Veterinary Services
Safeguarding Animal Health

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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Quarterly Submission Acknowledgement Summaries

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Notes:

Quarterly Submission Acknowledgment Summaries

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1. Purpose and Scope

The Center for Veterinary Biologics (CVB) distributes quarterly acknowledgement summaries for firms without portal access, in lieu of individual regulatory response letters, for routine or minor submissions to Policy, Evaluation, and Licensing (PEL) that are not considered time sensitive and to which the CVB does not take exception. Every submission to the PEL is acknowledged either by individual letter, portal notice (firms that are portal-enabled) or quarterly acknowledgement summary.

Associated guidance: CVB Notice 13-02

2. Eligibility for Inclusion

Any submission logged out without response will be included on the summary. The reviewer determines eligibility of individual submissions for inclusion in the quarterly summary on a case-by-case basis. Eligible submissions may include, but are not limited to:

- Preliminary proof-of-concept studies filed solely for information (unless feedback is specifically requested)
- Simple non-pivotal study summaries submitted as follow-up to authorizations under title 9, *Code of Federal Regulations* (9 CFR), part 103.3
- Label inactivation requests
- License termination requests (after licensee surrenders licenses to the CVB)
- Return of superseded licenses (e.g., after reissue). Notification of intent to discontinue product development (converting license applications to inactive status)
- Removal of personnel from list of USDA liaisons and assistant liaisons
- Inspection-Compliance (IC) submissions submitted to PEL staff by mistake (e.g., facility documents). IC staff will respond in real time, but PEL acknowledgement of transfer to IC will be on summary
- Regulatory review priority lists
- Adverse event monitoring summaries, when required on an established periodic basis for license maintenance, and provided the CVB has no particular comments to communicate
- Routine updates to filed documents for unlicensed products exported under the Food and Drug Administration's Export Reform and Enhancement Act of 1996
- Lists of critical study dates
- Routine periodic reference monitoring data (submitted every 2.5 years, per Veterinary Services Memorandum No. 800.211), when a response letter would only indicate that the reporting requirements have been met and there will be no change in reference dating. Used for references that have at least 2 remaining years of dating. (Letters will be sent if there are concerns with reference stability or there is little remaining time left on the current dating period.)

If the reviewer determines a response letter is necessary, even if the submission appears to be eligible for the quarterly acknowledgement summary report, it is acceptable for the reviewer to respond with a letter, rather than by the quarterly summary report. Eligibility is determined on a

case by case basis. If a submission involves a request for PEL action (e.g., label inactivations, forwarding items to IC), actions continue to be initiated upon receipt, but confirmation of the completed action is communicated to the submitter via the quarterly acknowledgement summary.

3. Completing Mail Log Entries for Optimum Appearance on Summaries

The summaries are generated as reports from the PEL Mail Log and will include any item bearing the tag *Log Out Without Response* and having an exit date from the Primary Review activity within the designated quarter.

[redacted]

4. Distribution of Summaries

The summaries are generated at the end of each calendar year quarter (March 31, June 30, September 30, December 31) and distributed to the primary USDA liaison for the establishment within two weeks afterward. Unless otherwise requested by the submitter, summaries in PDF format are distributed by electronic mail from the CVB Distributions email account.

The quarterly acknowledgement summary is intended only for simple acknowledgement responses that are not time sensitive and will not impact the progress of product development plans. If, however, a submitter wishes to verify the disposition of a particular submission prior to the end of the quarter, an interim summary may be requested at any time.

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