December 22, 1999

VETERINARY SERVICES MEMORANDUM NO. 800.62

Subject: Relabeling, Rebottling, and Reprocessing Veterinary Biological Products

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

I. PURPOSE

This memorandum describes acceptable procedures for relabeling, rebottling, and reprocessing serials of biological products according to 9 CFR 112.1, 114.14, 114.17, and 114.18.

II. CANCELLATION

This memorandum cancels Veterinary Services Memorandum No. 800.62, dated December 10, 1997.

III. GENERAL

The Directors, Center for Veterinary Biologics (CVB), may authorize licensees and permittees (firms) to relabel, rebottle, and reprocess veterinary biological products under the following conditions.

A. Procedures Must Not Adversely Affect Product Quality.

B. Firms Must Submit Requests to CVB

Submit requests and documents for serials of licensed products to the Center For Veterinary Biologics-Inspection and Compliance (CVB-IC). Submit requests and documents for serials of prelicense and outline revision products to the Center for Veterinary Biologics-Licensing and Policy Development (CVB-LPD).

C. Firms Need Written CVB Authorization

To relabel, rebottle, or reprocess products, firms must have written CVB authorization that includes a description of any special conditions and stipulations. If a firm uses the APHIS Form 2008, Veterinary Biologics Production and Test Report, as a request or as documentation, the firm must not release the serial until CVB-IC has reviewed and processed the form indicating the serial is eligible for release.

IV. RELABELING

Firms must obtain written authorization from CVB before relabeling product to change the number of doses per container or to show a new expiration date on a serial of product. Relabeling guidelines are as follows:

A. Relabeling to Change the Number of Doses

Firms may change the number of doses per container on the label only if fill volume, lyophilization procedures, and containers for the product indicated in the filed Outline of Production are identical for both dose sizes.

1. *Supporting Materials* - The licensee must submit a supplementary APHIS Form 2008 for each serial or subserial that is relabeled to show inventory adjustment and, if appropriate, relevant test data.

2. *Increases in the Number of Doses per Container For Released Serials of Product* - If relabeling to show an increase in the number of doses per container for a released serial of product:

a. The firm must submit an APHIS Form 2008 for the serial to CVB-IC that includes the results of retests conducted on the serial to support the increase in the number of doses per container. CVB-IC will process the APHIS Form 2008 according to Veterinary Services Memorandum No. 800.53.

b. The firm must also submit amended labels to CVB-L, Biological Materials Processing Section Sample Repository, for each sample of the serial previously submitted to CVB-L with an APHIS Form 2020 that states: “Labels submitted for Sample No.(number previously assigned by CVB to the sample). Relabel to show an increase in the number of doses per container.”

c. CVB may request additional samples of the serial for testing.

B. Relabeling to Show the New Expiration Date

When relabeling in conjunction with a firm’s request to extend the expiration date of a serial, the firm must submit a supplementary APHIS Form 2008 to CVB-IC for each serial showing appropriate test data and the new expiration date. Note on the APHIS Form 2008 the inventory amounts, the location of the inventory, and, if appropriate, the method of relabeling.

C. Relabeling for Other Purposes

Firms may relabel serials of product for purposes other than to change the number of

doses or to show new expiration dates without special authorization. Label records maintained according to 9 CFR 116.3 must reflect all the procedures followed.

V. REBOTTLING

Firms that rebottle a released serial or portions of a released serial must identify such serial with a new serial number, appropriately retest the serial, and select new samples from the serial according to 9 CFR 113.3. The firm must also submit an APHIS Form 2008 to CVB-IC for each rebottled serial with test data and adjusted inventory.

VI. REPROCESSING

A. Definition of Reprocessing

After all the ingredients that make up the serial have been combined according to the procedures indicated in the Outline of Production and the product is in its final form and composition, making any modifications is considered reprocessing.

B. Authorization Required

Except as provided in section VI. D. of this memorandum, firms must obtain authorization from CVB-IC before reprocessing a serial of product.

C. Requests for Authorization

Firms should submit their request for authorization to reprocess a serial of product to CVB-IC. Such request must describe the methods to be used for reprocessing and state the proposed serial number the firm will assign to the reprocessed serial. Firms must also submit a completed APHIS Form 2008 for the serial with each request.

D. Authorized Reprocessing Procedures

If two serials of product are produced according to the same Outline of Production, a firm may add one serial of product to the other in order to adjust the content of antigen without prior approval from CVB-IC. In this case, both serials should be formulated within the specifications provided in the Outline of Production. The firm should identify the serial numbers of the serials added together and state the reason the initial serial of product was reprocessed in section 11 of the APHIS Form 2008 submitted for this reprocessed serial. If the firm has submitted samples for a serial that is used for such reprocessing procedures to CVB, the firm must submit an APHIS Form 2008 for that serial to CVB-IC, marking the appropriate disposition in Block 13.

E. Prohibited Reprocessing Procedures

CVB will not authorize the reprocessing of contaminated product.

F. Release Procedures

CVB will release reprocessed serials of product according to Veterinary Services Memorandum No. 800.53. The Center for Veterinary Biologics-Laboratory may conduct confirmatory tests on reprocessed serials of product.

/s/ Thomas E. Walton for

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