Act, or in the alternative section 306(b)(2)(B)(ii)(I) and (b)(2)(B)(iii) and under authority delegated to him, finds that Dr. Diamond is subject to debarment. The Chief Scientist has considered the relevant factors listed in section 306(c)(3) of the FD&C Act and determined that debarment for 10 years is appropriate.

As a result of the foregoing findings, Dr. Diamond is debarred for 10 years from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Dr. Diamond, in any capacity during his period of debarment, will be subject to civil money penalties. If Dr. Diamond, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Diamond during his period of debarment.

Any application by Dr. Diamond for termination of debarment under section 306(d) of the FD&C Act should be identified with Docket No. FDA–2000–N–0110 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain documents in the Docket at *http://www.regulations.gov/*.

Dated: November 4, 2013.

Jesse L. Goodman,

Chief Scientist.

[FR Doc. 2013–27186 Filed 11–13–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1279]

Medical Device Development Tools; Draft Guidance for Industry, Tool Developers, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Medical Device Development Tools.'' This document provides guidance to FDA staff, industry, healthcare providers, researchers, and patient and consumer groups on a new voluntary process within the Center for Devices and Radiological Health (CDRH) for qualification of medical device development tools (MDDT) for use in device development and evaluation programs. 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 on 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 February 12, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Medical Device Development Tools'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance 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: Kathryn O'Callaghan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3614, Silver Spring, MD 20993–0002, 301–796–6349.

SUPPLEMENTARY INFORMATION:

I. Background

The draft guidance describes the framework and process for the voluntary CDRH qualification of MDDT, including definitions of applicable terms, criteria for evaluating an MDDT for a specific context of use, the threshold for qualification, and the contents of a qualification submission. The intent of this voluntary qualification policy is to: (1) Enable faster, more efficient development of important life-saving and health-promoting medical devices; (2) promote the development of tools to facilitate more timely device evaluation; (3) provide a mechanism to better leverage advances in regulatory science; and (4) more quickly and more clearly communicate with CDRH stakeholders about important advances in regulatory science that may be leveraged to speed device development and regulatory evaluation. CDRH expects the qualification process to expedite development of publicly available tools which could potentially be used widely in multiple device development programs. Once an MDDT is qualified for a specific context of use, it can be used by any medical device developer for that context of use.

At some point in the future, FDA may initiate a pilot program for MDDT qualification submissions, which would help inform final guidance on this topic. FDA would publicly announce such a program prior to initiation.

This guidance does not discuss the review of MDDTs submitted as part of a specific medical device regulatory submission, nor does it address the specific evidentiary standards or performance requirements needed for purposes of qualification of a specific MDDT.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the qualification of MDDTs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all

CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*. To receive ''Medical Device Development Tools,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1882 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance contains information collection that is 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 part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 809 have been approved under OMB control number 0910–0485.

V. 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: November 4, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–27233 Filed 11–13–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0880]

Draft Guidance for Industry on Frequently Asked Questions About Medical Foods; Second Edition; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the draft guidance for industry entitled ''Frequently Asked Questions About Medical Foods; Second Edition.'' We are reopening the comment period in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by December 16, 2013.

ADDRESSES: Submit electronic comments on the draft guidance 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.

FOR FURTHER INFORMATION CONTACT: Shawne Suggs-Anderson, Center for Food Safety and Applied Nutrition (HFS–850), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1783.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 13, 2013 (78 FR 49271), we published a notice announcing the availability of an updated draft guidance for industry entitled ''Frequently Asked Questions About Medical Foods; Second Edition.'' (We had published earlier versions of the guidance in May 1997 and May 2007.) The draft guidance, when finalized, will update some responses to questions that appeared in earlier versions of the guidance and add new questions and responses regarding the definition, labeling, and availability of medical foods. We invited comment on the draft guidance by October 15, 2013.

II. Request for Comments

Following publication of the August 13, 2013, notice of availability, we received requests for a 60-day extension of the comment period. The requesters explained that they needed more time to review the guidance, develop comments, and assemble data.

If all of the guidance in the August 13, 2013, version were new, a reopening of the comment period for 60 additional days might be warranted. However, much of the draft guidance remains unchanged from our last revision in 2007. The additional content focuses on FDA's thinking relating to use of medical foods under supervision by a physician, whether medical foods should be sold by prescription only, and types of diseases and conditions that a medical food could be used to manage. We are, therefore, reopening the comment period for the draft guidance for an additional 30 days, until December 16, 2013. We believe that this reopening allows adequate time for interested persons to submit comments without significantly delaying further FDA action on this draft guidance. (We initially intended to extend the comment period, but, due to the lapse in appropriations and resulting cessation of many government operations from October 1 through October 16, 2013, we were unable to issue a notice extending the comment period before October 15, 2013; consequently, we are reopening the comment period for an additional 30 days.)

III. How To Submit Comments

Interested persons may submit either electronic comments regarding the draft guidance 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 may be posted to the docket at *http://www.regulations.gov*.

Dated: November 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–27213 Filed 11–13–13; 8:45 am]

BILLING CODE 4160–01–P