GENERAL PROCEDURAL POLICIES

FEDERAL REGISTER DOCUMENT PROCESSING

Background:

In the surge of New Deal legislation enacted in the 1930's, Congress delegated more and more responsibility to Federal departments and agencies in the form of authority to issue detailed regulations dealing with complex social and economic issues. As more regulations were written, a serious communications problem developed. Since there was no central publications system, there was no efficient way for the public to know about regulations which affected them.

In 1934, Congress recognized the need for a centralized system and enacted the FEDERAL REGISTER Act. It became law on July 26, 1935 (44 U.S.C. Chapter 15). The act established a uniform system for handling agency regulations by requiring the:

(1) Filing of documents with the Office of the FEDERAL REGISTER;

(2) Placement of documents on public display;

(3) Publication of documents in the FEDERAL REGISTER; and

(4) After a 1937 amendment, permanent codification (numerical arrangement) of rules in the Code of Federal Regulations.

Publication in the FEDERAL REGISTER has certain legal effects.

(1) Provides official notice of a document's existence and its contents;

(2) Establishes a text as a true copy of the original document;

(3) Indicates the date of the regulation's issuance; and

(4) Provides evidence that is acceptable to a court of law (prima-facie evidence).

Several important new dimensions were added to the FEDERAL REGISTER system by the

Administrative Procedure Act. The act became law on June 11, 1946 (5 U.S.C. 551 et seq.). The act:

(1) Introduced as a general requirement (with some stated exceptions) the right of the public to participate in the rulemaking process by commenting on the proposed rules;

(2) Required that the effective date for a regulation be not less than 30 days from the date of publication unless there was good cause for an earlier date; and

(3) Provided for publication of agency statements of organization and procedural rules.

These two laws, the FEDERAL REGISTER Act and the Administrative Procedure Act, define the basic functions of the FEDERAL REGISTER system and provide the framework for the promulgation of government regulations. The daily FEDERAL REGISTER (FR) contains revisions to the Code of Federal Regulations (CFR). These daily revisions are compiled, and a revised CFR is issued annually. The CFR is organized into titles, each in turn into several chapters. In the end of each CFR volume is a table of CFR titles and chapters. Title 21 is reserved for Food and Drugs; Chapter 1 of that title for the Food and Drug Administration; Subchapter E for Animal Drugs, Feeds, and Related Products. Subchapter E comprises most of the animal drug rules. It is subdivided into Parts 500 to 599. Each FR publication concerning a proposed rule or rules begins by referencing the portion of the CFR to be affected.

Contents of FEDERAL REGISTER Documents

All FEDERAL REGISTER documents follow the current format of the FEDERAL REGISTER Document Drafting Handbook (1997 Edition) requiring the following parts: A heading (identifying department and agency), CFR part number and part title (if codified), document title, summary, date, contact person, preamble (supplementary information in the document), authority statement and codified text, if applicable. As required by law and regulation, rulemaking documents address FOI provisions, NEPA reviews, the paperwork burden imposed, and economic impact (if required). Proposed rules provide for submission of comments.

1. Types of FEDERAL REGISTER Documents:

The three types of documents processed by the Center for FEDERAL REGISTER publication are notices, proposed rules, and rules and regulations.

a. Notices:

Publications that are not codified in the CFR such as:

(1) notice of filing of food additive petition, GRAS affirmation petition,

(2) notice of availability of guidelines, policy guides, public master files,

(3) notice of availability of environmental impact statement,

(4) notice of open meeting,

(5) notice of opportunity for hearing,

(6) notice of hearing,

(7) notice of withdrawal of approval of new animal drug or medicated feed applications, and

(8) notice of filing of an export application for an unapproved drug.

b. Proposed Rules:

An announcement of intent to promulgate a rule or regulation by publication of the text is a proposed rule. It provides an opportunity for comment as well as for public review of all comments received. Proposed rules include:

(1) proposed regulations,

(2) notice of intent to propose a regulation,

(3) tentative final regulation, and

(4) extension of comment period on a proposed regulation.

c. Rules and Regulations:

Rules and regulations promulgated by the agency have the effect of law. The Food and Drug Administration publishes in the daily FEDERAL REGISTER, and issues

a new CFR annually compiling all regulations as of April 1 each year. Rules and regulations include:

(1) regulations reflecting conditions of approval of original and supplemental new animal drug applications,

(2) regulations providing for the use of food additives, and GRAS substances,

(3) publication of final regulations based upon proposed rules,

(4) recodification (redesignation) of regulations, and

(5) withdrawal of regulations.

