

**United States Department of Agriculture
Center for Veterinary Biologics**

Standard Operating Procedure

Extension of Dating – Biologics Compliance Assistant Procedures

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Contact: Becky R. Rasmussen, (515) 663-7483 x138

Approvals:

/s/Steven A. Karli
Steven A. Karli, Director
Inspection and Compliance
Center for Veterinary Biologics

Date: 23May07

/s/Rebecca L.W. Hyde
Rebecca L.W. Hyde, Section Leader
Quality Assurance
Center for Veterinary Biologics

Date: 25May07

United States Department of Agriculture
Animal and Plant Health Inspection Service
P. O. Box 844
Ames, IA 50010

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Extension of Dating – Biologics Compliance Assistant Procedures

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1. Purpose

The Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) may authorize a manufacturer to extend the expiration date of a biological product, in accordance with the Code of Federal Regulations, Title 9 (9 CFR) Section 114.14. This document outlines the procedure followed by the Biologics Compliance Assistant (BCA) for processing these dating extensions.

2. Procedures for Completing an Extension of Dating (EOD) Worksheet

2.1 The BCA must verify release of the serial that the firm is requesting to extend the dating on and verify that no previous EODs have been granted for this serial. The APHIS release information (NBT/SAT) must be notated by the BCA in the “Remarks” Section of the IC copy of the APHIS Form 2008 (Form 2008), along with the BCA’s initials and date.

2.2 The BCA initiates an extension of dating worksheet (**ICFRM0107**), a serial status (Veterinary Biologics Information System [VBIS], Menu Item [REDACTED]), a photo copy of the previously released Form 2008 from the file room, and the current Outline of Production (the Policy, Evaluation, and Licensing [PEL] copy if available) to fill out the top portion of the worksheet.

2.3 The original expiration date that is required on the worksheet is obtained from the serial status report. This information should be verified by the copy of the previously released Form 2008 that has been pulled from the file room.

2.4 Potency requirements for the different fractions of the product can be found in Section V.C. of the Outline of Production.

2.5 The “Maximum Permitted Extension” is calculated from the date the potency test was started and adding the expiration dating period from Section VI.C. of the Outline of Production.

2.6 After the top portion of the worksheet is completed by the BCA, the worksheet, Outline of Production, serial status, and copy of the previously released Form 2008 are put in a purple folder and given to the Biologics Specialist (Specialist) that is currently assigned to the firm.

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3. Processing the Worksheet and Database Entry after Specialist Approval

3.1 After the Specialist approves the EOD request, the BCA will go into the VBIS and choose menu item **■** and do a “C” for change. The BCA enters the first 3 fields in the screen and hits the numerical “Enter”. This will pull up the existing serial record in the system. Tab down to the note field of the record and type in the following verbiage: Example – **EOD APPRV**/(name of Specialist) **FROM 10/22/04**, (date is derived from the expiration date field on the record) **3581 doses extended** (doses off the newly submitted Form 2008 requesting the EOD). The BCA will also put his/her initials at the end of the note in the VBIS.

3.2 If the request is approved, the new expiration date from the newly submitted Form 2008 is changed in the expiration field of the VBIS record. **Do not change the doses in the dose field.**

3.3 The BCA processes the Form 2008 according to the conclusion checked on the worksheet by the Specialist.

3.3.1 If the Specialist approves the EOD, the paper is processed as follows:

- APHIS disposition is marked “Other” and the BCA stamps “Extension of Dating Approved” on both copies of the Form 2008s.
- The BCA verifies that the Specialist has signed both copies of the Form 2008 if approved for processing.
- The BCA initials the top of IC copy of the Form 2008 which indicates that the computer work (note on the VBIS) and the paper copy have been processed.
- The BCA staples the IC copy of the Form 2008 EOD to the top of the original released Form 2008 from the file room and re-files in test folder “A” regardless of where the original Form 2008 was retrieved from.
- The BCA completes the IC Document Tracking Database and initials the top of the worksheet when this is completed. After the entry into the database is completed, the BCA submits the worksheet to the IC-Office Automation Assistant (IC-OAA) to be reviewed for quality before filing.

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3.3.2 If instructions are other than approved, please check with the Lead BCA, Product Manager, or the Inspection Section Leader regarding additional instructions on processing the request.

3.4 Recording and Mailing Back the Form 2008

If Form 2008s have been processed for serial release that day for the firm for which the EOD has been done, the EOD (Product Code and Serial Number) can be notated on the existing Action Sheet for that firm and sent back with their other releases for that day. If no other Form 2008s have been processed for the firm that day, an Action Report is prepared as follows: a blank piece of paper with the Establishment Number, Product Code, Serial Number, the date and BCA initials. This is completed by the BCA who processed the EOD and is filed in the BCA Serial Release pending drawer just as the other action sheets are filed.