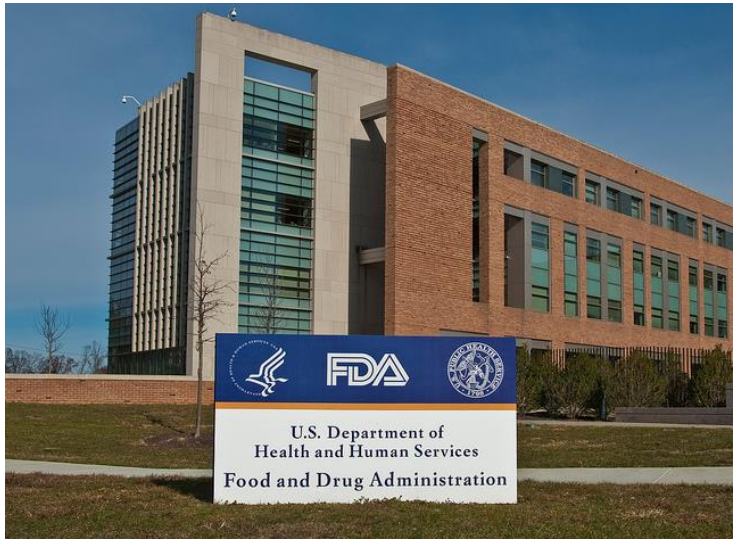
U.S. FDA Experience in Coordination and Consultation on Public Health Regulations



Committee on Technical Barriers to Trade

June 2019

FDA U.S. FOOD & DRUG ADMINISTRATION

Determining Regulatory Priorities

U.S. FOOD & DRUG ADMINISTRATION

Developing a Draft Regulation

CODEX ALIMENTARIUS

AOAC INTERNATIONAL

FDA U.S. FOOD & DRUG ADMINISTRATION

Reviewing a Draft Regulation

Federal Register
Vol. 58, No. 190
Monday, October 4, 1993

Presidential Documents

Title 3—

The President

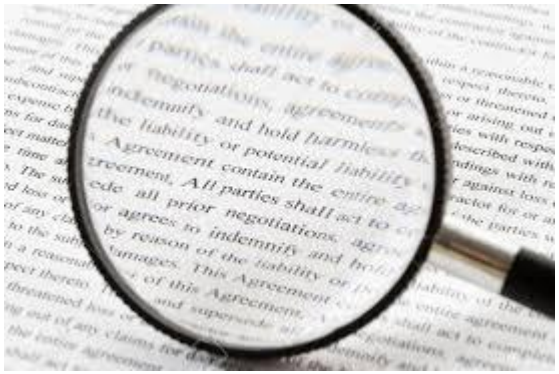
Executive Order 12866 of September 30, 1993

Regulatory Planning and Review

The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable. We do not have such a regulatory system today.

With this Executive order, the Federal Government begins a program to reform and make more efficient the regulatory process. The objectives of this Executive order are to enhance planning and coordination with respect to both new and existing regulations; to reaffirm the primacy of Federal agencies in the regulatory decision-making process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public. In pursuing these objectives, the regulatory process shall be conducted so as to meet applicable statutory requirements and with due regard to the discretion that has been entrusted to the Federal agencies.

Accordingly, by the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:



Notice & Comment on a Proposed Regulation

Example 1: UDI Rule Date Format

Proposed rule:	Final Rule:
• required U.S. format (e.g., JUN 19, 2013) for all dates on medical device labels • date formatting requirements effective for all devices in 1 year	• date format must be all numeric: YYYY-MM-DD (e.g., 2013-06-19); consistent with international standards • date formatting requirements phased in over five years based on device classification

Example 2: UDI Rule Direct Marking

Proposed rule:

- Direct Marking required for:
  - Implantable devices
  - Devices intended to be sterilized between patient use
  - Stand-alone software

Final Rule:

- Direct Marking required for all devices that are intended to be used more than once and "reprocessed" (cleaned, disinfected or sterilized) before each use [expanded sterilized to reprocessed]
- Direct marking requirements for implantable device removed
- Application to stand-alone software modified

Example 3: UDI Rule MRI Compatibility

Proposed rule:

- Would not have required information concerning magnetic resonance imaging (MRI) compatibility to be submitted to the Global UDI Database (GUDID)

Final Rule:

- Requires information to be submitted to GUDID concerning whether a patient may be safely exposed to MRI or similar technologies while using the device or while the device is implanted

Example 4: Additional Information for Nutrition Facts Label Rule

G/TBT/N/USA/893/Add.5

Generate document

0. Notification dates

1. Notified measure

Notifying Member

United States of America

Title of the notified measure & text

TITLE: Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Administrative Docket Update; Availability

AGENCY: Food and Drug Administration, HHS

ACTION: Proposed rule; notification

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of certain documents to update the administrative docket of the proposed rule to amend FDA's labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the Nutrition Facts and Supplement Facts labels to assist consumers in maintaining healthy dietary practices.

DATES: We are extending the comment period that was scheduled to close on 25 September 2015, until 13 October 2015.

Link to full text of notified document

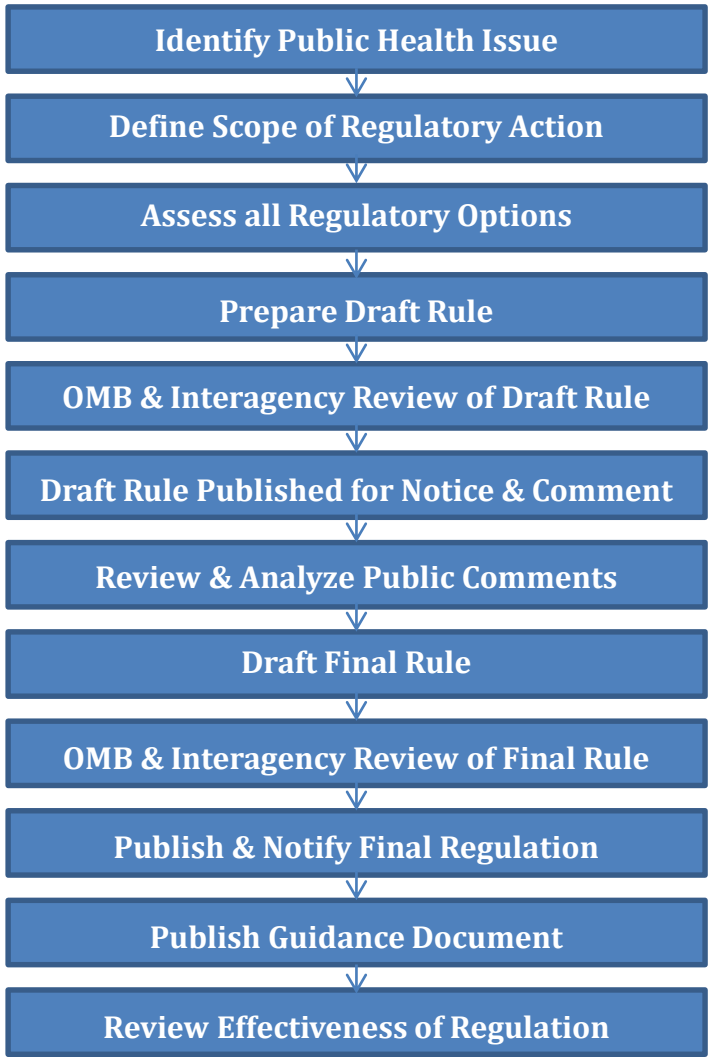
https://members.wto.org/crnattachments/2015/TBT/USA/15_3641_00_e.pdf

Language	Attachments

Issuing a Final Rule

U.S. FOOD & DRUG ADMINISTRATION

Review of Rulemaking Process



Questions?

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- **+1 240 401 9685**