
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

HANDLING AND REJECTING PAPER APPLICATIONS AND SUBMISSIONS

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I. PURPOSE

The Office of New Animal Drug Evaluation (ONADE) in the Center for Veterinary Medicine (CVM) has transitioned to a 100% electronic submission process as of October 1, 2018, with the reauthorization of the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA). This document describes the process for handling and rejecting paper applications and submissions received by ONADE after October 1, 2018. It also describes certain submissions and instances in which paper submissions to ONADE will be processed after this date.

The Records and Information Management (RIM) Team has implemented procedures for notifying drug sponsors and Veterinary Master File (VMF) holders that they must submit all information via CVM eSubmitter and that any incoming paper application or submission received after October 1, 2018, will be returned.

II. BACKGROUND

On October 1, 2018, ONADE implemented an electronic submission policy. All potential sponsors conducting regular business with and making submissions to ONADE are required to register as an eSubmitter user and establish an FDA Electronic Submission Gateway (ESG) and CVM Electronic Submission System (ESS) account. Beginning October 1, 2018, all applications and submissions made to ONADE under the Federal Food, Drug, and Cosmetic Act (FD&C Act) section 512(b) and 571 must be submitted to CVM electronically using the CVM eSubmitter tool.

If any paper application or submission is received, the sponsor will be notified (per Section VI below) that their submission is non-compliant with ADUFA and AGDUFA.

III. RECORDS AND INFORMATION MANAGEMENT TEAM HANDLING PAPER SUBMISSIONS

The U.S. Postal Service delivers mail to the Document Control Unit (DCU) of CVM twice daily. Shipping carriers (i.e., Fed Ex, UPS, DHL, etc.) make deliveries periodically throughout the day, and all deliveries are signed for by the RIM Team if they are addressed to:

Food and Drug Administration
Center for Veterinary Medicine
Document Control Unit, HFV-199
MPN 2, E150
12225 Wilkins Avenue
Rockville, MD 20852

When mail is delivered directly to an ONADE Division, that division brings it to the RIM Team to process according to the process describe within this P&P.

A. Data Entry for Document Receipt Log

When the RIM Team receives a submission, a member of the team will open the submission package and log the documents into the RIM Team Microsoft Excel® file, “New Submissions/New Applications-Document Receipt Log”, located on one of the network shared drives at Internal information redacted.

The RIM Team member will enter the following information into the “New Submissions/New Applications-Document Receipt Log” Microsoft Excel® spreadsheet:

1. Information From the Sponsor Letter:
 - Doc Type: (I, A, N, etc.)
 - Doc #: Document number
 - Sponsor: Sponsor name
2. Information From the Package:
 - Mailed by: Name of carrier
 - Receipt code: Air bill number
 - Vols: # of volumes received
3. Additional Important Information:
 - COMMENTS: Any miscellaneous notes regarding the contents and/or condition of the submission (e.g., physical artifacts such as samples, CDs, large labels, etc.).

IV. INVOLVEMENT OF OTHER DIVISIONS

After recording receipt of the application or submission into the applicable logs, the RIM Team will scan the cover letter for the application or submission and send an email to the division of the intended recipient.

- If the application or submission is addressed only to a reviewer within a division or team, the RIM Team will email the team leaders of the division and copy the division director.

- If the submission clearly identifies the team within ONADE, the RIM Team will send the email to the team leader of that team and copy the division director.
- If the submission is addressed only to the division director, the RIM Team will email the division director and copy the team leaders of that division.

The email will inform the recipient that a paper submission or amendment for an existing document, or a new application was received by the RIM Team. The RIM Team will use the Consulting Review Points of Contact document on the ONADE Template page in SharePoint to identify current team leaders of ONADE work units.¹ The RIM Team will always copy the following distribution lists on the notification email:
Internal information redacted.

The division has five business days to respond to the RIM Team email. The division has two options:

1. instruct the RIM Team to reject the paper application or submission, or
2. instruct the RIM Team to accept the application or submission and let the RIM Team know which exception they believe applies (see Section V below for exceptions).

Depending on how the division responds, a CVM rejection notification will be created and issued, or the application or submission will be processed, because it falls within the exceptions to the rejection process.

V. EXCEPTIONS TO REJECTION OF PAPER APPLICATION OR SUBMISSION

ONADE intends to use a flexible approach to the implementation of electronic submissions and therefore, does not expect all inquiries from sponsors to be electronic. The RIM Team creates new applications or submissions in our Submission Tracking and Reporting System (STARS) only if a new paper submission falls within the exceptions described below, and/or a response to the “Notifying Divisions” email is received instructing the RIM Team to do so.

