Work Flow for Initiating a Regulatory Action or Regulatory Correspondence Using the Mail Log System and Portal

CONTROLLED//PROPIN//BASIC

Source Document: CVB-SOP-0037, *Investigation and Processing of Alleged Violations of the Virus-Serum-Toxin Act*

I. Background:

Several avenues are available to initiate the document for a regulatory action or correspondence.

1. **If there are one or more serious actions in an inspection report, the LSRTIS Inspection system will automatically initiate a Mail Log (ML) to the *Team Leader* for addressing the issue(s). The ML will be initiated post finalization of the inspection report. (SEE II)**

DO NOT INITITATE AN INFRACTION BEFORE THE FINALIZATION OF AN INSPECTION REPORT UNLESS DIRECTED TO DO SO.

2. **Regulatory actions in any other instance can be initiated as a stand-alone ML and may be linked to an inspection report as well as other ML letters. (SEE III)**

A. *Regulatory actions* include the following:

1. Letter of Advice
2. Infraction Notice
3. Letter of Warning
4. Voluntary Stop Distribution and Sale
5. Mandated Stop Distribution and Sale
6. Hold Release

B. *Regulatory correspondence* include the following:

1. Rescind of a regulatory action
2. Rescind of a Mandated Stop Distribution and Sale
3. Lifting of a Hold Release action
4. Acknowledgement of a firm's lifting of a Voluntary Stop Distribution and Sale
5. Letters related to regulatory actions

6. Letter related to investigations (not Letter of Warning)

II. Serious Action Items Identified from an Inspection

See **CVB-WI-0136**, *Inspection: Specialist Routing of Inspection Reports*. All Serious Action items initiate a ML in "My Queues." Once the inspection report is finalized (post "Pending Finalization"), the Team Leader of the inspection will receive a ML notification.

A. If there are one or more serious action items post finalization, the Team Leader will receive an email similar to the one below.

From: [redacted]
To: XXXXXXX
Subject: New Mail Items
Date: Wednesday, June 5, 2019 10:48:06 AM

Hello!

There is a new Mail Item for Inspection [redacted] for your immediate review! Please visit the CVB Mail Log website to see the items awaiting your actions!

MailLog #: XXXXX
Activity: Initial Entry - IC
Type: General Correspondence (IC)

https://[redacted]

B. The Team Leader's Mail log queue will look similar to this:

Mail Log #	Firm	Product	Brief Description	Type	Submitted Date	Status
[redacted]	[redacted]		There are 1 Serious Action Item(s)	General Correspondence (IC)	[redacted]	Completed
[redacted]			There are 1 Serious Action Item(s). [redacted]	General Correspondence (IC)	[redacted]	Completed
[redacted]			There are 3 Serious Action Item(s) - [redacted]	General Correspondence (IC)	[redacted]	Completed

1. The ML will need to be corrected and cleaned to be more appropriate for the action intended.

    a. Correct "Brief Submission Description" to a more appropriate description, such as "Infraction from Inspection"
    b. Functionally or Informationally link ML items, if needed
    c. Select the appropriate "Submission Subtype"
        1) Letter of Advice

2) Infraction Notice
3) Letter of Warning
4) Voluntary Stop Distribution and Sale
5) Mandated Stop Distribution and Sale

d. Regulatory action source should be "Inspection"
e. Select the correct "9 CFR Violations" – more than one can be selected – Select "+ Add"
f. Select "Tag" and add the appropriate tag(s) – at minimum Regulatory Action
g. Select "Update"

2. Write the appropriate regulatory action using the appropriate template.
   a. See Decision Tracker Subtypes CVB-TEM
   b. Save the letter to the [redacted]

   Note: More than one regulatory letter can be written for an inspection. If needed, create a new regulatory letter from ML system.

