

VETERINARY SERVICES MEMORANDUM DRAFT NO. 336

TO: Veterinary Services Management Team
Directors, Center for Veterinary Biologics
Biologics Licensees, Permittees, and Applicants

FROM: John R. Clifford
Deputy Administrator

SUBJECT: Electronic Freedom of Information Act Involving Veterinary Biological Products

I. PURPOSE

This memorandum provides guidelines concerning the Center for Veterinary Biologics (CVB) implementation of the Electronic Freedom of Information Act (EFOIA) as it applies to materials submitted to the CVB by manufacturers for new veterinary biological products. See Veterinary Services Memorandum No. 800.66, *Freedom of Information Act Requests Involving Veterinary Biological Products*, for guidelines pertaining to confidentiality.

II. BACKGROUND

The Freedom of Information Act provides for the right of public access, enforceable in court, to federal agency records, except for certain records protected from disclosure by one of nine exemptions or one of three exclusions. Since its enactment in 1966, the Freedom of Information Act has been amended seven times (1974, 1976, 1978, 1984, 1986, 1996, and 2007). With each amendment, the original Act has been broadened to encompass additional information deemed necessary to the public, including the oversight of the federal government. Specifically, under the Electronic Freedom of Information Act Amendments of 1996 (EFOIA), Pub. L. No. 104-231, 5 U.S.C. § 552 (as amended), federal agencies are required to automatically make certain categories of information available to the public in electronic form. As a result, the CVB will prepare and publish electronic summaries for all efficacy and safety studies used to support licenses, permits, and product revisions for public access via the agency's website.

III. POLICY

The CVB will publish summary data and information submitted by the licensee/permittee to support label claims approved by the agency during the licensing process. The EFOIA summary will be drafted by the CVB staff and reviewed by the manufacturer for accuracy. The summary shall provide safety/efficacy data and information in sufficient

detail to show the basis on which the agency approved the biological license or permit. At license issuance, EFOIA summaries will be made public through the CVB website (www.aphis.usda.gov/vs/cvb). Such summaries will not constitute the full reports of experimental investigations. Confidential business information such as manufacturing methods and sales or distribution information, will not be publicly disclosed. In addition, the CVB will make public all approved labeling and environmental documents (e.g., Environmental Assessment or Environmental Impact Statement) associated with each product.

IV. GUIDELINES

- A. Purpose of EFOIA Summaries—The EFOIA summaries are designed to provide an outline by which results of pivotal studies conducted and consequently approved by the CVB will be published as meeting licensing requirements of a veterinary biologic product.

Since the intent of the EFOIA is to inform the public at large of the basis for CVB licensure of a biological product, the EFOIA summary must be written clearly and, as much as possible, in language that the average person can understand. However, this does not mean that scientific accuracy or detail will be sacrificed, nor does it preclude the use of medical or scientific terms.

The CVB will provide information related to each significant item included in the summary, as described in Section IV.E. below.

- B. Release of Safety and Efficacy Data—When a product is licensed, a summary of the efficacy and safety information accepted to support the approval of the license application will be publicly released by the CVB in accordance with the EFOIA of 1996. The CVB reviewer for the firm will prepare a summary that will be posted on the CVB web site.

For products licensed prior to the implementation of this policy, a standard statement will be provided to indicate that licensing was based on the firm meeting general licensing requirements. If additional claims are added to an existing product, a summary will be written summarizing the data generated to support approval of the new claim.

- C. Approvals Requiring an EFOIA Summary

1. An EFOIA summary will be released after license issuance for all products licensed once/after the implementation date is published by the CVB. A summary is required for all newly licensed products, including those supported by reference to data in previously licensed products. In situations where the CVB believes that a previously prepared summary is relevant to a newly licensed product, the CVB may cross-reference to earlier summaries.

2. Additional claims for previously licensed products. An EFOIA summary will be released for each supplemental submission that affects safety and/or efficacy. If an EFOIA summary for the original claim(s) exists, it will be linked to any additional summaries to be posted for new/additional claims.

D. Public Display of Documents by the CVB—The EFOIA summaries, together with the approved labeling and if pertinent, environmental documents (e.g., Environmental Assessment or Environmental Impact Statement), will be placed on public display in the EFOIA section of the CVB web site at the time the product license is issued. New summaries for previously licensed products will be posted upon study approval.

All EFOIA summaries will be released to the licensee/permittee to review for accuracy prior to publication on the CVB website. Licensees and permittees should provide comments on the summaries to their respective reviewer within 2 weeks of receipt. If there are no comments received within the 2 week timeframe, the summary will be posted as written.

E. EFOIA Summary Format

1. *Efficacy/DOI studies:*

- Establishment Number
- Product Code/True Name
- Study Identifier
- Submission Date
- Study Purpose
- Number and volume of product doses/timing and route of administration
- Number of animals/group, type of animals, and age at first vaccination
- Challenge organism and dose, method and timing of challenge
- Description of outcome/results
- APHIS conclusions/Label claim approved

2. *Safety studies:*

- Establishment Number
- Product Code/True Name
- Study Identifier
- Submission date
- Study Purpose
- Number and volume of product doses/timing and route of administration
- Number of animals/group, type of animals: age, sex, weight, etc., at first vaccination
- Pertinent parameters used to measure adverse events, duration of observations
- Results

- Adverse Events: If adverse events were encountered, they will be fully described. If no adverse events were observed, a statement to that effect will be included.
- APHIS conclusions

F. Exemption from the Electronic Freedom of Information Act:

All summaries are considered public knowledge, subject to the APHIS Policy Statement on the Protection of Privileged or Confidential Business Information (APHIS Notice 85-406). If the licensee/permittee considers certain summary information to be exempt from the provision of the Freedom of Information Act, (5 USC 552), a statement describing the specific adverse effects they would experience if any portion of the summary was disclosed should be provided to the CVB for consideration.