PROCESSING SUITABILITY PETITIONS

I. PURPOSE

This guide describes the procedures for processing suitability petitions.

II. PROCESSING SUITABILITY PETITIONS

Suitability petitions for new animal drugs are defined in section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act which became law on November 16, 1988. If a sponsor wants to submit an abbreviated application for a new animal drug whose active ingredients, route of administration, dosage form, or strength differ from that of an approved new animal drug, or whose use with other animal drugs in animal feed differs from that of an approved new animal drug, the sponsor must submit a suitability petition seeking permission to file such an application. 21 U.S.C. § 360b(n)(3). Suitability petitions are processed in the Center for Veterinary Medicine (CVM) as a special type of citizen petition. See CVM Program Policy and Procedures Manual Guide 1240.2030 for information on Citizen Petitions Policy and Procedures.

The Dockets Management Branch (HFA-305) forwards the filed petition to the Generic Animal Drug Team, Office of New Animal Drug Evaluation (ONADE), CVM for preparation of a written response. CVM, by statute, specifically 21 U.S.C. § 360b(n)(3), must approve or disapprove a suitability petition within 90 days of the date the petition is submitted.

The Director and Deputy Director of ONADE are authorized to issue responses to citizen petitions submitted under 21 CRF § 10.30, seeking a determination of the suitability of an abbreviated new animal drug application for an animal drug product. 21 CFR § 5.31(f)(7).

The response to a suitability petition may consist of: (1) Approval of the petition; (2) Denial of the petition, which generally will include a discussion of the reasons for the denial; or (3) A tentative response, indicating why the agency is unable to reach a decision on the petition.

The procedures ONADE should follow in reviewing and acting on suitability petitions follow:

A. For routine Suitability Petitions (e.g., change in strength for immediate release solid oral)

1) A sponsor submits a suitability petition following the procedures for citizen petitions set forth in 21 CFR § 10.30.

2) The Dockets Management Branch forwards the filed petition to the Generic Animal Drug Team for preparation of a written response.

3) The Generic Animal Drug Team reviews the suitability petition and prepares a review and a letter recommending approval or denial of the suitability petition, which are forwarded to the appropriate primary review division. For purposes of this document, primary review division refers to the division that would be responsible for the approval of the new animal drug based upon the intended use of the drug if the new animal drug were a pioneer.

4) The Director of the primary review division reviews the Generic Animal Drug Team's review and recommendation.

5) If the primary review Division Director concurs with the Generic Animal Drug Team's review and recommendation, the petition goes to the ONADE Office Director for sign-off (directly or through the Office of Chief Counsel (OCC)). The Generic Animal Drug Team will forward the draft response to OCC, after sign off by the primary review Division Director and before Office Director sign off, in those instances in which there may be legal issues.[1]

[1] As of October 2001, the Generic Animal Drug Team and OCC agreed that where suitability petitions are essentially carbon copies of previous suitability petitions, the Generic Animal Drug Team will issue a response without OCC concurrence. In those instances in which a suitability petition raises new or precedent-setting issues or requires review for legal accuracy, the response will be sent to OCC for review.

6) If the primary review Division Director does not concur with the Generic Animal Drug Team's review and recommendation, the Generic Animal Drug Team will summarize the issues on which there is disagreement. Then, the Deputy Office Director will convene the Suitability Petition Committee to discuss and resolve the issues relating to the suitability petition. The Deputy Office Director will chair the committee. The Suitability Petition Committee will consist of ONADE Division Directors, the Team leader and responsible reviewer from the Generic Animal Drug Team, a Pharmacokinetics specialist, Office policy staff, relevant experts, and a representative from OCC for unusual or precedent setting cases. Based on the decisions of the Suitability Petition Committee, the Generic Animal Drug Team will prepare a final draft of the review and letter recommending approval or denial of the suitability petition and forward it to the Suitability Petition Committee for review and concurrence. When the Suitability Petition Committee concurs, the final draft letter to the sponsor will be forwarded for sign-off to the primary review Division Director, OCC, as appropriate, and the ONADE Director.

