comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Scott McNamee, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3416, Silver Spring, MD 20993–0002, 301–796–5523; or Charles Durfor, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G424, Silver Spring, MD 20993–0002, 301–796–6970.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance entitled ''Medical Devices Containing Materials Derived From Animal Sources (Except for In Vitro Diagnostic Devices)'' is intended to update the 1998 guidance of the same name regarding the use of animal-derived material in medical device manufacturing. The 1998 guidance addressed ways to reduce the potential for exposure to bovine spongiform encephalopathy. The draft guidance continues to focus on the control of transmissible disease, and contains recommendations for documenting the source of animal tissue, conducting viral inactivation validation studies, as well as recommendations about the role of careful animal husbandry in ensuring safe tissue sources.

The information in this guidance is applicable to all medical devices that contain or are exposed to animal-derived materials (e.g., bovine, ovine, porcine, avian materials) with the exception of in vitro diagnostic devices. The guidance describes the information you should document at the manufacturing facility and include in any premarket submissions. Consideration of these issues should aid in reducing the risk of infectious disease transmission by medical devices.

This draft guidance, when finalized, will supersede the guidance entitled ''Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices)'', announced in the **Federal Register** of November 6, 1998 (63 FR 60009).

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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on medical devices containing materials derived from animal sources (except for in vitro diagnostic devices). 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 Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices)'' 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 2206 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

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 part 807 subpart E have been approved under OMB control number 0910–0120; 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 814 subpart H have been approved under OMB control number 0910–0332; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

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: January 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–01232 Filed 1–22–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0319]

Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry and FDA staff entitled ''Dear Health Care Provider Letters: Improving Communication of Important Safety Information.'' This guidance offers specific recommendations to industry on the content and format of Dear Health Care Provider (DHCP) letters. These letters are sent by manufacturers or distributors to health care providers to communicate an important drug warning, a change in prescribing information, or a correction of misinformation in prescription drug promotional labeling or advertising. This guidance provides recommendations on when to use a DHCP letter, the types of information to include in the DHCP letter, how to organize the information so that it is communicated effectively to health care providers, and formatting techniques to make the information more accessible. This guidance finalizes the draft guidance issued in November 2010.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that

office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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: Lori A. Bickel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6353, Silver Spring, MD 20993, 301–796–0210; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled ''Dear Health Care Provider Letters: Improving Communication of Important Safety Information.'' This document offers specific guidance to industry and FDA staff on the content and format of DHCP letters. These letters are sent by manufacturers or distributors to health care providers to communicate an important drug warning, a change in prescribing information, or a correction of misinformation in prescription drug promotional labeling or advertising. This guidance gives specific instruction on what should and should not be included in DHCP letters. To date, some DHCP letters have been too long, have contained promotional material, or otherwise have not met the goals set forth in the applicable regulation (21 CFR 200.5). In some cases, health care providers have not been aware of important new information, and have been unable to communicate it to patients, because the letters' content and length have made it difficult to find the relevant information. In addition, letters have sometimes been sent for the wrong reasons.

In addition to content and format recommendations for each type of DHCP letter, the guidance also includes advice on consulting with FDA to develop a DHCP letter, when to send a letter, what type of letter to send, and conducting an assessment of the letter's impact.

In the **Federal Register** of November 12, 2010 (75 FR 69449), FDA announced the availability of a draft guidance for industry and FDA staff entitled ''Dear Health Care Provider Letters: Improving Communication of Important Safety Information.'' The notice gave interested persons an opportunity to comment by January 11, 2011. The Agency received several comments from health care providers, firms, and other groups. We have carefully considered the comments and, where appropriate, have made corrections, added information, or clarified information in the guidance in response to the comments or on our own initiative. This guidance finalizes the draft guidance issued in November 2010.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on ''Dear Health Care Provider Letters: Improving Communication of Important Safety Information.'' 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 statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 this guidance were approved under OMB control number 0910–0754.

III. 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*.

IV. Electronic Access

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

Dated: January 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–01305 Filed 1–22–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0032]

Improving the Quality of Abbreviated New Drug Application Submissions to the Food and Drug Administration; Establishment of a Public 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 public docket to receive input and suggestions from the public on ways to improve the quality of abbreviated new drug applications (ANDAs) and associated amendments and supplements to FDA's Office of Generic Drugs (OGD). Specifically, FDA is interested in hearing about any difficulties sponsors are having developing and preparing their ANDA submissions that FDA could help address, for example by providing more or better information to industry. This action is intended to solicit suggestions that will improve the completeness and quality of ANDA submissions to FDA. FDA is also seeking input on how to best share suggestions for improving the quality of ANDAs with the generic drug industry. More complete, higher quality ANDA submissions will positively affect the availability of low-cost, high-quality generic drugs to the public.

DATES: Although FDA welcomes comments at any time, to help FDA address issues related to ANDA submission quality in a timely fashion, we encourage submission of electronic or written comments by March 24, 2014.

ADDRESSES: Submit electronic comments 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. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7519