." *United States v. Pro-Ag, Inc.*, 968 F.2d 681, 683 (8th Cir. 1992).

For the foregoing reasons, we deny your citizen petition.

Sincerely yours,



John M. Taylor, III
Associate Commissioner
for Regulatory Affairs