
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

PROCESSING SUITABILITY PETITIONS

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I. PURPOSE

This document describes how to process a suitability petition (SP) submitted requesting change(s) from a reference listed new animal drug (RLNAD) for an abbreviated new animal drug application (ANADA).

II. SUITABILITY PETITIONS

An SP is a type of citizen petition. Citizen petitions provide interested persons the opportunity to petition the FDA to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. An SP is used to seek permission to pursue an approval for a generic new animal drug that differs from the RLNAD in certain acceptable ways (see P&P 1240.2030). Section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) identifies permissible changes from the RLNAD through an SP. A person may submit an SP for a generic new animal drug that would differ from its RLNAD for the following acceptable differences: ¹

- change in route of administration,
- change in dosage form,
- change in strength (concentration),
- a change in one of the active ingredients in the reference listed combination new animal drug, and/or
- a change in one of the Type A medicated articles in a reference listed feed use combination new animal drug.

A person seeking a generic approval that differs from the RLNAD as described above should have an approved SP from CVM before an ANADA can be accepted for filing. It is ideal that an SP is approved before opening the generic investigational new animal drug (JINAD) file. The response to an SP is an approval or denial. If the SP is denied, the denial letter includes reasons for the denial. The copy of the submitted SP and the letter FDA sends in response to the petition are made publicly available at www.regulations.gov through the Dockets Management Staff (DMS).

III. PROCESSING SUITABILITY PETITIONS

Under section 512(n)(3) of the FD&C Act, CVM must approve or deny an SP within 90 days of its submission. The process for handling and reviewing SPs is discussed

¹ The language used here to describe the acceptable differences is different from what is found in the FD&C Act. This language is similar to that in Policy Letter II on the implementation of Generic Animal Drug and Patent Term Restoration Act (GADPTRA), which clarified language in the FD&C Act.

below. Please note that under the current process, SPs are not processed through the Submission Tracking and Reporting System (STARS). Therefore, they are not closed out through Appian or handled by the Document Control Unit (DCU).

A. Submission to DDM and routing to the Division of Generic Animal Drugs (DGAD)

1. A person submits an SP following the procedures for citizen petitions outlined in 21 CFR 10.30.
2. DMS (HFA-305) emails electronic copies of the filed petition to DGAD in the Office of New Animal Drug Evaluation (ONADE), for evaluation and preparation of a written response.

B. Processing and evaluation by DGAD

1. DGAD maintains an SP spreadsheet on the division's shared drive Internal information redacted containing the specifics of each SP submitted to CVM. The SP spreadsheet maintained by DGAD contains more information than what is included in the Green Book regarding SPs. Once received from DDM, the DGAD point of contact (POC), typically a reviewer assigned by division management, updates the SP spreadsheet with a summary of the SP request and saves an electronic copy of the SP on the S: drive. The DGAD POC also emails the spreadsheet, highlighting the SP number that is updated, to Internal information redacted to notify the Business Informatics Team to update the Green Book.² The SP status will be listed as "pending" in the spreadsheet and in the Green Book. The DGAD POC also notifies division management to assign the SP to a DGAD reviewer. When the primary reviewer (PR) is assigned the SP, the DGAD POC forwards the email from DDM containing the SP documents to the PR.
2. The DGAD PR sends an email containing the SP documents to the ONADE Policy Team and the division director (DD) of the target animal division (TAD) for the RLNAD within a few days of being assigned the SP to notify them that the SP was received.
3. The PR schedules a meeting with the ONADE Policy Team to occur within 45 calendar days of the filing date of the SP. Meeting attendees should include the ONADE Policy Team members assigned the SP and the PR's team leader (TL). DGAD's DD may be included as an optional attendee if the SP is complex. If the ONADE Policy Team determines this meeting is not needed, it is canceled.

For any SP that warrants expertise from the Office of Chief Counsel (OCC), the PR consults with the ONADE Policy Team to determine if OCC should be contacted. OCC should never be approached without first consulting with the ONADE Policy Team.

