GENERAL PROCEDURAL POLICIES

FEDERAL REGISTER DOCUMENT ACTIVITY: RULE-MAKING PROCEDURES

Background:

The Administration issued Executive Order 12498 on January 4, 1985 revising the regulatory planning process. Each year the Director of the Office of Management and Budget (OMB) is required to publish the "Regulatory Program of the United States Government." The regulatory program describes the "Significant Regulatory Actions" of the 17 agencies included in the program. The Commissioner has requested that an enforcement strategy accompany new or substantially revised regulations so that he can be assured they will be properly enforced.

1. Purpose:

   This guide outlines the internal procedures to be followed by Center personnel in the preparation of all proposed policy-oriented or major impact FEDERAL REGISTER rule-making documents (i.e., regulations).

2. Contact Person:

   Emphasis is placed on establishing individual responsibility for all aspects of document activity. The Commissioner has requested that an individual be designated as responsible for expediting and monitoring the progress of the document from inception to final action. It is essential for all Center personnel involved to be aware of the function of that individual.

   a. Selection

      Any Center employee may be designated the responsible individual and be named as the "contact person." It will usually be the team leader or the project officer. The designation of the contact person should be made as early as possible to expedite the development of the regulatory strategy and subsequent actions.

   b. Responsibilities

The duties of the contact person include:

(1) preparation of the action memorandum, enforcement strategy and appropriate clearance under the Paperwork Reduction Act of 1980;

(2) assuring that the administrative file is complete and accurate and that supporting material is properly indexed, tabbed and filed with the Dockets Management Branch;

(3) being prepared to respond to questions from within the agency, including the Commissioner, regarding the status of a document at any time (Following publication, questions may also be received from the general public.); and

(4) being familiar with the administrative and technical aspects of the proposed action.

3. FEDERAL REGISTER

The contact person will coordinate with the Policy and Regulations Team (HFV-6) who will prepare a draft of the FEDERAL REGISTER "proposal" document. The document will be based upon the administrative file and in consultation with the contact person. See CVM Guide 1240.2020 FEDERAL REGISTER Document Processing. As required, the Dockets Management Branch will establish a docket for public availability of information such as the administrative file, comments, and responses to comments.

4. The Administrative File

The administrative file shall contain all related documentation including relevant evaluations, reviews, memoranda, letters, opinions of consultants, minutes of meetings, records of private communications between FDA employees and those outside the agency, and all other written material pertinent to the matter as required by 21 CFR 10.70. (This does not include copies of Action Memoranda, Strategy Documents, other internal working papers, or distribution and concurrences.) Copies of literature reprints and other supporting material from the administrative file shall be appropriately indexed and tabbed, and shall accompany the draft FEDERAL REGISTER document when it is forwarded for review and concurrence. Those portions which are intended for filing with the Dockets Management Branch should be purged in accordance with the FOI regulations and

accompany the document when circulated for concurrences and signature. Upon the initial publication in the FEDERAL REGISTER, the administrative file will be publicly available.

5. Proposed Responses and Final Order:

Responses to the FEDERAL REGISTER proposal received by the Dockets Management Branch are placed in the docket and a copy forwarded to the Policy and Regulations Team who collate and summarize the comments and forward them to the contact person. The contact person will coordinate the review, evaluation, and preparation of responses to the issues. The Policy and Regulations Team will prepare subsequent FEDERAL REGISTER documents (whether an amended proposal, tentative final, final, etc.).

6. Other Requirements of the FEDERAL REGISTER Document Activities:

Enforcement Strategy

Any proposed or final regulation which imposes new or substantially changed regulatory requirements on industry must be accompanied by an enforcement strategy document to assure proper enforcement. Most food additive and new animal drug regulations will not require preparing an enforcement strategy.