The Regulatory Process of the U.S. Food and Drug Administration

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Overview

• Terminology and Basics
• Review of the FDA Administrative Process
• Recent Administrative Orders Expected to Influence Regulatory Process
A regulation is a general statement issued by an agency, board, or commission that has the force and effect of law.

Congress, in the text of the laws that it passes, frequently grants agencies the authority to issue regulations and flexibility in deciding how best to implement those laws.

- Congress may specifically require agencies to issue a regulation.
- Alternatively, Congress grants agencies the discretion to issue a regulation.

Rulemaking can also take the form of guidance and policies.
Rulemaking Overview

- FDA publishes regulations in the Federal Register, the federal government's official publication for notifying the public of many kinds of agency actions.
- Rulemaking procedures come from U.S. law, Executive Orders (EO’s) and memoranda issued by the President, and FDA’s own regulations.
- FDA’s most frequently used process for issuing rules is “notice and comment rulemaking”
Step One

Initiating Events

Agency Initiatives
Agency initiatives for rulemaking originate from such things as:
- Agency priorities and plans
- New scientific data
- New technologies
- Accidents

Required Reviews

Statutory Mandates

Recommendations from Other Agencies/External Groups/States/Federal Advisory Committees

Lawsuits

Petitions

OMB Prompt Letters

Agendas for Rules Under Development or Review

Unified Regulatory Agenda
The Unified Regulatory Agenda provides information concerning agency rules under development or review.
The Unified Regulatory Agenda is published in the Federal Register in the spring and fall of each year.

Regulatory Plan
The Regulatory Plan provides information concerning the most important significant regulatory actions that the agency is planning to take.
The Regulatory Plan is published in the Unified Regulatory Agenda in the fall of each year.

Regulatory Flexibility Agenda
The Regulatory Flexibility Agenda provides information concerning any rule that an agency expects to prepare or promulgate that is likely to have a significant economic impact on a substantial number of small entities.
Agency regulatory flexibility agendas are published as part of the Unified Regulatory Agenda in the spring and fall of each year.
**Step Two**

**Determination Whether a Rule Is Needed**

**Administrative Procedure Act Provisions**

Under the Administrative Procedure Act provisions that are included as part of the Freedom of Information Act at 5 U.S.C. 552, agencies are required to publish in the Federal Register:

- Substantive rules of general applicability
- Interpretive rules
- Statements of general policy
- Rules of procedure
- Information about forms
- Information concerning agency organization and methods of operation

**Step Three**

**Preparation of Proposed Rule**

**Proposed Rule**

A notice of proposed rulemaking proposes to add, change, or delete regulatory text and contains a request for public comments.

**Administrative Procedure Act Provisions**

Under the Administrative Procedure Act provisions at 5 U.S.C. 553, rules may be established only after proposed rulemaking procedures (steps three through six) have been followed, unless an exemption applies. The following are exempted:

- Rules concerning military or foreign affairs functions
- Rules concerning agency management or personnel
- Rules concerning public property, loans, grants, benefits, or contracts
- Interpretive rules
- General statements of policy
- Rules of agency organization, procedure, or practice
- Nonsignificant rules for which the agency determines that public input is not warranted
- Rules published on an emergency basis

*Note: Even if an exemption applies under the Administrative Procedure Act provisions, other statutory authority or agency policy may require that proposed rulemaking procedures be followed.*

**Step Four**

**OMB Review of Proposed Rule**

**OMB Review Under Executive Order 12866**

OMB reviews only those rulemaking actions determined to be “significant.” Independent agencies are exempt from OMB review.

**Administrative Procedure Act Provisions**


**Step Five**

**Publication of Proposed Rule**

**Optional Supplementary Procedures to Help Prepare a Proposed Rule**

**Advance Notice of Proposed Rulemaking**

An advance notice of proposed rulemaking requests information needed for developing a proposed rule.

**Negotiated Rulemaking**

Negotiated rulemaking is a mechanism under the Negotiated Rulemaking Act (5 U.S.C. 561-570) for bringing together representatives of an agency and the various interests to negotiate the text of a proposed rule.
ANPRM

• Where FDA needs more information or has not decided on the details of a regulatory path, FDA will sometimes issue a request for comments or an advance notice of proposed rulemaking (ANPRM)
• ANPRM is a Federal Register notice that asks for public comment on broad issues or questions and seeks data or other information
• FDA uses the information provided to formulate the specific policy to be put forth in a subsequent proposed rule
Generally, the first public step in the notice and comment rulemaking process is for FDA to issue a “notice of proposed rulemaking” (NPRM), otherwise called a proposed rule.

