

BCA Entry and Review of Incoming Correspondence

Background

This document is to provide guidance and information for doing the preliminary review of Inspection and Compliance (IC) correspondence received in hard copy through outside channels such as USPS mail, courier, and also mail received through the NCAH Portal (electronic). See Section B for the entry process when a submission is sent in electronically through the NCAH Portal.

Submission types:

AIR Correspondence
AER Correspondence
Facility Document
General Correspondence (IC)
Inspection
Investigation
Personnel
Product Correspondence (IC)

The submission type is based on the file room organization. Most submissions are self-explanatory. **General Correspondence (IC)** includes letters referencing more than one product code. Product correspondence are letters that are product specific and have only one code referenced in the incoming letter. **Most regulatory and compliance letters are related to a specific product code or an investigation, so they would be entered under Product Correspondence or a Veterinary Biologics Investigation number (VBI) if assigned.**

Biologics Compliance Assistants (BCAs) are responsible for Mail Log (ML) items received through the NCAH Portal related to their assigned firms.

Firms that are not yet assigned to a Specialist and a BCA are processed by the Lead BCA and by default are handled by the Section Leader, Inspection, until the firm is given a permanent assignment to IC personnel. The BCA can choose to edit any information before moving forward for Specialist review.

A. Receiving Incoming General Correspondence - Hard Copy

Choose "Create Mail Log Item" from the dashboard

1. Enter Establishment Number – if no Establishment Number, enter NA
2. Enter Product Code, if applicable – if no Product Code, leave blank or type "NA" and select "add"

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3. Enter Serial Number, if applicable – not mandatory
4. VBI Number – enter if referenced in the correspondence
5. Enter date submitted (date of firm’s letter)
6. Enter date received (CVB-IC’s received stamp date)
7. Enter Submission Type from the drop down menu

Determine the submission type: (see background for details regarding each)

8. Enter Submission Subtype from the drop down – include subtypes for the following submission types:
 - a. *General Correspondence*:
Hold Release, Regulatory, Immediate Notification, Preliminary Facility Drawings
 - b. *Product Correspondence*:
Hold Release, Process Deviation, Autogenous Requests, Bench Records
 - c. *Personnel*:
Government Sampler
9. Enter a brief description, if applicable, (for facility documents enter city/state here) or any other pertinent information you would like to capture in the “Comment Field.”
10. Choose “Create”
11. Uploading Item to Mail Log
 - a. Select “Documents” tab
 - b. Choose “Create New Document Record”
 - c. Select “Hard Copy”
 - d. Choose Type=incoming submission (core)
 - e. Select “Save and Return to Item Record”
12. Move the Record to the Biologics Specialist Assigned to the Firm
 - a. Choose “Move Forward” button
 - b. Choose Activity=“Review Specialist”
 - c. Select the name of the specialist you are sending it to from the drop down
 - d. Choose “Move Item”

B. Receiving Incoming General Correspondence through the NCAH Portal (electronic)

1. Choose “IC Inbox” tab on the dashboard

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2. Choose “Self-Assign” tab for Mail Log for your assigned firm

Once an Item is self-assigned, it moves from the IC Inbox pool to the BCA’s active Mail Log queue.

3. Choose the corresponding ML number by double clicking on it
4. Whether received through the NCAH Portal (or in hard copy), the BCA will review the incoming mail for the following:
 - a. Read and review for content
 - b. Edit and or add descriptive content to ML
 - c. Suggest linkage of other MLs
 - d. Provide pertinent background information to Specialist for review if applicable
5. Choose “Move Forward”
6. Choose Review Specialist from the drop down menu
7. Choose the Specialist it is to be forwarded to for review
8. Choose Move Item