TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Information for the Proposed Proper Name for Applicable Biological Products Submitted Under Section 351(k) of the PHS Act	3	2	6	420	2,520
Total					19,320

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This guidance also refers to previously approved collections of information found in FDA regulations. The collection of information related to the submission of a BLA under section 351(k) of the PHS Act (biosimilar products and interchangeable products) has been approved under OMB control number 0910–0719. The guidance also refers to a previously approved collection of information found in FDA regulations that is expected to change as a result of the guidance and the retrospective application of the naming convention. The collections of information in 21 CFR part 601 related to the submission of a biologics license application (BLA) and changes to an approved application have been approved under OMB control number 0910–0338. As a result of the guidance, the estimated number of additional responses for the annual burden for changes to an approved application under § 601.12 would be increased by approximately 25 responses.

FDA is issuing this final guidance subject to OMB approval of the collections of information. Before implementing the information collection provisions of the guidance, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the collections of information, including OMB control number(s) for newly approved collections.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: January 10, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00694 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–2016–N–3389]

Evaluation of the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates; Request For Scientific Data, Information, and Comments; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the document requesting scientific data, information, and comments entitled ''Evaluation of the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates'' that appeared in the **Federal Register** of November 23, 2016 (81 FR 84595). In the document, we requested 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'' for purposes of being declared as dietary fiber on a Nutrition Facts or Supplement Facts label. We also announced in the document the availability for comment of a scientific literature review document that we conducted that summarizes clinical studies associated with 26 specific isolated or synthetic non-digestible carbohydrates. We are taking this action in response to requests to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by February 13, 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–2016–N–3389 for ''Evaluation of the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates; Request for Scientific Data, Information, and Comments.'' 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.'' 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]

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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