
GENERAL PROCEDURAL POLICIES

**CITIZEN PETITIONS
POLICY AND PROCEDURES**

Background:

An interested person may 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. In addition, the request for a formal advisory opinion under 21 CFR 10.85 is processed as a citizen petition. The submission of citizen petitions is governed by §10.30. Petitions are submitted to the Division of Dockets Management (HFA-305) (DM) where they are reviewed for compliance with §10.30. If the petition is acceptable for filing, DM files, acknowledges, and assigns a docket number to the petition. If the petition is not adequate for filing, DM returns it to the petitioner.

1. Processing Citizen Petitions (excluding Suitability Petitions):

DM forwards filed petitions to the appropriate Center or Office for preparation of a response. Under 21 CFR 10.30(e)(2), a written response to the petition is required within 180 days of filing. The response may consist of:

- a. Approval of the petition, which may result in appropriate administrative action such as publication of a FEDERAL REGISTER document;
- b. Denial of the petition, which generally will include a discussion of the basis for denial; (Note: A petitioner whose petition has been denied may request administrative reconsideration under §10.33. A request for reconsideration is normally required to be submitted within 30 days of the denial.)
- c. A tentative response, indicating why the agency is unable to reach a decision on the petition. The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished.

The agency administrative record for the citizen petition is maintained by the DM, showing: (1) the docket number (assigned by DM); (2) the date the petition was filed by the DM; (3) the name of the petitioner; (4) the subject matter involved; and (5) the

GENERAL PROCEDURAL POLICIES

disposition of the petition.

The Policy and Regulations Staff, HFV-6, is the contact point within the Center for Veterinary Medicine (CVM) for receipt and assignment of the petition; coordination among offices, if necessary; consolidating the necessary reviews and actions; logging the movements of the petition and response package; circulating the response package for proper signatures; and monitoring timeliness of the response.

When received by HFV-6, the petition is logged into the CVM pending list indicating Docket Number, the 180-day due date, and other identifying information, such as the name and mail code of the CVM unit(s) where it is assigned for consulting review and preparation of correspondence.

The preparation of the formal response to a citizen petition may be assigned to any unit within CVM, depending on the expertise involved. The expertise and resources required for response are determined by the Director of the Policy and Regulations Staff, in consultation with the appropriate Office Directors.

Ordinarily a final response will be prepared with the assistance of an attorney in the Office of Chief Counsel (OCC) assigned to review CVM matters; OCC must sign off on the response. The response package should then be circulated for sign-off by the appropriate Division Director, appropriate Office Director, and Center Director. If the issue impacts more than one division or office, concurrence should be obtained from all relevant divisions/offices.

2. Signatures on Responses to Citizen Petitions (excluding Suitability Petitions):

- a. Under SMG [1410.30](#) of the FDA Staff Manual, the Center Director or Deputy Director may sign a *tentative* response to a citizen petition. Tentative responses are prepared by the Policy and Regulations Staff, HFV-6, and issued by the Center Director's Office (HFV-1). In addition, pursuant to SMG 1410.30, the Center Director and Deputy Director are authorized to sign *final* responses to citizen petitions that: (1) are from sponsors of investigational new animal drug applications who request approval to ship in interstate commerce an investigational new animal drug for animal use containing a chlorofluorocarbon;

GENERAL PROCEDURAL POLICIES

and (2) that involve the issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.

- b. The signing of other *final* responses to citizen petitions is ordinarily the responsibility of the Associate Commissioner for Regulatory Affairs (ACRA, HFC-1). Appropriate FDA units prepare petition responses for his or her signature. However, when a citizen petition is closely related to a proposed or final rule, the final response will be prepared for the signature of the Associate Commissioner for Policy.

Following final sign-off by the Center, final responses for the signature of the ACRA are packaged and routed by HFV-6 to the Division of Compliance Policy (HFC-230), which will log it into their tracking system. From there, the package goes to HFC-200, then to HFC-1 for signature. The package from HFV-6 needs to include a copy of the petition and a “Routing and Transmittal Slip” on the front, indicating OCC’s and CVM’s clearances, as well as a short description of the purpose of the letter enclosed. The docket number should be in the upper-right-hand corner of the first page of the final response.

Once the final response is signed by the ACRA, the entire package is returned to HFV-6 for issuance of the response and distribution of copies, including those to DM. The “bcc” list for copies includes the following offices: HFC-1, HFC-200, HFC-230, GCF-1, HFV-1, HFV-2, HFV-3, HFV-6, and either HFV-100 or HFV-200, whichever is appropriate. Internal working papers or memoranda that are protected from disclosure under the Freedom of Information Act should not be forwarded to DM.

- c. If the petition response involves a FEDERAL REGISTER publication, HFV-6 will route the CVM-cleared package to the Regulations and Policy Management Staff (HF-26) to obtain clearance. Once cleared, the package will then be forwarded by HFV-6 to the Associate Commissioner for Policy (HF-22) for signature. Issuance of the letter and distribution of copies can be done by either HFV-6 or HF-22, based on mutual agreement.

3. Processing Suitability Petitions:

Suitability petitions for new animal drugs are defined in section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act and are processed in CVM as a special type of citizen petition. If the 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)). The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM, are authorized to sign suitability petitions. Additional specific information on how to process suitability petitions is provided in Program Policy and Procedures Manual 1243.3040.

Version History

4/19/05- revisions
8/9/07 - revisions
8/28/07 –minor revisions
9/27/07 – minor revisions
06/30/09 - Updated hyperlink to SMG 1410.30