DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0376]

Policy Regarding Quantitative Labeling of Dietary Supplements Containing Live Microbials; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Policy Regarding Quantitative Labeling of Dietary Supplements Containing Live Microbials.'' The draft guidance, when finalized, will advise firms that manufacturer, market, or distribute dietary supplements of FDA's intent to exercise enforcement discretion if a firm wishes to specify the amount of a live microbial in colony forming units (CFUs) in addition to the currently required unit of measure (milligrams) in the Supplement Facts label.

DATES: Submit either electronic or written comments on the draft guidance by November 6, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2011–D–0376 for ''Policy Regarding Quantitative Labeling of Dietary Supplements Containing Live Microbials: Draft 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.'' 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 *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 draft guidance to the Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Steven Tave, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2878.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Policy Regarding Quantitative Labeling of Dietary Supplements Containing Live Microbials.'' We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 alternate approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

The draft guidance, when finalized, would advise firms that manufacture, market, or distribute dietary supplements of FDA's intent to exercise enforcement discretion with respect to declaration of live microbial quantity in CFUs, in addition to the quantitative amount by weight declaration required by regulation, within the Supplement Facts label of dietary supplements containing live microbials, provided that certain conditions are met.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance 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.

III. Paperwork Reduction Act

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 101.36 have been approved under OMB control number 0910–0381.

Dated: August 31, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19367 Filed 9–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Charter Renewal for the Advisory Committee on Organ Transplantation

AGENCY: Health Resources and Services Administration (HRSA), The Department of Health and Human Services (HHS).

ACTION: Notice of charter renewal.

SUMMARY: HHS is hereby giving notice that the Advisory Committee on Organ Transplantation (ACOT) has been rechartered. The effective date of the renewed charter is August 31, 2018.

FOR FURTHER INFORMATION CONTACT: Robert Walsh, Executive Secretary, Advisory Committee on Organ Transplantation, Health Resources and Services Administration, Department of Health and Human Services, Room 08W60, 5600 Fishers Lane, Rockville, Maryland 20857. Phone: (301) 443–6839; fax: (301) 594–6095; email: *rwalsh@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The ACOT was authorized by section 121.12 of the amended Final Rule of the Organ Procurement and Transplantation Network (OPTN) (42 CFR part 121). In accordance with the Federal Advisory Committee Act (FACA), Public Law 92–463, it was initially chartered on September 1, 2000, and was renewed at the appropriate intervals.

The ACOT provides advice to the Secretary on all aspects of organ donation, procurement, allocation, and transplantation, and on such other matters that the Secretary determines. The recommendations of the ACOT will facilitate the Department's efforts to oversee the Organ Procurement and Transplantation Network (OPTN), as set forth in the National Organ Transplant Act of 1984, as amended.

The charter renewal for the ACOT was approved on August 31, 2018, which will also stand as the filing date. Renewal of the ACOT charter gives authorization for the Committee to operate until August 31, 2020.

A copy of the ACOT charter is available on the ACOT website at: *http://www.organdonor.gov/legislation/advisory.html.* A copy of the charter can also be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website for the FACA database is *http://www.facadatabase.gov/.*

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–19454 Filed 9–6–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding is Sought and Responsible Prospective Contractors (Office of the Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Ms. Diane Dean, Director, Division of Grants Compliance and Oversight, Office of Policy for Extramural Research Administration, Office of Extramural Research, National Institutes of Health, 6705 Rockledge Drive, Room 3525, Bethesda, MD 20892, or call non-toll-free number (301) 435–0930 or Email your request, including your address to: *deand@od31em1.od.nih.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on March 16, 2018, (FR 83 pages 11763–11765) and allowed 60 days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment.

The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service (PHS) Funding is Sought 42 CFR part 50 subpart F and Responsible Prospective Contractors 45 CFR part 94, 0925–0417, expiration date 2/28/2015, REINSTATEMENT WITHOUT CHANGE, Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER), National Institutes of Health (NIH).

Need and Use of Information Collection: This request is for Office of Management and Budget (OMB) approval of a Reinstatement Without Change of a currently approved collection resulting from the development of revised regulations regarding the Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR part 50, subpart F) and Responsible Prospective Contractors (45 CFR part 94). The purpose of these regulations is to promote objectivity in research by requiring institutions to establish standards to ensure that there is no reasonable expectation that the design, conduct, or reporting of PHS-