
GENERAL PROCEDURAL POLICIES

FREEDOM OF INFORMATION REQUESTS FOR INFORMATION

1. **Purpose:**

This document establishes the policy and procedures for processing Freedom of Information requests for information concerning the regulatory status of animal drugs, devices, or foods. It also addresses the relevance of the Freedom of Information (FOI).

2. **Policy:**

- a. All requests for information submitted under the Freedom of Information Act regarding the regulatory/legal status of animal drugs, devices, or food products shall be submitted in writing. If the request is for animal drugs, devices or food products, under 21 CFR part 20, the request and response must conform to the requirements of that regulation.
- b. All responses to requests for information will be reviewed and released according to 21 CFR part 20 and will reflect the Presidents Transparency order and the disclosable information available will represent the position of the Center and Agency regarding that subject at that time.
- c. Before any response to a request for information is rendered appropriate individuals and sections of the Center will be contacted and asked to provide responsive records to the Center FOI OFFICER for review and release to the FOI requestor.
- d. Responses to formal FOI Requests 21 CFR part 20 binding unless appealed by the requestor. At which time a formal Appeal will be submitted by the Agency FOI Denials and Appeals Officer to the Center for reevaluation.

3. **Responsibility:**

It is the responsibility of the Office of Communications/Office of the Director to process Freedom of Information requests for information concerning the regulatory status of animal drug, devices, or foods in the accordance with 21 CFR parts 20 and to develop clear and accurate responses to our requestors.

If needed, other offices in the Center will be responsible for medical evaluations and other technical comment. The final response will be prepared by the Center FOI OFFICER.

4. **Caution to Observe:**

Any material given to a member of the public, whether or not in response to a written request, constitutes making that material public. It is then available to other persons requesting the same material under the FOI Act. This does not include draft documents under preparation, which are not releasable, but rather finalized documents.

History

10/23/85 – Original

11/19/85 – Minor changes

03/29/11 - New PPM no. assigned (previously 1240.2010); minor change