

# Good Regulatory Practices: A Regulator's Perspective

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#### Good Regulatory Practices (GRPs)

Internationally-recognized processes and procedures that improve the quality and costeffectiveness of domestic regulations

# FDA

#### GRPs guide regulatory authorities in:

- Setting appropriate regulatory requirements
- Formulating decisions that are clear, transparent, consistent, timely, and based on sound science



#### **GRPs** at **FDA**

Three general principles for the use of GRPs in the rulemaking process include the following:





## **Rulemaking Process**

- Consider initiating events Decide whether public notice is needed Develop proposed rule Send proposed rule for review Publish proposed rule Analyze public comments 6 **Develop final rule** Send final rule for review
  - Publish final rule

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## Identifying Regulatory Priorities



#### New rules can arise from multiple sources, including:

U.S. Congress

Identified public health need or public health emergency Administration, Department, or FDA priorities and recommendations

Court decisions, petitions, new technology/research, advisory committee recommendations, public comments on requests for information, etc.

## Who are stakeholders?



FDA



#### Why seek input?

Regulators benefit from public participation in important ways.

- Supporting transparency, accountability, confidence, and trust in the rulemaking process
- Producing a better regulation by allowing those affected to provide input to improve clarity of regulatory requirements and avoid unintended consequences
- Providing regulators with data and information to inform rulemaking
- Promoting an understanding of how regulatory actions can have impacts beyond a country's borders

### **Developing a Draft Regulation**

FDA promotes transparency and facilitates public participation in a variety of ways, as applicable:

- Holding listening sessions and public meetings or public workshop
- Opening a docket on <u>regulations.gov</u> for comments on specific topics
- Seeking information, data, or alternatives via an Advanced Notice of Proposed Rulemaking (ANPRM)
- Maintaining an updated agenda of the Agency's upcoming rulemakings (<u>FDA-TRACK</u>)
- Consulting with advisory committees
- Considering scientific and voluntary <u>consensus standards</u>
- Abiding by the principles of <u>plain language</u>

### Benefits of Conducting RIA

- To understand the impacts of draft regulations, FDA conducts regulatory impact analyses (RIAs) when applicable.
- The RIA:
  - Provides an objective, unbiased assessment that is an essential component of policy development
  - Considers both qualitative and quantitative impacts
  - Can inform policy decisions



# Why conduct RIAs?

There are important benefits to regulators from well-conducted RIAs, including:



Indicating whether regulation is necessary and justified to achieve a social goal



Identifying the regulatory option that provides the largest net benefits to society

Providing comprehensive consideration of impacts and avoiding unintended consequences

The <u>OECD has developed best practice principles for RIAs</u>, and different countries make different determinations about the use of RIAs in the development of regulations.

# Why conduct RIAs?



Executive Order (EO) 12866 on Regulatory Planning and Review:

- Regulatory philosophy and principles related to when agencies should promulgate regulations and what agencies should consider in developing regulations.
- An agency must identify the nature and assess the significance of the problem it intends to address as well as possible alternative solutions to address the problem; and, where possible, select approaches that maximize net benefits to society.



# **Reviewing a Draft Regulation**

Draft regulations are subject to an intensive review process.



The Office of Management and Budget (OMB) coordinates interagency review of significant and economically significant rules.



<u>Reginfo.gov</u> provides information on regulatory actions currently under 12866 review.



Stakeholders may request <u>12866 meetings</u> with OIRA to discuss a rule under review.



### Notice and Comment (Public Consultation)

#### After OMB review, FDA will:

- Publish the draft regulation in the Federal Register
- Open a docket at <u>regulations.gov</u>

#### FDA may also:

- Alert the appropriate U.S. point of contact to notify the corresponding WTO committee
- Extend comment period (case-by-case basis)
- Hold listening sessions, public meetings, or public workshops to support commenting process

### **Analyzing Public Comments**

FDA reviews every comment filed during the comment period by the following:

- Gathering comments by unique identifier and commenter
- Consolidating form, duplicate, and out-of-scope comments
- Identifying issues and categorizing comments by topic
- Preparing high-level summaries of comments (including specific data or recommendations)
- Discussing and preparing detailed responses
- After considering substantive comments, drafting the final rule and clearly referencing any changes within comment response

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### Issuing a Final Rule

- FDA responds to comments received during the comment period that are within the scope of the rulemaking.
- OMB reviews significant final regulations and coordinates interagency comments and feedback.
- After internal and external feedback is evaluated and addressed, FDA publishes the final rule in the Federal Register and its effective date.
- FDA will periodically review the effectiveness of the rule.



#### **GRPs** at **FDA**

These best practices are foundational to developing regulations that protect and promote public health.