Proposed rules explain what FDA intends to require or do, as well as the basis (e.g., scientific and policy reasons) for the proposal.

FDA requests public comment on the proposed rule, which are generally submitted via the Federal Government’s electronic docket site (Regulations.gov)
Step Six
Public Comments

Comments
Under the Administrative Procedure Act provisions of 5 U.S.C. 553, an agency must provide the public the opportunity to submit written comments for consideration by the agency.

As required by Public Law No. 107-347, agencies must provide for submission of comments by electronic means and must make available online the comments and other materials included in the rulemaking docket under 5 U.S.C. 553(c).

Executive Order 12866 established 60 days as the standard for the comment period.

The holding of a public hearing is discretionary unless required by statute or agency policy.

Step Seven
Preparation of Final Rule, Interim Final Rule, or Direct Final Rule

Final Rule
A final rule adds, changes, deletes, or affirms regulatory text.

Special Types of Final Rules

Interim Final Rule
An interim final rule adds, changes, or deletes regulatory text and contains a request for comments. The subsequent final rule may make changes to the text of the interim final rule.

Direct Final Rule
A direct final rule adds, changes, or deletes regulatory text at a specified future time, with a duty to withdraw the rule if the agency receives adverse comments within the period specified by the agency.

Step Eight
OMB Review of Final Rule, Interim Final Rule, or Direct Final Rule

OMB Review Under Executive Order 12866
OMB reviews only those rulemaking actions determined to be "significant."

Independent agencies are exempt from OMB review.

Step Nine
Publication of Final Rule, Interim Final Rule, or Direct Final Rule

Congressional Review Act (5 U.S.C. 801-808)
An agency must submit most final rules, interim final rules, and direct final rules, along with supporting information, to both houses of Congress and the General Accounting Office before they can take effect.

Major rules are subject to a delayed effective date (with certain exceptions).

Action by Congress and the President could have an impact on the rule.

Administrative Procedure Act Provisions
Under the Administrative Procedure Act provisions that are included as part of the Freedom of Information Act at 5 U.S.C. 552, agencies are required to publish final rules, interim final rules, and direct final rules in the Federal Register.

Federal Register Act (44 U.S.C. 1501-1511)
The Federal Register Act at 44 U.S.C. 1510 (implemented at 1 CFR 8.1) requires rules that have general applicability and legal effect to be published in the Code of Federal Regulations.
Final Rules

- Once FDA has received and reviewed public comments, it decides whether further action is needed
- Based on public comments, FDA may end rulemaking process without issuing a regulation, issue a new proposed rule, or issue a final rule published in the Federal Register
- Final rules explain new regulatory requirements ("codified" portion), and discuss impact on industry and public and FDA’s response to comments on proposed rule ("preamble" portion)
- Codified portions of final rules are published under Title 21 of Code of Federal Regulations
## Specific Analyses for Steps Three and Seven

### Regulatory Planning and Review (E.O. 12866)
- Would the rule have a $100 million annual impact, raise new issues, and/or have other significant impacts?
- If yes: Prepare economic impact analysis.

### Federalism (E.O. 13132)
- Is the rule a discretionary rule that has federalism implications and imposes substantial unanticipated direct compliance costs on State and local governments?
- If yes: Prepare federalism summary impact statement.

### Indian Tribal Governments (E.O. 13175)
- Is the rule a discretionary rule that has tribal implications and imposes substantial unanticipated direct compliance costs on Indian tribal governments?
- If yes: Prepare tribal summary impact statement.

### National Environmental Policy Act (42 U.S.C. 4321–4347)
- Is the rule categorically excluded from review?
- If no: Prepare an environmental assessment or environmental impact statement, as appropriate.

### National Technology Transfer and Advancement Act (15 U.S.C. 272 note)
- Does the rule contain provisions for which the use of voluntary standards is applicable?
- If yes: Adopt voluntary consensus standards or explain why not.

### Governmental Actions and Interference with Constitutionally Protected Property Rights (E.O. 12630)
- Does the rule regulate private property use for the protection of public health or safety?
- If yes: Prepare takings analysis.

### Protection of Children from Environmental Health Risks and Safety Risks (E.O. 13045)
- Is the rulemaking a “covered regulatory action”?
- If yes: Prepare analysis of the environmental health or safety effects on children.

### Drafting Requirements for Rulemaking Documents

### Regulatory Planning and Review (E.O. 12866)
Rulemaking documents must comply with the specified regulatory philosophy and principles of regulation.

