GENERAL PROCEDURAL POLICIES

ADVISORY OPINIONS AND INFORMAL REQUESTS FOR INFORMATION

1. **Purpose:**

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

2. **Policy:**

a. All requests for information regarding the regulatory/legal status of animal products shall be submitted in writing. If the request is for a formal advisory opinion, under 21 CFR 10.85, the request and response must conform to the requirements of that regulation.

b. All responses to requests for information will manifest the best information available and will represent the position of the Center and Agency regarding that subject at that time.

c. Before any response to a request for information or opinion is rendered, appropriate individuals and sections of the Center will have an opportunity to make input and to concur.

d. Responses to formal advisory opinions given under 21 CFR 10.85 are binding until amended or revoked. Informal communications represent the best judgment of the respondent at the time, but according to 21 CFR 10.85(k) do not legally bind, obligate, or commit the Agency to the views expressed. This does not, however, relieve the Center from exercising the same degree of care and accuracy as for the formal advisory opinions. The recipient should be able to rely upon informal opinions as well as formal advisory opinions. Despite the wording of the regulation, in a practical sense a recipient of an informal opinion has the right to rely upon the opinion until it is revised or revoked.

3. **Responsibility:**

It is the responsibility of the Division of Compliance (HFV-230) to process requests for advisory opinions in the accordance with 21 CFR 10.85 and to develop or clear responses to informal requests for regulatory opinion.

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 Division of Compliance which will be responsible for obtaining all necessary concurrences.

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.