



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-2986]

Technical Document for Using the Inactive Ingredient Database; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA, or the Agency) is announcing the establishment of a public docket to receive comments from interested parties on enhancing the utility and usability of the Inactive Ingredient Database (IID) (also known as the Inactive Ingredient Guide). These comments will help FDA identify best practices to assist Agency staff in designing the IID and maintaining the information contained therein. We intend to identify and further develop these best practices in a technical guide or draft guidance to be issued at a later date.

DATES: Submit either electronic or written comments by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, rm. 1670, Silver Spring, MD 20993-0002, 240-402-7930.

SUPPLEMENTARY INFORMATION:

I. Background

The IID provides information on inactive ingredients in FDA-approved drug products. An inactive ingredient, or excipient, is any component of a drug product other than an active ingredient (21 CFR 210.3(b)(8)). Generally, the IID identifies excipients that appear in approved drug products for a particular dosage form and route of administration.

In September 2011, FDA created the IID Working Group to develop a set of questions and answers to facilitate use of the IID. During the development of questions and answers, FDA has worked with the International Pharmaceutical Excipients Council (IPEC Americas).¹ FDA is opening a public docket to solicit comments from additional stakeholders on enhancing the utility and usability of the IID. FDA will then develop a comprehensive technical guide or draft guidance for industry and reviewers.

II. Establishment of a Public Docket and Request for Comments

To help FDA identify and ultimately establish best practices and issue a technical guide or draft guidance, FDA is requesting public comments regarding the enhancement of the IID.

FDA is requesting comments and supporting information, including proposed questions and proposed answers, on the following topics related to the IID:

1. How can we improve nomenclature in the IID (e.g., use of preferred ingredient names and synonyms in the database)?

¹ See Meetings between FDA and the International Pharmaceutical Excipients Council (IPEC), available at <http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm380688.htm>.

2. How should we identify excipient amounts listed in the IID?
3. How should we reflect updates to the current IID to ensure completeness and accuracy?
4. Should we restructure the IID, and if so, how?
5. Are there additional suggestions or comments for IID improvement?

FDA will consider all comments submitted. FDA generally will not respond directly to the person or organization submitting the comment.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: August 14, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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