

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

Standard Operating Policy/Procedure

Processing of Prelicensing Serials by Inspection and Compliance

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Processing of Prelicensing Serials by Inspection and Compliance

Table of Contents

- 1. Purpose and Scope**
- 2. Definitions/Acronyms**
- 3. Responsibilities**
- 4. Processing Prelicensing Serials**
- 5. Summary of Revisions**

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Processing of Prelicensing Serials by Inspection and Compliance

1. Purpose and Scope

The purpose of this document is to describe the processing of APHIS Form 2008 (Form 2008) submitted in support of licensure, after receipt from the Center for Veterinary Biologics (CVB) Policy, Evaluation, and Licensing (PEL).

2. Definitions/Acronyms

2.1 Form 2008: Veterinary Biologics Production and Test Report, or an equivalent approved by the Animal and Plant Health Inspection Service (APHIS), reports the entire testing summary for one serial or subserial submitted to CVB as prelicensing serials and/or serials eligible for marketing. Form 2008A is used as a continuation page for summaries requiring more than one page.

2.2 Licensing, Serial Release, Testing, and Inspection System (LSRTIS): This oracle-based system is the information management system used by the CVB. It is accessed through the Internet Explorer, located at

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2.3 CVB Mail Log: The CVB Mail Log provides an electronic workflow/processing system, capable of utilizing hard copy or electronic documents, and created with flexibility to shift workflow processes as program needs necessitate. It is accessed through the Internet Explorer, located at

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2.4 Mock Form 2008 (Mock): This computerized Form 2008 is completed by Inspection and Compliance (IC) Biologics Specialists (Specialists) or PEL staff for each product, based on tests required by Section V of the stamped Outline of Production (OP). Electronic copies of the mocks are found within the LSRTIS system.

3. Responsibilities

3.1 If a Form 2008, or acceptable equivalent, is submitted in support of licensure, the firm will note the purpose clearly in Block 11. Upon review by PEL, the Mail Log record with the form will be forwarded to IC (see the current version of **ICWI0240**, *Receipt of "Electronic Submissions" from PEL APHIS Form 2007s and APHIS Form 2008*). Except for the 7-day or 3-day limit on the initiation of confirmatory tests by the CVB Laboratory, procedures will then be the same as for market serials. Prelicense submissions will be held by APHIS pending issuance of the product license and/or establishment license if a prelicense firm, or permit if a foreign manufacturer (Veterinary Services Memorandum 800.53).

3.2 The Biologics Compliance Assistant (BCA) receives the notification from the Mail Log system for licensure actions by PEL. The LSRTIS record for the prelicense

Processing of Prelicensing Serials by Inspection and Compliance

serial will also move into the BCA Ready for Approval area, if the Form 2008 has been reviewed by a Specialist. The BCA compiles all licensing documentation, and processes the release of prelicensing serials.

4. Processing Prelicensing Serials

4.1 If Section V testing is complete and the Forms 2008s are submitted by the firm with all Section V testing and other information completed, the Form 2008s should be entered into LSRTIS. Move the 2008 to the Specialist Review area, after BCA Initial Review within LSRTIS, for the Specialist to review the Form 2008 with the OP and mock. The category Prelicense should be automatically chosen by LSRTIS.

4.2 If a mock has not been created at this time, give to the Specialist to create a mock. **ALL prelicense serials must be checked against the mock and initialed by the Specialist PRIOR to release in LSRTIS.**

4.3 If the Form 2008s have been entered and reviewed previously, and the license has been signed by PEL, this would prompt the movement of the 2008 into the BCA Ready for Approval. These serials are ready for release.

4.4 The Serial Status report will indicate the disposition of the prelicense serials, if tested. The LSRTIS system should indicate the disposition the BCA should process the Form 2008s (SAT, UNSAT).

4.5 The BCA processes the Form 2008s as follows: “Prelicense - Tests Completed SAT”, “Prelicense - Tests Completed UNSAT”, “Prelicense – Expired”, or “Prelicense Serial - Release for Market”.

4.6 The BCA submits the Form 2008s to the Specialist for signature, and the Specialist will release the serials in LSRTIS.

The Lead BCA or Product Specialist should be consulted if there are questions regarding processing.

4.7 The BCA sorts through the prelicense folder and sends the required documents to the File Room for filing (see the current version of **PIMSSOP0037**, *Filing Procedure Guidelines for Center for Veterinary Biologics [CVB] Inspection and Compliance [IC] and Policy, Evaluation, and Licensing [PEL]*).

4.8 **Note:** The Email Notification for Serial Release (ENSR) will be sent out to the firm, only if the firm has a valid email address in the LSRTIS system (see the current version of **ICWI0239**, *Process for Email Address for Electronic Notification of Serial Release*).

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Processing of Prelicensing Serials by Inspection and Compliance

5. Summary of Revisions

Version .02

- HP3000 was replaced with LSRTIS.
- Incorporated the use of Mail Log.
- The document was updated to reflect current procedures

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