with premarket review regulations and performance standards under sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) would be impractical.

Effective on July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) implemented changes to the custom device exemption contained in section 520(b) of the FD&C Act. The new provision amended the existing custom device exemption and introduced new concepts and procedures applicable to custom devices, addressing, among other things:

- Devices created or modified in order to comply with the order of an individual physician or dentist;
- the potential for multiple units of a device type not to exceed five units per year qualifying for the custom device exemption; and
- annual reporting requirements by the manufacturer to FDA about devices manufactured and distributed under section 520(b) of the FD&C Act.

Under FDASIA, devices that qualify for the custom device exemption were clarified to include no more than ''five units per year of a particular device type'' that otherwise meet all the requirements necessary to qualify for the custom device exemption. In this guidance, FDA interprets the five units in terms of five new custom devices per year (*i.e.,* five new patients for the patient-focused custom device or five new physicians for the physician-focused custom device, assuming all other required elements for the custom device exemption are satisfied). The five-unit limitation includes all devices provided by a manufacturer to, and remaining in the possession of, the ordering physician and/or patient.

The guidance defines terms used in the custom device exemption, explains how FDA plans to interpret the term ''five units per year of a particular device type'' set forth in section 520(b)(2)(B) of the FD&C Act, describes what information manufacturers should submit in a custom device annual report to FDA, and provides guidance on how to submit an annual report for devices distributed under the custom device exemption.

On January 14, 2014, FDA issued the draft guidance entitled ''Custom Device Exemption'' (Ref. 1). The Agency has reviewed the comments submitted for the draft guidance and has incorporated many of the recommendations in this final guidance.

II. Significance of Guidance

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 custom 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 Center for Devices and Radiological Health 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 ''Custom Device Exemption,'' you may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1820 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA (44 U.S.C. 3501–3520). The collections of information in 21 CFR 814, subparts B and E have been approved under OMB control number 0910–0231; the collections of information in 21 part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 part 807, subpart E have been approved under OMB control number 0910–0120; and the collections of custom device annual reporting have been approved under OMB control number 0910–0767.

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**). 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.*

VI. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. The FDA draft guidance entitled ''Custom Device Exemption,'' available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM380497.pdf.*

Dated: September 18, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22683 Filed 9–23–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1352]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH GL52); Draft Guidance for Industry on Bioequivalence: Blood Level Bioequivalence Study; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (GFI #224) entitled ''Draft Guidance for Industry, Bioequivalence: Blood Level Bioequivalence Study'' (VICH GL52). This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft VICH guidance document is intended to harmonize the data recommendations associated with in vivo blood level bioequivalence (BE) for veterinary pharmaceutical products.

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 November 24, 2014.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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: Marilyn Martinez, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0635, *Marilyn.Martinez@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry (GFI #224) entitled ''Draft Guidance for Industry, Bioequivalence: Blood Level Bioequivalence Study'' (VICH GL52). In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission; European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; FDA; U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Six observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, one representative from the industry of Canada, one representative from the government of South Africa, and one representative from the industry of South Africa. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

II. Draft Guidance on Bioequivalence: Blood Level Bioequivalence Study

The VICH Steering Committee held a meeting in November 2013 and agreed that the draft guidance document entitled ''Draft Guidance for Industry, Bioequivalence: Blood Level Bioequivalence Study'' (VICH GL52) should be made available for public comment. This draft VICH guidance document is intended to harmonize the data recommendations associated with in vivo blood level BE for veterinary pharmaceutical products. To meet this objective, the draft guidance addresses the following topics: A harmonized definition of BE, factors/variables that should be considered when developing scientifically sound blood level BE study designs, and information that should be included in a blood level BE study report.

FDA and the VICH Expert Working Group will consider comments about the draft guidance document.

III. Significance of Guidance

This draft guidance, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated ''guidance'' rather than ''guideline.'' In addition, guidance documents must not include mandatory language such as ''shall,'' ''must,'' ''require,'' or ''requirement,'' unless FDA is using these words to describe a statutory or regulatory requirement.

The draft guidance, when finalized, will represent the Agency's current thinking on this topic. 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 applicable statutes and regulations.

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 Action of 1995 (44 U.S.C. 3501–3520). The collections of information in this draft guidance have been approved under OMB control numbers 0910–0032 and 0910–0669.

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.*

VI. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: September 18, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22681 Filed 9–23–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.