3. Select the "Documents" tab of the ML.

4. Select "+ Create New Document Record."

5. Select "Select File Location" as "Uploaded File."

6. Select "File to Upload" by:
   a. Select Browse button to find the regulatory action or letter document, select it, then click open to attach document
   b. Select "Type" arrow
      i. Select "**Outgoing Compliance Corr**"
      ii. Ignore "Tags"
   c. Select "Save and Add Another Document"
   d. Select Browse to find the WRP document, select it, then click open to attach document (Note: WRP is not written for a Hold Release for references or lifting of a Hold Release for references.)
   e. Select on "Type" arrow
      i. Select "**WRP Correspondence**"
   f. Ignore "Tags"

7. Select "Save and Return to Item Record" Button.

Mail Log Info Screen

8. Select the "Move Forward" tab.

9. Select "OK" if you are sure it is appropriate to move the document(s).

10. On the drop down select "Section Leader Review (IC)."

11. The route of the letter may go to (in Priority):
    a. Section Leader, Compliance
    b. Investigation Manager
    c. Section Leader, Inspection
    d. Director, Inspection and Compliance

12. Select "Move Item."

13. Select "OK" if you are sure of moving the documents.

14. The item is now in the Queue of the person selected.

III. Initiating a Regulatory Action (Not from Inspection)

Note: If the regulatory action is associated with a current ML item, the regulatory action may be added to that ML or there must be an informational link to that ML item if a new ML is generated.

A. Write the appropriate regulatory action/letter using the appropriate template.
   1. See Decision Tracker Subtypes CVB-TEM

   2. Save the letter to the [redacted]

B. On ML home page, choose "Create Mail Item."
   1. Enter or select establishment.

   2. Enter product code, if applicable – then select "Add," enter serial number if appropriate. Then select "Set Serial Number."
      a. If no serial number – then select "No Serial Number" (multiple products and/or serials may be added).
      b. **Note**: an infraction, voluntary stop sale, mandated stop sale, hold release requires a product code.

   3. Enter the VBI number, if applicable.

   4. Select the "Date Submitted" – this will be the current date.

5. Select "Submission Type." Even with no incoming submission, a selection needs to be made. Select "General Correspondence," "Investigation," or "Product Correspondence," whichever one is the most appropriate.

6. Select the appropriate "Submission Subtype."
   a. If you are writing a **regulatory action**:
      i. Letter of Advice
      ii. Infraction Notice
      iii. Letter of Warning
      iv. Voluntary Stop Distribution and Sale
      v. Mandated Stop Distribution and Sale
      vi. Hold Release
   b. If you are writing **regulatory correspondence:**
      i. NA

7. Select the "Add" button.

8. Select the "Regulatory Action Source" from drop down LOV
   a. Firm Submission
   b. Inspection
   c. Investigation

9. Select the "9 CFR Violations" from drop down list (multiple violations may be added), click "Add."

10. Select the "Tag" "Regulatory Action" for these actions only:
    a. Letter of Advice
    b. Infraction Notice
    c. Letter of Warning
    d. Voluntary Stop Distribution and Sale
    e. Mandated Stop Distribution and Sale
    f. Hold Release

11. Select the "Tag" "Regulatory Correspondence" for all correspondence associated with a regulatory action.

12. Select the "Tag" "No Incoming submission" if not associated with ML letter.

13. If the Level of Regulatory Action is either of the following two actions:
    a. Voluntary Stop Distribution and Sale
    b. Mandated Stop Distribution and Sale

14. Select the level of the regulatory action
    a. All Known Persons
    b. All Wholesalers or Distributors
    c. Licensed Premises

15. Write a brief description of the regulatory action taken by including in BOLD the type of regulatory action at the beginning of the sentence, for example:
    a. INFRACTION
    b. VOL STOP
    c. **Note**: This description shows up in the "Brief Description" and must be performed for a timely response in Section Leader Queue.

16. Informationally link Mail Item if any ML is associated with this new ML.

C. Select "Create."

Create Attachment Screen

D. Note "Mail Item" number created.

E. Select "Select File Location" as "Uploaded File."

F. Select "File to Upload" by:
    1. Select Browse button to find the regulatory action or letter document, select it, then click "Open" to attach document.

    2. Select "Type" arrow
        a. Select "Outgoing Compliance Corr"
        b. Ignore "Tags"

    3. Select "Save and Add Another Document"

    4. Select Browse to find the WRP document, select it, then click open to attach document (Note: WRP is not written for a Hold Release for references or lifting of a Hold Release for references.)

