

October 21, 1999

VETERINARY SERVICES MEMORANDUM NO. 800.66

Subject: Freedom of Information Act Requests Involving
Veterinary Biological Products

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

I. PURPOSE

This memorandum provides guidelines concerning Animal and Plant Health Inspection Service (APHIS) implementation of the Freedom of Information Act (FOIA) as it applies to materials submitted to the Center for Veterinary Biologics (CVB) by manufacturers of veterinary biological products.

II. CANCELLATION

This memorandum cancels Veterinary Services Memorandum No. 800.66 dated May 7, 1985.

II. BACKGROUND

APHIS receives requests under the FOIA for materials that are submitted to CVB by manufacturers of veterinary biological products in support of applications for licenses, permits, and product revisions. In many instances, the submitters (manufacturers) do not want some of these materials to be disseminated because they consider them to be confidential.

Under the terms of the FOIA, as interpreted by the courts, APHIS has the sole responsibility for determining whether the material is confidential within the meaning of the FOIA. The courts have determined that information submitted to the Government is confidential if its release would be likely either: (1) to impair the Government's ability to obtain necessary information in the future or (2) to cause substantial competitive harm to the submitter.

If a manufacturer would like APHIS to protect information from disclosure, each submission containing information to be protected must be accompanied by a statement indicating specific reasons why release of the information is likely to cause substantial harm to the competitive position of the submitter.

III. GUIDELINES

A. Confidentiality Statements from the Manufacturer

The burden placed on the Government to sustain withholding of information is high. Therefore, the manufacturer's accompanying reasons for withholding information should directly specify how release of a particular piece of information would be likely to substantially harm a competitive position. Mere conclusive statements have consistently been held to be insufficient to satisfy the Government's burden.

1. *Content of Confidentiality Statements* - Confidentiality statements should be specific and complete.

a. Specify the parts, sections, paragraphs, lines, or words in each document the manufacturer considers confidential.

b. Include the reasons that disclosure of the specified information would cause substantial harm to the competitive position of the manufacturer.

2. *Presentation of Confidentiality Statements* - Manufacturers should provide confidentiality statements with Outlines of Production, outline page revisions, labels, facilities documents, protocols, data, and other materials that they consider confidential as follows:

a. Include the statement in Section VI. E. of new and completely revised Outlines of Production.

b. Add the statement to the summary of changes page when submitting outline page revisions.

c. Include the statement in the body of protocols, data submissions, production and test reports, comments on program directives, and facilities documents.

d. Include the statement on mounting sheets for label sketches and prelicense labels.

B. APHIS Processing

APHIS will process requests for information concerning veterinary biological products under the FOIA as follows:

1. The APHIS FOIA Coordinator will review all the information related to the request for confidentiality.

2. Disclosure of information related to the request for confidentiality will be made only after consultation with the licensee, permittee, or applicant.

/s/ Thomas E. Walton for

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