shall provide such person a written statement of the classification (if any) of such device and the requirements of the FD&C Act applicable to the device.

The guidance document entitled ''Guidance for Industry and Food and Drug Administration Staff; FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act'' establishes procedures for submitting, reviewing, and responding to requests for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act that are submitted in accordance with section 513(g) of the FD&C Act. FDA does not review data related to substantial equivalence or safety and effectiveness in a 513(g) request for information. FDA's responses to 513(g) requests for information are not device classification decisions and do not constitute FDA clearance or approval for marketing. Classification decisions and clearance or approval for marketing require submissions under different sections of the FD&C Act. Additionally, the FD&C Act, as amended by the FDA Amendments Act of 2007 (Public Law 110–85), requires FDA to collect user fees for 513(g) requests for information. The guidance document entitled ''Guidance for Industry and Food and Drug Administration Staff; User Fees for 513(g) Requests for Information'' assists FDA staff and regulated industry by describing the user fees associated with 513(g) requests. The Medical Device User Fee Cover Sheet (Form FDA 3601), which accompanies the supplemental material described in this information collection, is approved under OMB control number 0910–0511 and expires April 30, 2016.

In the **Federal Register** of July 22, 2014 (79 FR 42517), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Center for Devices and Radiological Health 513(g) requests	114	1	114	12	1,368
Center for Biologics Evaluation and Research 513(g) requests	4	1	4	12	48
Total					1,416

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents to this collection of information are mostly device manufacturers; however, anyone may submit a 513(g) request for information. The total number of annual responses is based on the average number of 513(g) requests received each year by the Agency.

Dated: March 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–05358 Filed 3–6–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0166]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Studies To Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Marker Residue Depletion Studies To Establish Product Withdrawal Periods; Revised Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry (GFI #207) entitled ''Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Marker Residue Depletion Studies to Establish Product Withdrawal Periods'' (VICH GL48(R)). This revised guidance, which provides minor updates to a final guidance on the same topic for which a notice of availability was published in the **Federal Register** of September 15, 2011 (2011 guidance), has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This revised VICH guidance is intended to provide study design recommendations that will facilitate the universal acceptance of the generated residue depletion data to fulfill the national/regional requirements.

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

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 guidance document.

Submit electronic comments on the revised guidance to *http://www.regulations.gov.* Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Julia Oriani, Center for Veterinary Medicine (HFV–151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0788, *julia.oriani@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

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, Japanese Veterinary Pharmaceutical Association, Japanese Association of Veterinary Biologics, and 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. Revised Guidance on Studies To Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Marker Residue Depletion Studies To Establish Product Withdrawal Periods

In June 2014, the VICH Steering Committee agreed that a revised guidance document entitled ''Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Marker Residue Depletion Studies to Establish Product Withdrawal Periods'' (VICH GL48(R)) should be made available to the public. The revised guidance is a revision of a final guidance on the same topic for which a notice of availability was published in the **Federal Register** of September 15, 2011 (76 FR 57056). The revised guidance includes minor changes that clarify recommendations for conducting a single timepoint study for products proposed for a 0-day withdrawal period or a 0-day milk discard time. In addition, the design for a 0-day milk discard timestudy was described, and a definition for preruminant was added. This revised guidance is a product of the Metabolism and Residue Kinetics Expert Working Group of the VICH.

As part of the approval process for veterinary medicinal products in food-producing animals, national/regional regulatory authorities require data from marker residue depletion studies in order to establish appropriate withdrawal periods in edible tissues, including meat, milk, and eggs. The objective of this guidance is to provide study design recommendations that will facilitate the universal acceptance of the generated residue depletion data to fulfill the national/regional requirements.

III. Significance of Guidance

As a result of Level 2 revisions, this VICH revised guidance is being issued in final, consistent with FDA's good guidance practice (GGP) regulations at 21 CFR 10.115(g)(4). This guidance, developed under the VICH process, has been revised to conform to FDA's GGP 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.

This VICH guidance represents 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 revised 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 514 have been approved under OMB control number 0910–0032.

V. Comments

Interested persons may submit either electronic comments regarding this document to *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 guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: March 3, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–05345 Filed 3–6–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Bioequivalence Recommendations; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR