September 17, 1999

VETERINARY SERVICES MEMORANDUM NO. 800.57

Subject: Market Suspensions

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

I. PURPOSE

This memorandum provides guidance for taking action to stop the distribution and sale of released serials or subserials of veterinary biological products according to 9 CFR 105.3(b) and 115.2.

II. CANCELLATION

This memorandum cancels Veterinary Services Memorandum No. 800.57 dated November 14, 1986.

III. BACKGROUND

Information may emerge indicating that the purity, safety, potency, or efficacy of a particular serial(s) or subserial(s) of a licensed veterinary biological product or of an entire licensed product is questionable or unsatisfactory. Such information may come from inspection findings, an investigation, an adverse event report, or tests conducted by the Center for Veterinary Biologics (CVB) or by the licensee or permittee. Action to stop distribution and sale of product may be necessary to prevent a risk to the health of animals, to the public health or well-being, or to the environment. The level of the action to stop distribution and sale will depend on the actual or potential adverse impact created by use of the product. The level may change as more information becomes available.

IV. PROCEDURES

A. APHIS Actions to Stop Distribution and Sale

When the Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) has reason to believe a product may be unsatisfactory, CVB-IC will make all determinations, notifications, and disposition instructions to licensees and permittees concerning all actions to stop distribution and sale.

1. *CVB-IC Notification* - CVB-IC will notify the licensee or permittee to stop distribution and sale at one of the following levels:

a. Premises of the licensee or permittee; or

b. All branches and distribution points of the licensee or permittee; or

c. All wholesalers and distributors known to have received the product; or

d. All persons known to have received the product.

2. *Licensee or Permittee Actions* - When notified to stop distribution and sale of a serial or subserial, the licensee or permittee must take the following steps:

a. Stop further distribution and sale.

b. Send warnings by telegram, telephone, or other immediate communication method to each person at the level established in the CVB-IC notification.

c. Request a report of the quantity of the product at each location.

d. Document each communication in writing.

e. As instructed by CVB-IC, either submit a copy of each communication and reply to CVB-IC or maintain such documents as part of the firms records as specified in 9 CFR 116.1 and 116.2.

f. Hold the product pending disposition instructions from CVB-IC.

B. Licensee and Permittee Actions

1. If at any time, there are indications which raise questions regarding purity, safety, potency, or efficacy of a product, or if it appears that there may be a problem regarding preparation, testing, or distribution of a product, the licensee. permittee, or foreign manufacturer shall immediately inform CVB-IC according to 9 CFR 116.5.

2. When a product is found unsatisfactory by a licensee or permittee, the licensee or permittee must take action to stop distribution and sale as specified in IV. A. 2. a-f, above.

a. *Notify CVB-IC of Action* - The licensee or permittee should notify CVB-IC at the time such action is taken.

b. *Notify CVB-IC of Method of Disposition* - The licensee or permittee should also notify CVB-IC of the proposed method of disposition of the product at least 48 hours in advance.

C. Exported Products Subsequently Found Unsatisfactory

1. *Notification of Consignees* - When an exported serial or subserial is subsequently found unsatisfactory, the licensee or permittee must notify all consignees that the product has been found unacceptable for marketing in the United States.

2. *Notification of National Government Officials* - If an APHIS Form 2017, Official Export Certificate for Animal Biological Products, was issued for a serial or subserial subsequently found unsatisfactory, CVB will notify the appropriate National Government officials of the importing country that the product has been found unacceptable for marketing in the United States.

/s/ Thomas E. Walton for

Alfonso Torres
Deputy Administrator
Veterinary Services