### Civil Justice Reform (E.O. 12988)
Rulemaking documents must be written in clear language designed to help reduce litigation.

### Presidential Memorandum on Plain Language (63 FR 31885)
Rulemaking documents must comply with plain language principles.

### Federal Register Publications
Rulemaking documents must comply with the Federal Register regulations (1 CFR). Additional guidance and requirements are contained in the Federal Register’s Document Drafting Handbook.
Review Outside of FDA

• Rules are reviewed by other parts of the federal government
• Office of the Secretary of Department of Health and Human Services (HHS) or other HHS sister agencies may review a draft rule before it is published
• FDA may also consult with non-HHS agencies when working on a rulemaking that has a broader impact
• If rules are deemed "significant" under E.O. 12866 (among other tests), Office of Management and Budget’s (OMB) Office of Information and Regulatory Affairs (OIRA) must review and coordinate with other Federal agencies with an interest in the issues
Recent Administrative Actions Impacting Regulation

- January 20, 2017 White House Memorandum – Halting or Postponing Regulatory Actions
- January 23, 2017 Presidential Memorandum – “Regarding the Hiring Freeze”
  - Orders a freeze on the hiring of federal civilian employees to be applied across the board in the executive branch
- February 24, 2017 Executive Order – “Enforcing the Regulatory Reform Agenda”
- March 13, 2017 Executive Order – “Comprehensive Plan for Reorganizing the Executive Branch”
January 20, 2017 White House Memorandum – Halting or Postponing Regulatory Actions

• Directed the heads of all executive departments and agencies to halt or postpone regulatory actions until review and approval by the new administration’s appointed head
  • No regulations were to be sent to Office of the Federal Register (“OFR”) until review and approval conducted
  • Regulations sent to OFR, but not published were to be withdrawn until review and approval
  • Published regulations that had not taken effect, had their effective dates temporarily postponed for 60 days from January 20, 2017, for review
    • Where appropriate and as permitted by law, consideration is to be given for proposing a rule for notice and comment to delay the effective date beyond the 60-day period, and potentially proposing further notice-and-comment rulemaking
January 30, 2017 Executive Order 13771 – “Reducing Regulation and Controlling Regulatory Costs”

- Directs that agencies repeal two existing regulations prior to promulgating every new regulation
  - Unless prohibited by law, when an executive department or agency (agency) publicly proposes for notice and comment or otherwise promulgates a new regulation, it must identify at least two existing regulations to be repealed
  - Total incremental cost of all new regulations (including repealed regulations) to be finalized shall be no greater than zero, unless otherwise required by law or consistent with written advice by the Director of the Office of Management and Budget
February 24, 2017 Executive Order 13777 – “Enforcing the Regulatory Reform Agenda”

- Agencies are required to appoint Regulatory Reform Officers (RROs)
- RROs oversee implementation of regulatory reform initiatives and policies:
  - Executive Order 13771 of January 30, 2017 (Reducing Regulation and Controlling Regulatory Costs), regarding offsetting the number and cost of new regulations;
  - Executive Order 12866 of September 30, 1993 (Regulatory Planning and Review), as amended, regarding regulatory planning and review;
  - Section 6 of Executive Order 13563 of January 18, 2011 (Improving Regulation and Regulatory Review), regarding retrospective review; and
  - Termination of programs and activities that have been rescinded.
March 13, 2017 Executive Order 13781 – “Comprehensive Plan for Reorganizing the Executive Branch”

• Within 180 days, the head of each agency shall submit a proposed plan to reorganize the agency, in order to improve efficiency, effectiveness, and accountability
• Publish notice in the Federal Register inviting public to suggest improvements in organization and functioning of executive branch
• Submit proposed plan with recommendations to eliminate unnecessary agencies, components of agencies, and agency programs, and to merge functions, including recommendations for any legislation or administrative measures necessary to achieve reorganization
Seth Mailhot is a partner and lead of the FDA Regulatory Practice Group in Michael Best & Friedrich’s Washington D.C. office. His 14 years working in the U.S. Food and Drug Administration (FDA) has provided him a unique perspective when counseling clients on a broad range of matters involving the FDA.

Seth’s practice includes representation of the medical device, pharmaceutical, dietary supplement, tobacco and food industries, and covers both premarket and post-market issues. His practice is focused on development of premarket submission strategies, and FDA enforcement of good manufacturing practices, both domestically and abroad.

Admissions
- District of Columbia
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Education
- New England School of Law, J.D., Valedictorian, summa cum laude
- University of Massachusetts, B.S., Chemical Engineering