7) The letter granting or denying the suitability petition will be sent to the sponsor. Copies of the letter should be forwarded to the Dockets Management Branch, the Greenbook, the R: drive, OCC, and others, as appropriate. A copy of the original petition and the letter to the sponsor should be kept in the Generic Animal Drug Team's files along with any supporting documentation and review. The copy of the letter forwarded to the Dockets Management Branch will become part of the public file. Thus, the distribution copy of the letter filed with the Dockets Management Branch should not include concurrence and distribution information.

B. For complex (non-routine) Suitability Petitions (e.g., novel dosage form, novel technology)

1) A sponsor submits a suitability petition following the procedures for citizen petitions set forth in 21 CFR § 10.30.

2) The Dockets Management Branch forwards the filed petition to the Generic Animal Drug Team for preparation of a written response.

3) The Generic Animal Drug Team will review the suitability petition and prepare a summary of the non-routine issues.

4) The Deputy Office Director will convene the Suitability Petition Committee. (The committee membership is discussed in paragraph A.6. above.). The Deputy Office Director will chair the committee. The Suitability Petition Committee will discuss the petition, focusing on the non-routine issues.

5) The Generic Animal Drug Team will prepare a draft final letter and supporting documentation to forward to the Suitability Petition Committee for review and concurrence. When the Suitability Petition Committee concurs, the final draft letter to the sponsor will be forwarded for sign-off to the primary review Division Director, OCC, as appropriate, and the ONADE Director.

6) The letter granting or denying the suitability petition will be sent to the sponsor. Copies of the review and letter should be forwarded to the Dockets Management Branch, the Greenbook, the R: drive, OCC, and others, as appropriate. A copy of the original petition and the letter to the sponsor should be kept in the Generic Animal Drug Team's files along with any supporting documentation and review. The copy of the letter forwarded to the Dockets Management Branch will become part of the public file. Thus, the distribution copy of the letter filed with the Dockets Management Branch should not include concurrence and distribution information.

The Administrative Record for the Suitability Petition is maintained by the Dockets Management Branch, showing: (1) The docket number; (2) The date the petition was filed by the Dockets Management Branch; (3) The name of the petitioner; (4) The subject matter involved; and (5) The disposition of the petition.

A petitioner whose petition has been denied may request administrative reconsideration of the denial following the procedures in 21 CFR § 10.33. Such a request may not be based on information and views not contained in the original petition (21 CFR § 10.33(e)) and must be submitted in accordance with §10.20 in the format outlined in §10.33. 21 CFR § 10.33(b). A request for reconsideration must be submitted within 30 days after the date of the denial of the Suitability Petition, and is also filed with the Dockets Management Branch. 21 CFR § 10.33(b). A response to a petition for reconsideration under §10.33 must be signed by the Senior Associate Commissioner for Policy, Planning, and Legislation or the Associate Commissioner for Policy. 21 CFR § 5.20(f)(2)(iii).

If there is additional information, not included as part of the original petition, that the petitioner would like the agency to consider, a new Suitability Petition should be submitted under § 10.30 including all the necessary information. 21 CFR § 10.33(e).

