



**Animal and Plant
Health Inspection
Service**

Veterinary Services

**Center for Veterinary
Biologics**

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Serial Release - Extension of Dating - Process

Document Number: CVB-WI-0117

Revision: 02

Previous Number: ICWI0107.04

Vault: CVB-Released

Section/Area: CVB-WI-IC

Effective Date: 07 Nov 2022

Notes:

Extension of Dating – Process

Background:

Extension of expiration dating for a serial or subserial is allowed for in accordance with title 9, *Code of Federal Regulations* (9 CFR), part 114.14. This is part of the regulatory flexibility built into the 9 CFR regulations.

Most steps follow the outline as listed in **CVB-SOP-0032**, *Processing Serial Records*, with the following additions.

Biologics Compliance Assistant (BCA) Initial Review:

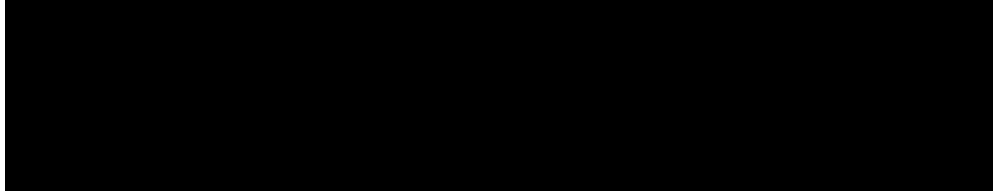
1. The BCA reviews the information on the incoming APHIS Form 2008 (2008) request (hardcopy or NCAH Portal submission) for accuracy and completeness. The **CVB-FRM-0099**, *Extension of Dating Worksheet (9 CFR 114.14)*, is used to document the review.
2. The BCA may audit the submission back in accordance with the current version of **CVB-WI-0104**, *Audits and Reference Slips for IC Documents*, for the following reasons:
 - a. The proposed new date is longer than allowed for under the maximum permitted extension;
 - b. Results of all potency tests for the fractions listed in the Outline of Production (OP) are not included on the 2008 – see Section V.C. in the OP for the list of fractions;
 - c. If the location of the containers is not included in the submission;
 - d. If the location of the containers is off premises and there is no letter attached explaining why;
 - e. If the serial has not been previously released;
 - f. If the submission is otherwise incomplete.
3. If the submission is not audited back, it should be submitted to the Specialist for review, with the reason to Specialist as “EOD”.
 - a. **CVB-FRM-0099** should be filled out and uploaded as an attachment
 - b. If hardcopy 2008 submission for the EOD, include 2008

Specialist Review:

1. Review submission in accordance with the regulations listed in 9 CFR 114.14. All fractions must meet or exceed the potency release requirement(s) listed in the OP.
2. Review the information.
3. NOTE – EOD IS NOT GRANTED for products containing a rabies fraction.
4. If testing is going to be requested, contact the firm and request new samples be submitted prior to approval of the request.

5. If the OP does not indicate that expiration dating has been confirmed for this product, use the following guidelines when making decisions:

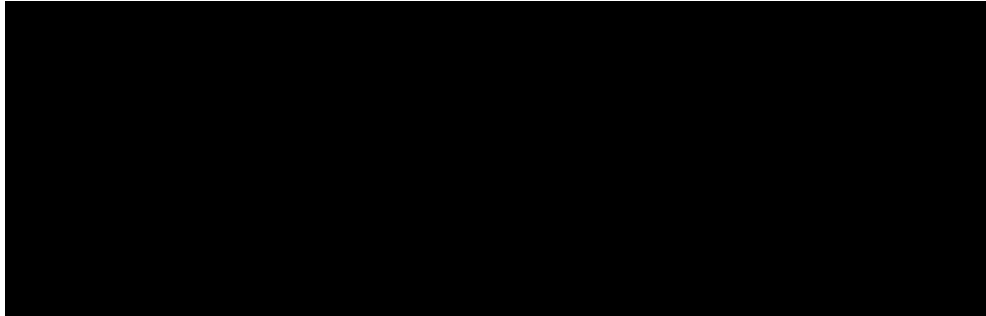
- a. Has the product been licensed for a sufficient period of time to allow for real-time stability data to be generated?



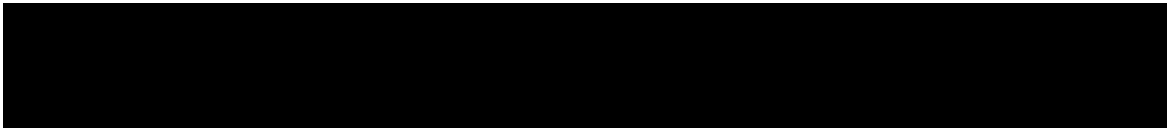
- b. Has data been submitted to PEL and pending review?



- c. Has PEL responded to a data submission requesting additional information regarding confirmation of dating?



6. Are the fractions, in general, stable? [Yes/No] This may require communicating with the antigen expert at the laboratory.



8. Review test results of the originally released 2008 and determine if there has been a significant drop in potency. This is most useful with live virus titrations and live bacterial counts but may also be beneficial in situations in which serology or relative potency is used as the potency test.

9. Compare the number of doses requested for extension to the original released inventory. This may provide some insight.

NOTE:

- Just because they request an EOD does not mean we need to grant it or grant it for the length of dating they request. We may want to consider not granting another full dating period. (If CVB shortens the expiration date, an audit is required with a note stating how long will be granted for the firm to resubmit).
- Only ONE extension of dating can be allowed per serial.
- We may also consider testing the product at the CVB-Laboratory.
- We may consider adding release criteria on the serial for the firm to test at mid and/or end of dating

10. Submit the 2008 (electronic and/or hardcopy) to the BCA for finalization.

Signature Manifest

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All dates and times are in Central Standard Time.

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Review for Doc Format

Name/Signature	Title	Date	Meaning/Reason
TIANA BLANCO (TABLANCO)	Quality Management Assistant	03 Nov 2022, 01:17:42 PM	Approved

Final Quality Check

Name/Signature	Title	Date	Meaning/Reason
CROSLEY HERR (CRHERR)	QA Specialist/CVB MC SME	07 Nov 2022, 01:31:51 PM	Approved