    5. Select on "Type" arrow
        a. Select "WRP Correspondence"

    6. Ignore "Tags"

G. Select "Save and Return to Item Record" Button.

Note: The Specialist should edit the Mail Item to include any requested follow-up within the content of the regulatory action or letter.

Mail Log Item Screen

H. Select the "Move Forward" tab.

I. Select "OK" if you are sure it is appropriate to move the document(s).

J. On the drop down, select "Section Leader Review (IC)."

K. The route of the letter may go to:
   1. Section Leader, Compliance
   2. Investigation Manager
   3. Section Leader, Inspection
   4. Director, Inspection and Compliance

L. Select "Move Item."

M. Select "OK" if you are sure of moving the documents.

N. The item is now in the Queue of the person selected.

IV. Section Leader or Acting Review and Approval – Word Document

Portal Notes:

1. It is important to review the "Type" of document as this will determine which document is delivered via the portal to the firm, if applicable.

2. The final version of each document type is the document delivered to the firm other than internally routed documents.

3. If a document has an incorrect type, it must be changed to the correct type. This is performed by editing the ML.

4. Go to "My Queries," "Active Tab" and check if there is a folder with corresponding ML number.

5. Select the appropriate ML number.

Mail Log Item Screen

1. Select "Documents" tab, select the regulatory document to review under the "File Name."
   a. Save the attachment and include your initials in the naming convention
   b. Open the attachment for review
   c. Utilize the "Review" tab. Select "Track Changes" and/or add comments
   d. Save the reviewed document

2. If no changes are needed, go to **Step 6**.

3. If review changes require addressing, send the document back to the author for revision.
   a. Select "Create New Document Record"
   b. Select "Browse" to find the reviewed and edited document
   c. Select "Type" as "Outgoing Compliance Correspondence"
   d. Ignore "Tags"
   e. Select "Save and Return to Item Record" OR add the edited WRP item by following the last series of steps through "Save and Add Another Document"
   f. Select the "Move Forward" button to move the document(s) back to the author for revision. Click "OK" if appropriate.
   g. Select the role – normally "Review Specialist"
   h. Select the author
   i. Select "Move Item"
   j. IMPORTANT: a message appears that asks: "Are you moving this item because you are giving final approval?"
      i. If the revisions are minor and you are comfortable in approving, select "OK" as this will allow the documents to be revised and subsequently moved for finalization (BOTH the WRP AND REGULATORY DOCUMENT).
      ii. If the revisions are major, select "Cancel" and the process will go through Section Leader revision again once the documents are updated.

4. If no changes are needed in the regulatory or WRP document:
   a. Move forward to "Finalization (IC)"
   b. Select the Biologics Compliance Assistant (BCA) assigned to the firm or IC In-box Pool for investigations dealing with unlicensed entities.
   c. Email the author to let them know where their documents are at.

V. BCA Finalization

1. The BCA finalizes the document as per normal procedures.

2. See CVB-WI-0101

3. The end product will be a pdf document.

VI. Follow-Up – Role: Section Leader, Investigation Manager, Team Leader, or Biologics Specialist

1. At the final approval, the Section Leader, Investigation Manager Team Leader, or Biologics Specialist may edit the Mail Log item for follow-up.
   a. Select Mail Log to edit
   b. Select "Edit Mail Log item # "
   c. Scroll to "Follow-Up" and select "Yes"
   d. Enter follow-up Due Date
   e. Select "Update"

VII. Follow-Up Completed – Role: Section Leader, Investigation Manager, Team Leader, or Biologics Specialist

1. The "For Follow-Up" tab will list the Mail Log items requiring a follow-up.

2. When the follow-up is satisfactorily completed:
   a. Select the Mail Log Item #
   b. Select "Edit Mail Item #"
   c. Scroll to "Follow-Up" and enter completion date
   d. Enter follow-up description
   e. Select "Update"

VIII. Final Authorization: Delivery to Recipient – Portal or Certified Mail

1. Portal Delivery
   a. Review all types
   b. Move to Records Management for Portal Delivery
2. Certified Mail
   a. Review
   b. Send to Section Leader for Approval
   c. Move to Certified Receipt