4. The PR prepares background research regarding the change from the RLNAD proposed in the SP. If needed, the PR discusses the proposed change with the appropriate TAD TL and reviewers.

² The Green Book can be found at <https://animaldrugsatfda.fda.gov/adafda/views/#/search>

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5. The PR discusses a tentative decision regarding the SP with the reviewer's TL and/or DGAD's DD.
 6. The PR holds the scheduled meeting with the ONADE Policy Team. Once there is agreement between DGAD and the Policy Team on the decision regarding the SP, the PR emails the RLNAD TAD DD to determine if there are concerns with the SP recommendation.
 7. If the RLNAD TAD DD has concerns, the PR prepares a written summary of the issues on which there is disagreement and schedules a meeting to discuss the petition. The following CVM personnel may be included in that meeting:
 - PR and their TL,
 - DGAD and RLNAD TAD DDs,
 - ONADE Policy Team personnel,
 - relevant subject matter experts (e.g., a pharmacokinetics expert), and
 - a representative from OCC, if recommended by the ONADE Policy Team
 8. Once agreement is reached on the recommendation, the PR prepares draft Word documents (review and letter) using DGAD templates. Each draft document should include an internal routing information table for signatures.³ If the reviewer has a scientific disagreement with management, a standalone submission summary can be created (see P&P 1243.3009, Section IV).
 9. The PR submits these Word documents to their TL and DGAD's DD for edits and comment.
 10. Following document review by the PR's TL and DGAD's DD, the PR emails the draft review and letter to the RLNAD TAD DD for edits and comment. The PR consults with DGAD's DD to determine if the draft review and letter should be sent to ONADE's director (OD) for edits and comment. If the petition will be denied, the PR emails the draft review and letter to the ONADE Policy Team at Internal information redacted for edits and comment.

C. Creating final review documentation and distribution of documentation

1. The PR creates clean, final copies of the review and letter. The PR generates an additional copy of the letter without the internal routing information table.⁴
2. The PR generates PDF versions of all three documents:
 - review with internal routing information table
 - letter with internal routing information table

³ The "other administrative information" block at the end of the review should be enlarged, and the internal routing information table is placed inside that block. For the letter, the internal routing information table replaces the signature. This table should have two columns to accommodate the printed names and titles in one column and electronic signatures in the second column for the DGAD reviewer, TL, DGAD DD, and the RLNAD TAD DD.

⁴ Because SPs are not signed out through Appian, the internal routing table in the review and letter are meant to imitate the electronic signature *or esign* copy in Appian that is maintained for CVM records. The additional copy of the letter without the internal routing table is meant to imitate the digitally signed *or dsign* version that is sent to the petitioner.

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- letter without internal routing information table
3. The PR signs the PDF versions of the review and letter with internal routing information table electronically. To sign, the PR selects "Certificates" under the "Forms & Signatures" section of the "Tools" tab in Adobe and then select "Digitally Sign." Next, the PR obtains electronic signatures on the PDF versions of the review and letter with internal routing information table from the following people (in order): the reviewer's TL, DGAD's DD, and the RLNAD TAD DD. The PR performs the following steps.
- Open the subfolder named "Suitability Petitions" on the shared drive
Internal information redacted
 - Create a subfolder, and name it based on the docket number for the SP.
 - Place the review and letter with internal routing information table awaiting signature from management in the subfolder named based on the docket number for the SP.
 - Use the Outlook template on DGAD's SharePoint site to notify the reviewer's TL that the documents are ready for signature.
 - Once the PR's TL has signed the documents, use the Outlook template to notify the other signees (DGAD's DD and the RLNAD TAD DD, in that order) that the documents are ready for signature.
4. Once the above signatures are collected, the PR obtains electronic signatures on both copies of the letter (with and without the internal routing information table) from the OD or ONADE deputy director (if the OD is unavailable). Under Staff Manual Guide 1410.30, the OD and ONADE deputy are authorized to respond to SPs. The OD or ONADE deputy director signs above the signature block on both copies of the letter. The PR performs the following steps.
- Access the subfolder named based on the docket number for the SP (as referenced in Step 3 above).
 - Place the PDF version of the letter without the internal routing information table in the subfolder. The review and letter with internal routing information table should be in the subfolder already with signatures from the PR, the PR's TL, and the DGAD and RLNAD TAD DDs.
 - Use the Outlook template on DGAD's SharePoint to notify the OD or ONADE deputy director that both copies of the letter are ready for signature.
 - Once the OD or deputy director has signed both copies of the letter, move the subfolder containing the final, signed documents and place the subfolder within the SP archive folder on the division's shared drive
Internal information redacted
- The HFV-170 folder within the work area on the S: drive is meant as a temporary location to facilitate signing of SP documents, as this location allows for access for signatures; it is not meant to serve as an archive for SP documents.

