USDA
United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 24-05

TO: Biologics Licensees, Permittees, and Applicants

FROM: Geetha Srinivas
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Date: 2024.03.13 22:36:01 -05'00'

SUBJECT: Availability of a Pilot Project to Implement a Focused Review Option for Review of Outlines of Production Submitted through the NCAH Portal

I. PURPOSE

The Center for Veterinary Biologics (CVB) is announcing a limited Focused Review (FR) pilot project to allow a more rapid review of simple, administrative changes to Outlines of Production (OPs) and Special Outlines (SOs) while preserving the integrity of the overall quality managed review of a regulated firm's manufacturing processes. If successful, the process will become a permanent component of the review process for electronically submitted OPs and SOs. All regulated firms that are portal-enabled are eligible to participate.

II. BACKGROUND

The NCAH Portal was updated to accept electronic OPs and SOs on March 16, 2017. In Notice 17-03 "Expanded NCAH Portal Functionality: Electronic Outlines of Production and Special Outlines", the CVB expanded the functionality of the web based NCAH Portal to include submission of OPs and SOs. At the time, it was noted that "[t]he procedure for submitting and reviewing electronic Outlines [would be] substantially different from the traditional paper process. It will leverage efficiencies of electronic document comparison and facilitate document navigation." Relevant to this pilot process, the CVB no longer accepted "page change" submissions for OPs and SOs, as the rapid document comparison available for electronic submissions sped the time of review from the traditional paper-based review process.

In response to industry feedback, the CVB has created a FR pilot project to re-incorporate the elements of the traditional "page change" review into the current electronic submission format, which is currently limited to Complete Reviews (CRs). FRs will enable regulated firms to implement a specific approved change within a shorter time frame.

III. ACTION (or POLICY)

To participate in the FR pilot project, regulated firms will indicate this type of review only for those instances of minor changes CVB previously approved in a Mail Log (ML) letter and which do not necessitate a complete review of the OP or SO. A FR implies evaluation of only the requested changes within the OP or SO. The Firm will limit revisions submitted to those supported by a previous CVB Policy, Evaluation, and Licensing (CVB-PEL) approval (i.e., approval letter to the firm). The CVB reserves the right to reject submissions that do not conform to the requirements of this pilot, and/or to perform a complete review of any submission under the existing policy, at its discretion.

IV. IMPLEMENTATION/ APPLICABILITY

Firms will indicate a FR request by adding "Focused Review request – changes from ML XXXXXX; [OP or SO] last reviewed on YY/ZZ/Year" in the Brief Description section of APHIS Form 2049 in the NCAH Portal as well as selecting the "Focused Review" tag in the dropdown menu and informationally linking the appropriate ML to the submitted OP or SO.

The FR submission must meet all of the following criteria:

- The OP or SO is not currently undergoing CVB-PEL review, and there are no open inspection or compliance concerns that require an OP or SO change to resolve the issue.
- There is a single, existing approval letter with an associated Mail Log number that leads to one or a set of related changes in one or several sections of the OP or SO, for example:
    - Minor assay modifications
    - New Confirmation of Dating approval
    - Exemptions
    - Reference qualification
    - Efficacy study updates (e.g., DOI, adding a route of administration or lowering pivotal potency)
    - Replacement of critical reagents
    - Other changes specifically requested by CVB correspondence and consistent with the criteria listed

- The Firm or CVB has previously reviewed and accepted the OP or SO within the last 12 months.
    - Indicate the previous revision date in the Brief Description as noted above
    - If the CVB has not reviewed the OP or SO in the last 12 months, the Reviewer may add an outgoing comment that the OP or SO must be submitted within 12 months for a complete review.
    - A FR does not eliminate the need for the Firm to perform an annual review of the entire Outline in accordance with title 9, *Code of Federal Regulations*, part 114.8(d).

The FR process cannot be used to address any unresolved issues with Section V testing (i.e., open issues with the CVB Laboratory) in the subject OP or SO.

If during the review process it is determined that the changes to the OP/SO tagged as FR do not follow the restrictions above, the submission will be sent directly back to the Firm as "Unprocessed" (UP); the request for a FR will be denied. The Firm has the option to resubmit without the FR request. If a firm does not follow the intent of this Notice, has repeated incorrect submissions (i.e., more than five (5) returned unprocessed), or uses serial FR submissions to avoid the normal periodic complete review process of OP/SO, FR submissions will no longer be allowed.

- **Note:** The FR process does not change or negate any other changes necessary to the SO or OP that are out of the scope of the specific FR request. However, the Firm may defer additional revisions on the approved version of the OP or SO until the next submission for complete review. For example, changes such as those requested by the CVB in response to a previous submission, clarifications, and/or corrections that were to be corrected at the next submission of an annual outline/special outline review may be deferred to maximize the efficiency and focus of the FR process. Previous comments will be included in the response to the FR request.

The CVB goal for completion of FR submissions is 90 percent completion within 20 business days, and 100 percent completion within 30 business days. Firms experiencing longer review times should contact the PEL Director for assistance.

This pilot project will be implemented upon the date of this Notice. The duration of this pilot project will be approximately 6 months (but no longer than 1 year) from the implementation date, and the results of the pilot project will be reviewed upon completion to determine if continued implementation is appropriate.