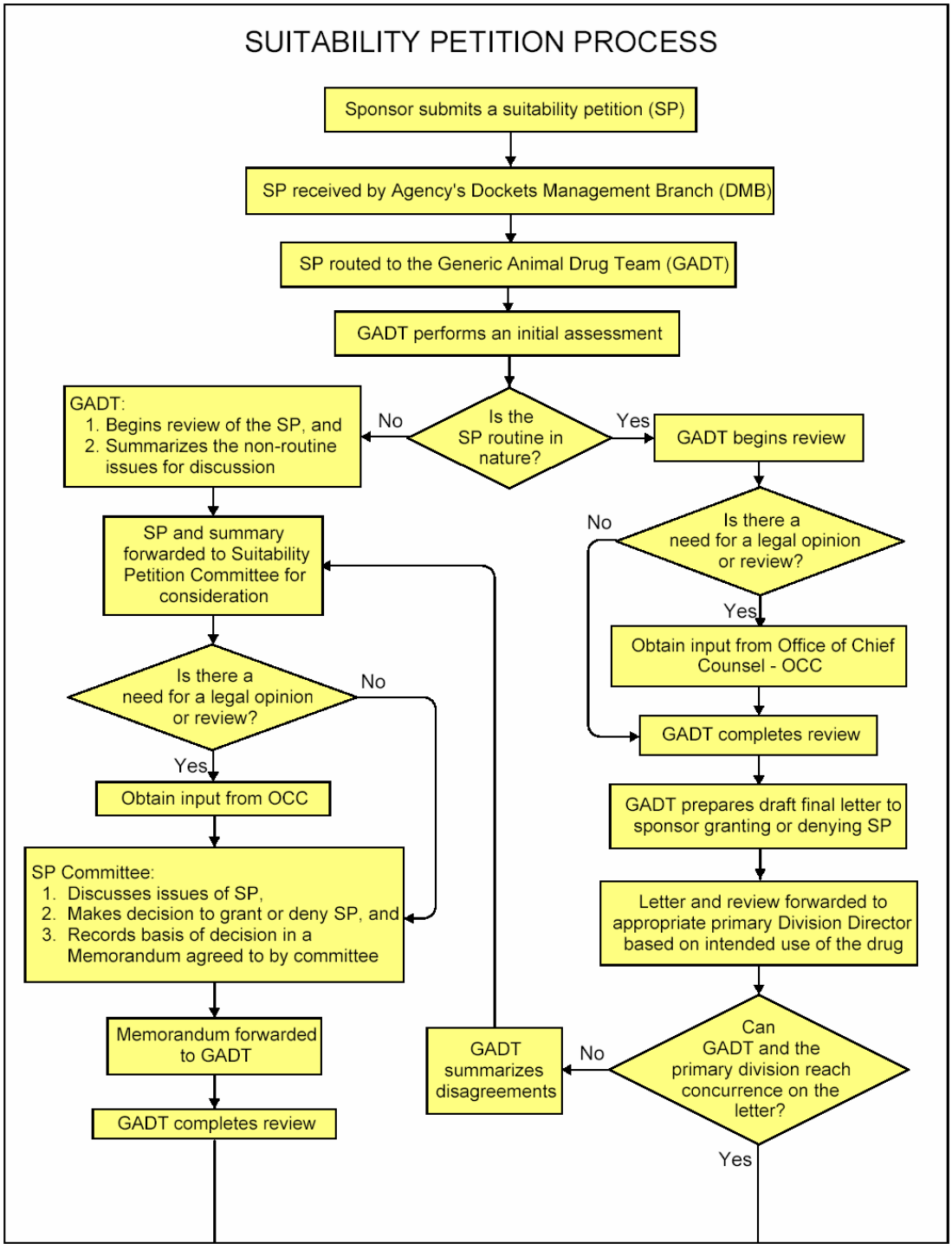
III. REFERENCES

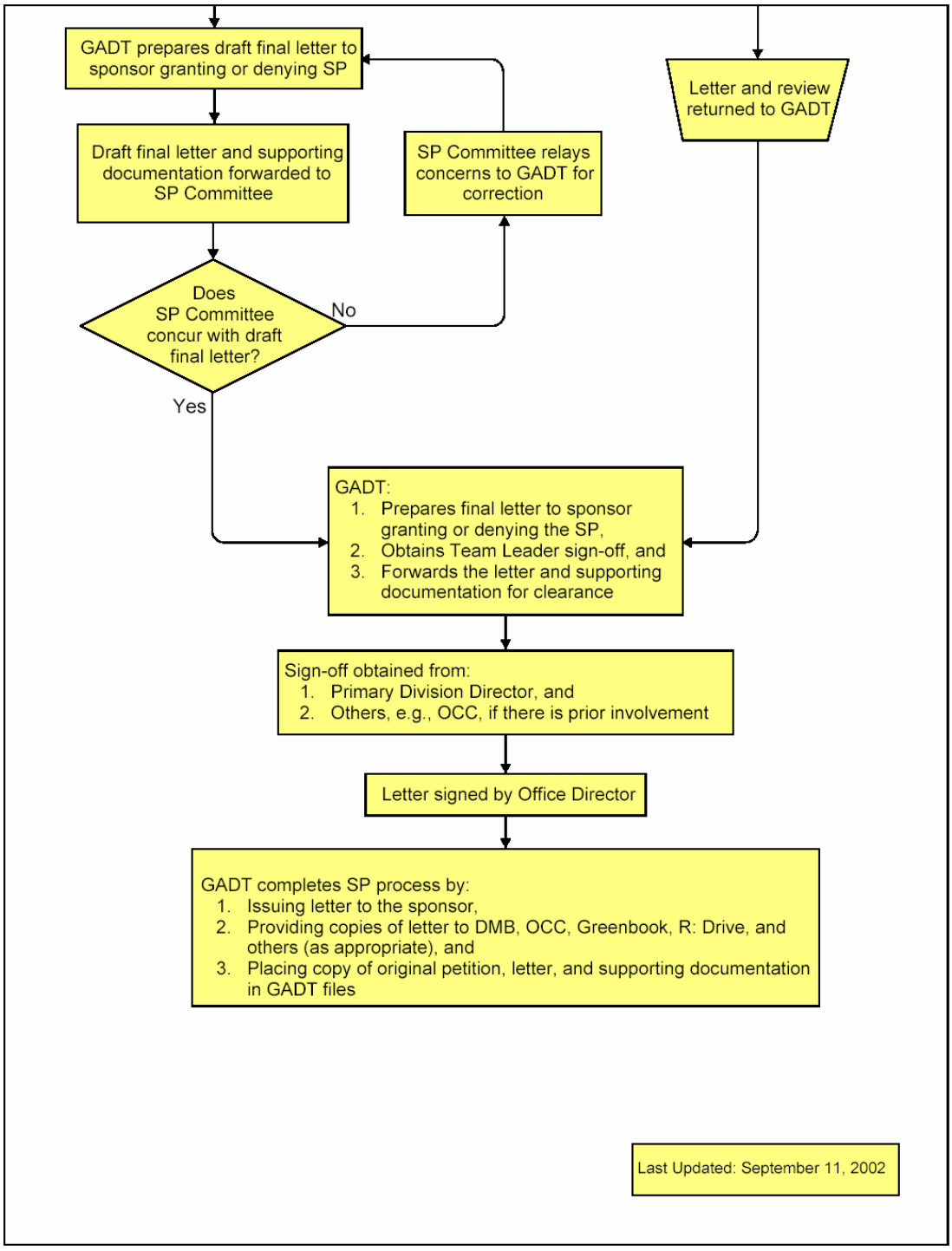
Federal Food, Drug, and Cosmetic Act, section 512(n)

Generic Animal Drug and Patent Term Restoration Act

21 CFR §§ 5.31, 10.20, 10.30, and 10.33

CVM Policy and Procedures Manual Guide 1240.2030


SUITABILITY PETITION PROCESS
Sponsor submits a suitability petition (SP)
SP received by Agency's Dockets Management Branch (DMB)
SP routed to the Generic Animal Drug Team (GADT)
GADT performs an initial assessment
Is the SP routine in nature?
No
Yes
GADT:
1. Begins review of the SP, and
2. Summarizes the non-routine issues for discussion
GADT begins review
SP and summary forwarded to Suitability Petition Committee for consideration
Is there a need for a legal opinion or review?
No
Yes
Obtain input from OCC
SP Committee:
1. Discusses issues of SP,
2. Makes decision to grant or deny SP, and
3. Records basis of decision in a Memorandum agreed to by committee
Memorandum forwarded to GADT
GADT completes review
Is there a need for a legal opinion or review?
No
Yes
Obtain input from Office of Chief Counsel - OCC
GADT completes review
GADT prepares draft final letter to sponsor granting or denying SP
Letter and review forwarded to appropriate primary Division Director based on intended use of the drug
Can GADT and the primary division reach concurrence on the letter?
No
Yes
GADT summarizes disagreements


GADT prepares draft final letter to sponsor granting or denying SP
Draft final letter and supporting documentation forwarded to SP Committee
SP Committee relays concerns to GADT for correction
Letter and review returned to GADT
Does SP Committee concur with draft final letter?
No
Yes
GADT:
1. Prepares final letter to sponsor granting or denying the SP,
2. Obtains Team Leader sign-off, and
3. Forwards the letter and supporting documentation for clearance
Sign-off obtained from:
1. Primary Division Director, and
2. Others, e.g., OCC, if there is prior involvement
Letter signed by Office Director
GADT completes SP process by:
1. Issuing letter to the sponsor,
2. Providing copies of letter to DMB, OCC, Greenbook, R: Drive, and others (as appropriate), and
3. Placing copy of original petition, letter, and supporting documentation in GADT files
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