
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

PROCESSING SUITABILITY PETITIONS

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I. PURPOSE

This document defines and 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.¹ 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. Section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (the 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: ²

- 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 the Center for Veterinary Medicine (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 will include reasons for the denial. The copy of the submitted SP and the letter FDA

¹ See CVM Program Policy and Procedures Manual 1240.2030 for information on citizen petitions policies and procedures.

² 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 GADPTRA, which clarified language in the FD&C Act.

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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 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 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, will update the SP spreadsheet with a summary of the SP request and save an electronic copy of the SP on the S: drive. The DGAD POC will also email the spreadsheet, highlighting the SP number that is updated, to CVMGreenBookandAnimalDrug@fda.hhs.gov to notify the Business Informatics Team to update the Green Book.³ The status of the SP will be listed as "pending" in the spreadsheet and in the Green Book. The DGAD POC will also notify division management to assign the SP to a DGAD reviewer. When the primary reviewer is assigned the SP, the DGAD POC will forward the email from DDM containing the SP documents to the assigned reviewer.
2. The DGAD primary reviewer will send an email containing the SP documents to the ONADE Policy Team and the division director 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 Green Book can be found on the Animal Drugs @ FDA website through the following link:
<https://animaldrugsatfda.fda.gov/adafda/views/#/search>

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3. The primary reviewer will schedule 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 primary reviewer's team leader (TL). DGAD's director may be included as an optional attendee if the SP is complex. If the ONADE Policy Team determines this meeting is not needed, it will be canceled.

For any SP that may warrant expertise from the Office of Chief Counsel (OCC), the primary reviewer will consult 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 primary reviewer will prepare background research regarding the change from the RLNAD proposed in the SP. If needed, the primary reviewer will discuss the proposed change with the appropriate TAD TL and reviewers.
5. The primary reviewer will discuss a tentative decision regarding the SP with the reviewer's TL and/or DGAD's director.
6. The primary reviewer will hold 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 primary reviewer will send an email to the director of the TAD for the RLNAD to determine if there are concerns with the SP recommendation.
7. If the director of the TAD for the RLNAD has concerns, the primary reviewer will prepare a written summary of the issues on which there is disagreement and schedule a meeting to discuss the petition. The following CVM personnel may be included in that meeting:
 - primary reviewer and their TL,
 - DGAD and RLNAD TAD directors,
 - 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 primary reviewer will prepare draft Word documents (review and letter) using DGAD templates. Each draft document should include an internal routing information table for

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signatures.⁴ If the reviewer has a scientific disagreement with management, a standalone submission summary can be created.⁵

9. The primary reviewer will submit these Word documents to their TL and DGAD's director for edits and comment.
10. Following document review by the primary reviewer's TL and DGAD's director, the primary reviewer will send the draft review and letter via email to the director of the TAD for the RLNAD for edits and comment. The primary reviewer should consult with DGAD's director to determine if the draft review and letter should be sent to ONADE's director for edits and comment. The primary reviewer will only send the draft review and letter via email to the ONADE Policy Team at CVMONADEPOLICYTEAM2@CVM.FDA.GOV for edits and comment if the petition will be denied.

C. Creating final review documentation and distribution of documentation

1. The primary reviewer will create clean, final copies of the review and letter. The primary reviewer will generate an additional copy of the letter without the internal routing information table.⁶
2. The primary reviewer will generate portable document format (PDF) versions of all three documents:
 - review with internal routing information table
 - letter with internal routing information table
 - letter without internal routing information table
3. The primary reviewer will sign the PDF versions of the review and letter with internal routing information table electronically. To sign, the primary reviewer should select "Certificates" under the "Forms & Signatures" section of the "Tools" tab in Adobe and then select "Digitally Sign." Next, the DGAD reviewer will obtain electronic signatures on the PDF versions of the review and letter

⁴ 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 director, and the RLNAD TAD director.

⁵ See CVM Program Policy and Procedures Manual 1243.3009 section IV for information on creating a standalone submission summary.

⁶ Because suitability petitions 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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with internal routing information table from the following people (in order): the reviewer's TL, DGAD's director, and the RLNAD TAD director. The primary reviewer will:

- 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 primary reviewer's TL has signed the documents, use the Outlook template to notify the other signees (DGAD's director and the RLNAD TAD director, in order) that the documents are ready for signature.
4. Once the above signatures are collected, the primary reviewer will obtain electronic signatures on both copies of the letter (with and without the internal routing information table) from the ONADE director or deputy director (if the ONADE director is unavailable). Under Staff Manual Guide (SMG) 1410.30, the director and deputy director of ONADE are authorized to respond to SPs. The ONADE director or deputy director will sign above the signature block on both copies of the letter. The primary reviewer will:
- 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 primary reviewer, the primary reviewer's TL, DGAD's director, and the RLNAD TAD director.
 - Use the Outlook template on DGAD's SharePoint site to notify the ONADE director or deputy director that both copies of the letter are ready for signature.
 - Once the ONADE director 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

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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.

5. The primary reviewer will distribute the review documentation as detailed below:

- a. Letter without internal routing information (has only the signature of the ONADE director or deputy director)

i. To the petitioner:

The primary reviewer will prepare an envelope addressed to the petitioner. This envelope will be used to send the letter to the petitioner.

The primary reviewer will place 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 primary reviewer will upload an electronic copy of the letter to DMS's SharePoint site.⁷ The primary reviewer will navigate to DMS's SharePoint site and select "Add document" to upload the letter.

The primary reviewer will post an electronic copy of the letter on DMS's shared network drive. The steps to do this are:

- Select ^{Internal information redacted}.
- Open the folder named "CVM-Comments-Submissions."
- Create a subfolder, and name it based on the docket number for the SP.

⁷ The url for the Dockets Management Staff SharePoint site is ^{Internal information redacted}

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- Place a copy of the letter in the subfolder, and it will become part of the public file.⁸

After the primary reviewer uploads the letter to DMS's SharePoint site and posts a copy of the letter to DMS's shared network drive, the primary reviewer will notify DMS by email that the letter is available. An Outlook template for this notification is on DGAD's SharePoint site.

b. Review and letter with internal routing information

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

The DGAD POC will inform 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}.⁹

IV. REFERENCES

FDA Statutes

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

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 GADPT RA

⁸ Also accessible from the FDA intranet webpage:
Internal information redacted

⁹ The Green Book can be found on the Animal Drugs @ FDA website through the following link:
<https://animaldrugsatfda.fda.gov/adafda/views/#/search>.

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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.