
POLICY AND PROCEDURES

OFFICE OF NEW DRUGS

Developing Indication-Specific Guidances

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PURPOSE

- This MAPP describes the process to be used by office and review division staff within the Office of New Drugs (OND) in the Center for Drug Evaluation and Research (CDER) when developing indication-specific guidances for industry.
- This MAPP applies to indication-specific guidances only. Policies and procedures for developing non-indication-specific guidances can be found in MAPP 4000.2 *Developing and Issuing Guidance*.

BACKGROUND

- For many years, OND has issued guidances for industry that recommend approaches for drug development for specific clinical indications (*indication-specific guidances*). The Food and Drug Administration (FDA) and industry agree that these guidances are useful in assisting sponsors in designing efficient drug development programs to support marketing applications.
- This MAPP aids the development of indication-specific guidances by outlining a process and providing a template to improve the quality,

consistency, and utility and increase the number of indication-specific guidances.¹

PRINCIPLES

- OND staff should consider writing an indication-specific guidance when there is need to describe the FDA's current thinking about drug development for a specific indication. This allows future interactions with the review division to focus on issues that are specific and unique to the investigational drug.
- Guidances based on the template will recommend approaches for scientifically valid development programs to support marketing applications for specific indications and provide advice based on best practices, regulatory precedents, and current scientific knowledge. When the template is used, the resulting guidance should:
 - Describe the FDA's recommended development program and its rationale
 - Describe the development milestones the FDA considers important and the sequence in which (relative to other steps) these milestones should be achieved
 - Be written in plain language with appropriate definitions of key technical terms
 - Be brief, succinct, and contain only the scientific and regulatory recommendations needed to guide drug development (if the topic is a new therapeutic area, a more detailed guidance may be appropriate)
 - Indication-specific guidances do not need to be all inclusive. They may focus on one aspect of the indication. Alternatively, an overarching (*umbrella*) guidance can be written that addresses common development points, followed by several brief guidances that each address a particular part of the indication or a sub-indication.
- The indication-specific guidance should answer the following questions:
 - What are the particular challenges the sponsor could face when developing the drug for the specific indication?

¹ The Indication-Specific Guidance Template is available on the Guidance and Policy Team intranet Web page or by contacting the Guidance and Policy Team Project Manager in OND. A template is also available for the notice of availability for indication-specific guidances.

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- How can the sponsor meet those challenges?
 - When should the sponsor seek additional guidance from the review division?
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POLICY

- The Indication-Specific Guidance Template will be used by all OND office and review division staff to write guidances for developing drugs for specific indications, with the exception of drugs developed under the animal efficacy rule (21 CFR 314.610(b)(1) and 601.91(b)(1)).² The template may be used with flexibility to accommodate unique issues that arise from the development of a drug. Such modifications should occur rarely, should be justified, and should be approved in advance by the division/Office of Drug Evaluation (ODE) management for the guidance.
- All guidances will be signed off by the division and ODE directors before they are forwarded to the Guidance and Policy Team (GPT) in the OND immediate office (IO) for content clearance, editing, and formal clearance.
- When using the Indication-Specific Guidance Template, office and review division staff will follow the conventions of the CDER Style Guide.³

RESPONSIBILITIES AND PROCEDURES

Office and Division Directors will:

- Consider which indications should be covered in indication-specific guidances.
- Determine what defines an indication, if needed.
- Determine whether an umbrella and subguidances should be written instead of one large guidance. Prioritize the order in which the guidances should be issued, and encourage staff to write these guidances.
- Provide staff schedule flexibility to write indication-specific guidances.

² Guidances for drugs developed under the animal efficacy rule should be written using the template mentioned in MAPP 4000.2.

³ The CDER Style Guide can be found on the Guidance and Policy Team intranet Web page.

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- Promote consistent use of the Indication-Specific Guidance Template within their offices and divisions for writing indication-specific guidances, approve modifications to the template infrequently, and provide a rationale for any modification.
 - Sign off on the content and structure of the guidance before it is sent to the GPT in the OND IO.

Individual Authors or Working Group Lead Authors will:

- Contact the Guidance and Policy Team Regulatory Project Manager (GPT RPM) as early as possible in the guidance development process to obtain additional information and assistance in the development and clearance of an indication-specific guidance.
- Complete a guidance initiation sheet and submit it to the GPT RPM as soon as possible, preferably before drafting begins.⁴
- Write the guidance using the Indication-Specific Guidance Template.⁵ During guidance development, the author is responsible for engaging in scientific and regulatory dialogue with the appropriate subject matter experts both within and outside CDER, as necessary, to develop complete and scientifically valid perspectives.
- Adhere to established CDER guidance development policies and procedures, as described in MAPP 4000.2 *Developing and Issuing Guidance*.
- Obtain sign-off of written guidance (content and structure) from the appropriate division and office director.
- Send written guidance, notice of availability, and office and division director sign-off to the GPT RPM.

The Guidance and Policy Team will:

- Provide advice about format, including templates
- Provide advice, if needed, about the use of umbrella guidances
- Ensure that the author obtains appropriate input from any CDER offices and FDA centers affected by the guidance

⁴ The guidance initiation sheet can be found on the Guidance and Policy Team intranet Web page.

⁵ The Indication-Specific Guidance Template is available on the Guidance and Policy Team intranet Web page.

- Ensure that the division director and ODE directors have signed off
- Provide editing and clearing services for the guidance

REFERENCES

1. MAPP 4000.2 *Developing and Issuing Guidance*
(<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/default.htm>)
2. Guidance and Policy Team intranet Web page

DEFINITIONS

- **Drug:** Refers to a drug or biologic product regulated in CDER that is developed to treat a particular indication or medical condition.
- **Indication-Specific Guidance:** A guidance for industry that recommends approaches for drug development for a specific clinical indication to support a marketing application.
- **Indication-Specific Guidance Template:** A structured outline and annotated table of contents that assists in the development of an indication-specific guidance. The Indication-Specific Guidance Template outlines the organization of content, promotes consistency of key elements in the guidance, and provides for easy retrieval of information from an indication-specific guidance.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
11/21/14	Rev. 1	This MAPP was updated to clarify responsibilities and procedures. The template was changed to update terminology and references, and to update content that should be included in an indication-specific guidance.