2. FEDERAL REGISTER Delegations of Authority:

All actions delegated to the Secretary by the FD&C Act have been redelegated to the Commissioner of Food and Drugs (21 CFR Part 5) with the exception of finding an imminent hazard to the health of man or animals (21 CFR 5.10). However, authority is reserved for the Secretary's approval of any rulemaking activity, particularly the establishment of procedural rules or documents of considerable significance (21 CFR 5.11). The Commissioner has in turn redelegated certain functions to specific operating units of FDA. The most important redelegation of functions to the Director and Deputy Director of the Center for Veterinary Medicine are specified in 21 CFR 5.83 and 5.84. Redelegated in turn to the Director and Deputy Director, Office of New Animal Drug Evaluation, and Director and Deputy Director, Office of Surveillance and Compliance, are the approval of certain supplemental new animal drug applications (21 CFR 5.83), and to the Director, Division of Manufacturing Technologies, approval of certain supplemental NADAs concerning chemistry, manufacturing, and controls. (See Center Guide 1240.2210 - Approval of New Animal Drug Applications and Supplements).

a. FEDERAL REGISTER documents signed by the Office of the Center Director are:

(1) Approval of original NADAs and certain Category II supplemental applications (21 CFR 5.83).

(2) Notices of opportunity for hearing on proposals to refuse approval or to withdraw approval of NADAs (21 CFR 5.84).

(3) Notices of refusal to approve or withdrawal of approval when opportunity for a hearing has been waived (21 CFR 5.84).

(4) Notices of filing pertaining to food additives or GRAS substances (21 CFR 5.61).

(5) Final regulations for food additives or GRAS substances that are non-controversial and do not involve the Delaney clause (21 CFR 5.61).

b. FEDERAL REGISTER documents approving Category I and certain Category II supplemental applications are signed by the Director and Deputy Director, Office of New Animal Drug Evaluation and Director and Deputy Director, Office of Surveillance and Compliance (21 CFR 5.83). FEDERAL REGISTER documents concerning export of unapproved new animal drugs are signed by the Director and Deputy Director, Office of New Animal Drug Evaluation, CVM (21 CFR 5.44).

c. FEDERAL REGISTER documents signed by the Office of the Commissioner include all actions not specifically redelegated and described above (21 CFR 5.10 and 5.11).

General Rules of Concurrence:

a. All FEDERAL REGISTER documents must have the concurrence of the Office of the Center Director (unless signature is redelegated to the Office of New Animal Drug Evaluation or the Office of Surveillance and Compliance, or further redelegated, as in 21 CFR 5.83) and Office of Chief Counsel (OCC) (except for those specifically exempted from OCC concurrence by agreement with CVM of Sep. 22, 1983).

b. Individuals providing input related to the document should be provided an opportunity to review and concur with it.

c. Concurrence should include surname, office identification (routing code) and date.

d. Any changes inserted in the circulating FEDERAL REGISTER document should be initialed and dated.

e. OCC Sign-Off of Approval Comments:

OCC has agreed that it would review routine approval document packages (original and supplemental NADAs) in draft. The OCC review package contains the draft FR document, briefing memo, approval letter, environmental staff memo, and FOI (including labeling). If

acceptable, the CVM liaison attorney or Deputy Chief Counsel for Program Review will endorse indicating concurrence. Further review by OCC is not needed unless substantive revisions occur. Such may require additional review and endorsement. OCC review has been waived for certain routine documents such as category I supplements (change of sponsor or sponsor name or address) or category II supplements that do not require new safety or effectiveness data. In addition, OCC review has been waived for notices of filing of food additive petitions, export applications, and for nonsubstantive editorial amendments.

For additional information on NADA processing, see P&P Manual Guide 1240.3100 et seq. For FAP processing, see 1240.3300 et seq.