

## 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 **ICSOP0010**, *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 **ICFRM0107**, *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 **ICWI0075**, *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 are not included on the 2008 – see Section V.C. in the outline of production 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 can be submitted to the Specialist for review.
  - a. **ICFRM0107**
  - b. If hardcopy 2008 submission for the EOD, include 2008
  - c. If originally released 2008 is hardcopy, make a copy
  - d. If originally released via NCAH Portal, print off Serial Stat – Export Profile

### 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 outline of production.
2. Review the information listed on **ICFRM0107**.
3. NOTE – Extension of Dating IS NOT GRANTED for products containing a rabies fraction.

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4. If testing is going to be requested, call the firm and request new samples be submitted prior to approval of the request.

5. If the outline of production does not indicate that stability has been confirmed for this product, use the following guidelines when making a decision:

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

Yes – Deny Request and ask the firm to submit a timeline in which data will be generated for submission to Policy, Evaluation, and Licensing (PEL) regarding confirmation of dating.

No – Ask if the firm has data to support the extension of dating requested.

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

Yes – discuss the submission with the PEL Reviewer. If the firm has provided evidence of a satisfactory potency result, you may grant the extension.

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

Yes – Determine if the request for data (what kind of data) outweighs the data submitted in support of the extension of dating. You may consider their extension.

NOTE – This may be a situation that would warrant mid-dating potency testing and submission of results to you, or granting an extension other than full dating. You may add **RELEASE REQUIREMENTS**, see current version of **ICWI0048, Section I. d. viii. 2.**

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

7. Is the potency test an adequate indicator of stability? [Yes/No] For example, live virus titrations or live bacterial counts can provide information about antigen degradation. Animal test may not provide information about antigen degradation.

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.

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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 extension of dating 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.
- Only ONE extension of dating can be allowed per serial.
- We may also consider testing the product at CVB-Laboratory.

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