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5. The PR distributes the review documentation as detailed below.
- a. Letter without internal routing information (has only the signature of the OD or ONADE deputy director)

i. To the petitioner:

The PR prepares an envelope addressed to the petitioner. This envelope is used to send the letter to the petitioner. The PR places the addressed envelope containing the letter in the outgoing mailbox on the third floor of MPN2. The outgoing mailbox is a tray located on the north wing of the third floor, under the division mailboxes. Postage will be applied after the envelope is picked up from the outgoing mailbox.

ii. To the public record via DMS:

The PR uploads an electronic copy of the letter to DMS's SharePoint site.⁵ The PR navigates to DMS's SharePoint and selects "Add document" to upload the letter. The PR posts an electronic copy of the letter on DMS's shared network drive. The steps to do this are as follows.

- Select Internal
- Open the folder named "CVM-Comments-Submissions."
- Create a subfolder and name it based on the SP docket.
- Place a copy of the letter in the subfolder, and it will become part of the public file.⁶

After the PR uploads the letter to DMS's SharePoint and posts a copy of the letter to DMS's shared network drive, the PR notifies DMS by email that the letter is available (using the Outlook template on DGAD's SharePoint).

- b. Review and letter with internal routing information

Once the PR has completed the petition review and response, they print a hard copy of the signed review and a hard copy of the letter with the internal routing information, give those copies to the DGAD POC to update the SP status in the SP spreadsheet on the S: drive, and file the hard copies in the SP binder. Alternatively, the PR may update the SP spreadsheet on the S: drive and file the hard copies in the SP binder; if this is done, the PR notifies the DGAD POC via email.

The DGAD POC informs the Business Informatics Team to update the status of the SP in the Green Book by emailing the updated SP spreadsheet to Internal information redacted

IV. REFERENCES

FDA Statutes

Federal Food, Drug, and Cosmetic Act, §512(n)

⁵ Dockets Management Staff SharePoint: Internal information redacted

⁶ Also accessible from the FDA intranet webpage:
Internal information redacted

Generic Animal Drug and Patent Term Restoration Act

21 CFR 5.31, 10.20, 10.30, and 10.33

CVM Program Policy and Procedures Manual

1240.2030 – Citizen Petitions Policy and Procedures

1243.3009 – Format and Style Conventions for Reviews and Submission Summaries

Policy Letter II on the implementation of GADPTRA

V. VERSION HISTORY

September 11, 2002 – Original document.

May 11, 2016 – Revised to describe current practices for processing suitability petitions.

October 27, 2016 – Revised to create a version that is not redacted and contains url for Division of Dockets Management network folder

October 25, 2017 – Revised to describe current practices for processing suitability petitions, including obtaining electronic signatures and reference to the DDM and DGAD SharePoint pages

December 10, 2019 – Revised to describe current practices for processing suitability petitions, including changes to mailing the letter to the petitioner.

May 05, 2020 – Revised to describe current practices for determining whether to send the draft review and letter to ONADE’s director for edits and comment. Revised to change all references to the Division of Dockets Management (DDM) to the Dockets Management Staff (DMS).

November 25, 2020 – Updated all internal links for SharePoint sites because FDA has migrated this information to a new version of SharePoint.

July 18, 2022 – Quality system review for minor formatting updates.