Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Burlington, Massachusetts, on June 8, 2018.

**Robert J. Ganley,**

*Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.*

[FR Doc. 2018–12873 Filed 6–14–18; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 101

**[Docket No. FDA–2018–D–1323]**

## The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels; Guidance for Industry; Availability

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

**ACTION:** Notification of availability.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled ''The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels; Guidance for Industry.'' The guidance identifies eight specific, additional isolated or synthetic non-digestible carbohydrates that we intend to add to our regulatory definition of ''dietary fiber'' through our regular rulemaking process. In the interim, the guidance also advises manufacturers of our policy for when one or more of these eight non-digestible carbohydrates, present in a food, are included in the declared amount of ''dietary fiber,'' and for the use of a caloric value for polydextrose of 1 kilocalorie per gram (kcal/g).

**DATES:** The announcement of the guidance is published in the **Federal Register** on June 15, 2018.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time 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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2018–D–1323 for ''The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels; Guidance for Industry.'' 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 Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

*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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Paula R. Trumbo, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Campus Dr., College Park, MD 20740, 240–402–2579.

**SUPPLEMENTARY INFORMATION:**

### I. Background

We are announcing the availability of a guidance for industry entitled ''The Declaration of Certain Isolated or Synthetic Non-Digestible Carbohydrates as Dietary Fiber on Nutrition and Supplement Facts Labels; Guidance for Industry.'' We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21

CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). We made this determination because this guidance sets out compliance policy that reduces burden and is consistent with the public health. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's GGP regulation.

Before 2016, FDA regulations did not define the term ''dietary fiber'' for purposes of the Nutrition Facts and Supplement Facts labels. In the **Federal Register** of May 27, 2016 (81 FR 33742), we published a final rule amending our Nutrition Facts and Supplement Facts Labels regulations (hereafter referred to as ''the final rule''). The final rule, among other things, defines dietary fiber as non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units), and lignin that are intrinsic and intact in plants; isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health (§ 101.9(c)(6)(i) (21 CFR 101.9(c)(6)(i))). The final rule also identifies seven isolated or synthetic non-digestible carbohydrates, each of which has a physiological effect that is beneficial to human health and that must be declared as dietary fiber on Nutrition and Supplement Facts labels when present in a food.

Interested parties can ask us to list additional isolated or synthetic non-digestible carbohydrates in the definition of dietary fiber in § 101.9(c)(6)(i). For example, a manufacturer can request FDA to include another added isolated or synthetic non-digestible carbohydrate in the listing of dietary fibers by submitting a citizen petition under 21 CFR 10.30. FDA would review the scientific evidence to determine whether the evidence supports the non-digestible carbohydrate as having a physiological effect that is beneficial to human health. If so, FDA would propose a rule to include the non-digestible carbohydrate in the listing of dietary fibers.

Based on our review of citizen petitions that FDA has received requesting that we identify additional isolated or synthetic non-digestible carbohydrates in the listing of dietary fibers, and comments that we have received on a draft guidance entitled ''Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30)'' and an accompanying document titled ''Evaluation of the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates,'' the availability of which we announced in the **Federal Register** of November 23, 2016 (81 FR 84516 and 81 FR 84595), in addition to our independent evaluation of the available scientific data, we intend to add certain isolated or synthetic non-digestible carbohydrates to the dietary fiber definition in § 101.9(c)(6)(i) through our regular rulemaking process. The eight non-digestible carbohydrates that we intend to add are: Mixed plant cell wall fibers; arabinoxylan; alginate, inulin and inulin-type fructans; high amylose starch (resistant starch 2); galactooligosaccharide; polydextrose; and resistant maltodextrin/dextrin. One category of non-digestible carbohydrate that we intend to add to § 101.9(c)(6)(i) through our regular rulemaking process—mixed plant cell wall fibers—encompasses a number of fiber ingredients, such as rice bran fibers, soy fibers, and sugar cane fibers. We have tentatively determined that each of these isolated or synthetic non-digestible carbohydrates has a physiological effect that is beneficial to human health. Several petitions are still pending with FDA and reviewing this information is a very high priority for FDA. Firms also can submit new citizen petitions, and we will review the petitions on a rolling basis. Firms whose non-digestible carbohydrates do not meet our regulatory definition of ''dietary fiber'' and are not one of the eight non-digestible carbohydrates identified in the guidance can still use those non-digestible carbohydrates in foods. Although those non-digestible carbohydrates cannot be listed as dietary fiber in the Nutrition Facts label, they would still be declared as part of the amount of total carbohydrate and listed by name in the ingredients on the food package. In addition, based on our review of the scientific evidence, including evidence we received in a citizen petition, we intend to establish a caloric value for polydextrose at 1 kcal/g in § 101.9(c)(1)(i)(C).

Pending completion of the rulemaking process, we are announcing a policy for the eight identified isolated or synthetic non-digestible carbohydrates when one or more are present in food and declared in the amount of ''dietary fiber'' on Nutrition Facts and Supplement Facts labels and when the caloric value of 1 kcal/g is used to determine the calorie contribution of polydextrose. Section 101.9(g) requires manufacturers to make and keep records to verify the amount of non-digestible carbohydrates added to food that do not meet the definition of dietary fiber. Under our policy, when a mixture of dietary fiber and one or more of these eight added non-digestible carbohydrates (that are not currently listed as a ''dietary fiber'' in the definition in § 101.9(c)(6)(i)) are present in a food, we do not expect manufacturers to make and keep records in accordance with § 101.9(g)(10) and (11) to verify the declared amount of one or more of these eight added non-digestible carbohydrates in the label and labeling of food.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

## II. Electronic Access

Persons with access to the internet may obtain the document at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov*. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: June 8, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–12867 Filed 6–14–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 876

**[Docket No. FDA–2018–N–1894]**

## Medical Devices; Gastroenterology-Urology Devices; Classification of the Fluid Jet System for Prostate Tissue Removal

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

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA or we) is classifying the fluid jet system for prostate tissue removal into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the fluid jet