Committee on Technical Barriers to Trade
June 2019

U.S. FDA Experience in Coordination and Consultation on Public Health Regulations
Determining Regulatory Priorities
Developing a Draft Regulation

About Advisory Committees

The FDA uses 50 committees and panels to obtain independent expert advice on scientific, technical, and policy matters.

CODEX ALIMENTARIUS

AOAC INTERNATIONAL
Reviewing a Draft Regulation

Presidential Documents

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

<table>
<thead>
<tr>
<th>Proposed rule:</th>
<th>Final Rule:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• required U.S. format (e.g., JUN 19, 2013) for all dates on medical device</td>
<td>• date format must be all numeric: YYYY-MM-DD (e.g., 2013-06-19); consistent with international</td>
</tr>
<tr>
<td>labels</td>
<td>standards</td>
</tr>
<tr>
<td>• date formatting requirements effective for all devices in 1 year</td>
<td>• date formatting requirements phased in over five years based on device classification</td>
</tr>
</tbody>
</table>
## Example 2: UDI Rule Direct Marking

<table>
<thead>
<tr>
<th>Proposed rule:</th>
<th>Final Rule:</th>
</tr>
</thead>
</table>
| • Direct Marking required for:  
   – Implantable devices  
   – Devices intended to be sterilized between patient use  
   – Stand-alone software | • 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

<table>
<thead>
<tr>
<th>Proposed rule:</th>
<th>Final Rule:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Would not have required information concerning magnetic resonance imaging (MRI) compatibility to be submitted to the Global UDI Database (GUDID)</td>
<td>• 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</td>
</tr>
</tbody>
</table>
Example 4: Additional Information for Nutrition Facts Label Rule

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/cmattachements/2015/TBT/USA/15_3641_00_e.pdf
Issuing a Final Rule
Review of Rulemaking Process

1. Identify Public Health Issue
2. Define Scope of Regulatory Action
3. Assess all Regulatory Options
4. Prepare Draft Rule
5. OMB & Interagency Review of Draft Rule
6. Draft Rule Published for Notice & Comment
7. Review & Analyze Public Comments
8. Draft Final Rule
9. OMB & Interagency Review of Final Rule
10. Publish & Notify Final Regulation
11. Publish Guidance Document
12. Review Effectiveness of Regulation
Questions?

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