A. The Following are Additional Exceptions to the Rejection of Paper Applications and Submissions Process

- VMF (Type VIII) import tolerance requests,
- a request made by a potential sponsor of products that include bioengineering or cellular therapies before they have established their ESG and ESS accounts to open an investigational new animal drug file or veterinary master file (INAD or VMF) to work with the Division of Animal Bioengineering and Cellular Therapies (DABCT) that involves: 1) situations where a delay in interactions with FDA may have a critical impact on public or animal health; or 2) to accommodate an initial

¹ Internal information redacted.

animal transfer, product shipment, or delivery. Contact the DABCT to determine eligibility for this exemption,

- G documents requesting general information from ONADE,
- physical artifacts that are amendments to submissions,
- K submissions,
- termination or transfer requests if it is the entire portfolio and the sponsor does not have existing CVM ESS and FDA ESG accounts,
- amendments to submissions originally made in paper,
- sponsors unable to electronically submit due to internal system error, internal system downtime, attempted to create an ESG and ESS accounts but were unable to do so by October 1, 2018, etc. Note: If you are contacted by a sponsor experiencing an outage or unable to set up their electronic submission accounts, instruct them to contact the Business Informatics Team using the CVM eSubmitter mailbox cvmesubmitter@fda.hhs.gov.

B. When the Response From “Notifying Divisions” Email Instructs the RIM Team to Accept a Paper Application or Submission

If the division identifies the application or submission as being an exception and they instruct the RIM Team to accept the paper application or submission for filing, refer to the Operation and Management Support of the Document Control Unit Standard Operation Procedures number 112013V3.1 in the RIM Team’s Standard Operating Procedures (SOP) folder located on the RIM Team’s SharePoint page.²

VI. PREPARING THE REJECTION NOTIFICATION

The RIM Team does not create/issue any notifications until the division that is the intended recipient of the submission responds to the RIM Team notification email with instructions either to reject or to create a new application and/or submission in STARS. If the division instructs the RIM Team to reject the submission, the RIM Team will create a rejection notification, create a CVM owned General Correspondence or GC file for processing the rejection of the submission, and issue a rejection notification. For more detailed information about these steps, see A., B., and C. below.

A. Creation of Rejection Notification

- Open the “Rejection Notification Template” located at S:\Rejection Notification Template\.
- Save a copy into the following folder S:\Rejection Notifications Issued\.
- Enter the application number (X-#####) (should only be the document type and document number because no submission was created). For new applications, leave this field blank.

² Internal information redacted.

- Enter sponsor's letter date.
- Put a check in "Your submission was received in paper format" and/or "Your physical electronic submission was less than 10 GB."

B. Creation of CVM Owned General Correspondence File

- Use the Rejection Notification to create and close a new submission for GC ###-###.
- Please refer to the Operation and Management Support of the Document Control Unit Standard Operation Procedures number 112013V3.1 in the RIM Team's SOP folder located on the RIM Team's SharePoint page.

C. Issuing the Rejection Notification

- Print out the completed rejection notification.
- Create and attach the corresponding address label to the envelope and issue the notification.
- CVM will not return the application or submission, unless contacted by sponsor requesting the return. CVM will retain the paper application or submission for 60 days. After this time period, it will be shredded.

VII. RETENTION INSTRUCTIONS

Any application or submission that is rejected is not considered an official record. CVM does not retain them, and they are not processed or scanned; they are retained for 60 days after the date of rejection notification, then destroyed. For other questions refer to the CVM Records Retention Schedules located on the RIM Team's SharePoint page.

VIII. REFERENCES

Federal Food, Drug and Cosmetic Act

Section 512(b)

Section 571

RIM Team SOPs

Operation and Management Support of the Document Control Unit Standard Operation Procedures number 112013V3.1

IX. VERSION HISTORY

September 10, 2018 – Original version

November 20, 2018 – Section IV updated to state email notification is sent to team leaders and division director of intended recipient. Email notification is not to be sent to the entire division.

August 26, 2019 – Updated to reflect the Animal Bioengineering and Cellular Therapies Team is now the Division of Animal Bioengineering and Cellular Therapies.

June 24, 2020 – Updated all internal links for SharePoint sites because FDA has migrated this information to a new version of SharePoint.

August 25, 2020 – Updated to replace the link to the ONADE template page that now has a new location.

March 12, 2021 – Updated to include the project management teams in the distribution list for the group emails.

November 9, 2023 – Cyclical quality management system review completed. No substantive revisions were needed. Minor corrections made. The document was placed into the current office template. In addition, the font was updated from Verdana 10-point to Arial 11-point font to align with the FDA Visual Identity Program approved font.