
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 suitability petitions (SP) submitted 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 Commissioner 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 reference listed new animal drug (RLNAD) in certain acceptable ways. Section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act ("the Act"), identifies possible deviations from the RLNAD that may be permissible under an abbreviated new animal drug application (ANADA) through an SP.

Specifically, under section 512(n)(3) of the Act, if a person wants to submit an abbreviated application for a generic new animal drug that would differ from its RLNAD in its

- active ingredients,
- route of administration,
- dosage form,
- strength, or
- in its use with other animal drugs in animal feed,

That person must first submit a suitability petition seeking permission to file such an application.

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

It should be noted that although a change in active ingredient is in limited circumstances a difference that could be permitted via suitability petition, substitution of an active ingredient in a single active ingredient animal drug product is not allowed. Such changes are almost never permissible in practice, however, because a suitability petition proposing a change that would require safety or effectiveness information must be denied under section 512(n)(3)(C) of the Act.

A person seeking a generic approval that differs from the RLNAD as described above must have an approved SP from the Center for Veterinary Medicine (CVM) before an ANADA can be accepted for filing. While it is ideal if an SP is approved before opening the JINAD file, until the currently pending Generic Regulations are finally promulgated, we may open a JINAD prior to the approval of an SP. The Generic Regulations will change this, however, and so it is advisable to avoid opening a JINAD prior to the approval of the relevant SP.

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 sends in response to the petition are made publicly available at www.regulations.gov through the Division of Dockets Management.

III. PROCESSING SUITABILITY PETITIONS

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

Please note that under the current process, SPs are not processed through the Submission Tracking and Recording System (STARS) and therefore are not closed out through Appian or handled by the Document Control Unit (DCU). Efforts to process SPs through eSubmitter, STARS, and Appian are underway.

1. A person submits an SP following the procedures for citizen petitions outlined in 21 CFR 10.30.
2. The Division of Dockets Management (DDM) (HFA-305) emails electronic copies of the filed petition to the Division of Generic Animal Drugs (DGAD), in Office of New Animal Drug Evaluation (ONADE), for evaluation and preparation of a written response.
3. DGAD maintains a SP spreadsheet on the DGAD SharePoint site containing relevant details of each suitability petition submitted to CVM. Once received from DDM, the DGAD point-of-contact (POC) will update the SP spreadsheet with a summary of the SP request and save an electronic copy of the SP on the DGAD SharePoint site. The DGAD POC will also email the spreadsheet, highlighting the SP number that is updated, to the Outlook mailbox setup for the Green Book and Animal Drugs at FDA maintenance to notify the Business Informatics Team to update the Green Book.² The status of the SP will be

² The Green Book can be found on the Animal Drugs @ FDA website through the following link:
<https://animaldrugsatfda.fda.gov>

listed as "pending" in the spreadsheet and in the Green Book. The DGAD POC will also notify the appropriate team leader (TL) to assign the SP to a reviewer.

4. The primary reviewer in DGAD will email the ONADE Policy Team and the appropriate RLNAD TAD(s) within a few days of being assigned the SP to notify them that the SP was received.
5. The primary reviewer in DGAD will contact the appropriate RLNAD target animal division(s) (TAD) to discuss the change requested in the petition.
6. After discussions with the RLNAD TAD team leader and internal division discussions, the DGAD reviewer will schedule a meeting with the ONADE Policy Team by day 45 of the review timeline to discuss a tentative outcome. In preparation for the meeting with the ONADE Policy Team, the DGAD reviewer should prepare any background research that would be helpful in the determination to approve or deny the petition and discuss a tentative decision with their TL and/or division director.

For any suitability petition that may warrant expertise from the Office of the Chief Counsel (OCC), the DGAD reviewer should 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.

7. Once the Policy Team concurs with a decision on the SP, the DGAD reviewer emails the RLNAD TAD director to see if they have any concerns about the recommendation on the SP.
8. If the RLNAD TAD director has any concerns, the DGAD reviewer will prepare a written summary of the issues on which there is disagreement and schedule a meeting to discuss the petition before drafting a review and letter to document the new recommendation. The following CVM personnel may be included in that meeting:
 - DGAD and RLNAD TAD division directors,
 - the DGAD reviewer and their TL,
 - Office Policy Team personnel,
 - relevant subject matter experts (e.g., a pharmacokinetics expert), and
 - a representative from OCC, if recommended by the ONADE Policy Team.
9. Once agreement is reached on the recommendation, the DGAD reviewer will prepare a draft of the review and letter, including an internal routing information table on both documents and submit both documents to the TL

and DGAD director for edits and comment.³ If the reviewer has is scientific disagreement with the DD, a standalone submission summary can be created.⁴

10. The DGAD reviewer will create clean final copies of the review and letter (using Division templates) and generate an additional copy of the letter without the internal routing information table.⁵
11. The DGAD 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
12. The DGAD reviewer will obtain electronic signatures on the review and letter with the internal routing information table from their TL, DGAD director, and RLNAD TAD director.
13. Once electronic signatures are obtained, the DGAD reviewer will email the review and both copies of the letter (with and without the internal routing information table) to the ONADE director. Under 21 CFR 10.30, the director and deputy director of ONADE are authorized to respond to SPs. The ONADE director (or deputy director) will review all documents and electronically sign the letter without the internal routing information table.
14. The DGAD 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)

1. To the petitioner:

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

The DGAD reviewer will take the envelope to the CVM mailroom for postage and delivery.

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 of the DGAD reviewer, TL, DGAD director, and the RLNAD TAD director.

⁴ See CVM Program Policy and Procedures Manual 1240.3009 section IV for information on creating a standalone submission summary

⁵ 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.

2. To the public record via DDM:

The DGAD reviewer will upload an electronic copy of the letter signed by the ONADE director (or deputy director) onto the DDM SharePoint page. The reviewer will also save an electronic copy of the letter signed by the ONADE director (or deputy director) to DDM's shared network folder (create a subfolder for your suitability petition docket number and place the letter in the folder) and it will become part of the public file.

After the DGAD reviewer uploads the letter to the DDM SharePoint and shared network folder, the DGAD reviewer will notify DDM by email, using the specified email address, that the letter is available.

B. Review and letter with internal routing information

Once the DGAD reviewer has completed the petition review and response, the DGAD reviewer will print a hard copy of the signed review and letter with the internal routing information and give those copies to the DGAD POC to update the status of the SP on the DGAD SharePoint site and file the hard copies in the SP binder.

That person will also inform the Business Informatics Team to update the status of the SP in the Green Book by emailing the SP spreadsheet to the Outlook mailbox setup for the Green Book and Animal Drugs at FDA maintenance.⁶

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

⁶ The Green Book can be found on the Animal Drugs @ FDA website through the following link:
<https://animaldrugsatfda.fda.gov/adafda/views/#/search>

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