

<http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Paula R. Trumbo, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2579.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of November 23, 2016 (81 FR 84595), we published a document requesting scientific data, information, and comments that would help us evaluate the beneficial physiological effects to human health of isolated or synthetic non-digestible carbohydrate that are added to food. We requested such scientific data,

information, and comments to help us determine whether a particular isolated or synthetic non-digestible carbohydrate should be added to our definition of “dietary fiber” that is found in the Nutrition and Supplement Facts label final rule, which appeared in the **Federal Register** of May 27, 2016 (81 FR 33741). Only those isolated or synthetic non-digestible carbohydrates that meet the definition can be declared as a dietary fiber on a Nutrition and Supplement Facts label. The notice also announced the availability of a document entitled “Science Review of Isolated and Synthetic Non-Digestible Carbohydrates,” which summarizes a scientific literature review that we conducted of clinical studies associated with the 26 specific isolated or synthetic non-digestible carbohydrates. We provided a 45-day comment period that ended on January 9, 2017.

We have received requests to extend the period during which interested parties may submit scientific data, information, and comments regarding isolated or synthetic non-digestible carbohydrates generally and regarding our scientific literature review summary document specifically. The requests conveyed concern that the original 45-day comment period would not allow sufficient time to develop meaningful or thoughtful scientific data, information, or comments.

We have considered the requests but were unable to issue a notice extending the comment period before January 9, 2017. Consequently, we are reopening the comment period for an additional 30 days. Interested parties have until February 13, 2017, to submit scientific data, information, or comments to the docket. We believe that this action allows adequate time for interested persons to submit additional scientific data, information and comments.

Dated: January 10, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-00725 Filed 1-12-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-0086]

#### Suggestions, Recommendations, and Comments for Topics That May Be Considered by the Food and Drug Administration Combination Product Policy Council; Establishment of a Docket

**AGENCY:** Food and Drug Administration, HHS.

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

**SUMMARY:** The Food and Drug Administration (FDA) is establishing a docket to receive suggestions, recommendations, and comments for topics from interested parties, including academic institutions, regulated industry, patient representatives, and other interested organizations, on policy issues that may be considered by the FDA Combination Product Policy Council (Council). These comments will help the Agency identify and address combination product policy issues that need clarification through guidance, notice and comment procedures, or other means.

**DATES:** Submit either electronic or written comments by April 13, 2017.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the

manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2017-N-0086 for “Suggestions, Recommendations, and Comments for Topics That May Be Considered by the Food and Drug Administration Combination Product Policy Council.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/>

*regulatoryinformation/dockets/default.htm.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Nina L. Hunter, Office of Medical Products and Tobacco (OMPT), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 2312, Silver Spring, MD 20993-0002, 301-796-6171, FAX: 301-847-8514, [CombinationProductCouncil@fda.hhs.gov](mailto:CombinationProductCouncil@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In April 2016, FDA established the Council to ensure better coordination of combination product policy development and implementation across the Agency and consistent, predictable communication of combination product policy decisions to the public through guidance, notice and comment procedures, or other means.

Chaired by the Deputy Commissioner of OMPT, the Council provides a senior-level forum through which combination product policy issues can be raised, considered, developed, and implemented. Council members include the following senior leaders: The Center Directors and one representative from the Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, and Center for Devices and Radiological Health; the Office Director from the Office of Combination Products (OCP); and the Associate Commissioner for Special Medical Programs. Additional staff from the Centers and other FDA offices provide expertise as needed for specific combination product policy topics under consideration. While there are various other mechanisms available to raise issues for Agency consideration, by establishing this docket, FDA seeks to provide a forum for the public to recommend specific topics that should have direct, collective engagement and consideration by the Council. The Agency believes that this process will also further enhance transparency in FDA’s approach to policy development and implementation.

##### II. Range of Policy Issues To Be Considered

FDA envisions a variety of combination product policy topics that may be appropriate for consideration by the Council, which typically would meet one or more of the following criteria:

- A novel combination product policy issue requiring senior management input;
- An identical issue on which FDA seems to have taken inconsistent combination product policy positions;
- An existing combination product policy position that should be reconsidered in light of scientific or regulatory advances; or
- A combination product policy that may be triggered by a specific combination product, but that will be applicable to other combination products.

##### III. Establishment of a Docket and Request for Comments

The docket is being made available for public suggestions, recommendations, and comments relating to the combination product policy criteria identified in this document that may warrant consideration by the Council. Submissions should describe the following: (1) The combination product policy issue recommended for discussion (*e.g.*, clarifying previous advice or precedents on a specified combination product policy topic, reconciling apparently differing perspectives within FDA or between FDA and regulated industry on a specified combination product policy topic); (2) the rationale for doing so, including why it requires direct engagement by the Council; (3) recommendations on how the combination product policy issue could be addressed; and (4) existing policy documents (*e.g.*, final guidance) relevant to the combination product policy issue.

Note that combination product policy issues concerning any draft guidance or proposed rule should be submitted to the docket for that draft guidance or rulemaking; product-specific disputes should first be addressed through the appropriate appeals mechanism of the Center or other Agency component involved; and general recommendations for topics to address through guidance or rulemaking should be made to the Center, OCP, or other relevant Agency component through the mechanisms provided by that component.

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

comment. In general, combination product policy decisions reached by the Council are communicated and implemented in accordance with FDA's good guidance practices regulation (21 CFR 10.115) or notice and comment procedures.

Dated: January 9, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-00646 Filed 1-12-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-D-0040]

#### How To Prepare a Pre-Request for Designation; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "How to Prepare a Pre-Request for Designation (Pre-RFD)." The purpose of this guidance is to explain the Pre-RFD process at the FDA Office of Combination Products (OCP), describe and help a sponsor understand the type of information that the sponsor should include in a Pre-RFD, and assist sponsors in obtaining a preliminary assessment from FDA through the Pre-RFD process. The Pre-RFD process is available to provide informal, non-binding feedback regarding the regulatory identity or classification of a human medical product as a drug, device, biological product, or combination product. In addition, this informal process provides information about a non-combination or combination product's assignment to the appropriate Agency Center (Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), or Center for Biologics Evaluation and Research (CBER)) for premarket review and regulation. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 13, 2017.

Submit either written or electronic comments on this collection of information by March 14, 2017.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2017-D-0040 for "How to Prepare a Pre-Request for Designation (Pre-RFD); Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be

made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues to the Office of Management and Budget in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or email to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the title, "How to Prepare a Pre-Request for Designation (Pre-RFD); Draft Guidance for Industry."

Submit written requests for single copies of the draft guidance document entitled "How to Prepare a Pre-Request for Designation (Pre-RFD)" to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8619. See the **SUPPLEMENTARY**