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

10.115(g)(5)), to ensure that the Agency considers your comments on these draft and revised draft guidances before it begins work on the final versions of the guidances, submit either electronic or written comments on the draft and revised draft product-specific BE recommendations listed in this notice by May 8, 2015.

ADDRESSES: Submit written requests for single copies of the individual BE guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance recommendations.

Submit electronic comments on the draft product-specific BE recommendations 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: Xiaoqiu Tang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), 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 at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*.

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. Under that process, draft recommendations are posted on FDA's Web site and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received, and either publishes final recommendations or publishes revised draft recommendations for comment. Recommendations were last announced in the **Federal Register** on December 30, 2014 (79 FR 78447). This notice announces draft product-specific recommendations, either new or revised, that are posted on FDA's Web site.

II. Drug Products for Which New Draft Product-Specific BE Recommendations Are Available

FDA is announcing the availability of a new draft guidance for industry on product-specific BE recommendations for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS

A	Avanafil.
	Azilsartan medoxomil; Chlorthalidone.
B	Buprenorphine hydrochloride; Naloxone hydrochloride.
C	Chlorpheniramine maleate; Ibuprofen; Phenylephrine hydrochloride.
	Cyclosporine (multiple reference listed drugs).
D	Deferiprone.
	Desoximetasone.
	Diclofenac.
	Dorzolamide.
	Doxepin hydrochloride.
E	Eltrombopag olamine.
	Emtricitabine; Rilpivirine hydrochloride; Tenofovir disoproxil fumarate.
F	Flucinolone acetonide; Hydroquinone; Tretinoin.
I	Ibrutinib.
	Ibuprofen.
	Ipratropium bromide.
	Isosorbide dinitrate.
	Isotretinoin.
	Ivacaftor.
L	Loperamide hydrochloride (multiple reference listed drugs and dosage forms).
M	Minocycline hydrochloride.
N	Naproxen sodium; Diphenhydramine hydrochloride.
O	Oseltamivir phosphate.
	Oxybutynin chloride.
P	Potassium chloride.
	Praziquantel.
	Pyrimethamine.
S	Sodium polystyrene sulfonate
	Spinosad.
	Sucroferric oxyhydroxide.
T	Ticagrelor.
	Topiramate (multiple reference listed drugs).
V	Vigabatrin.

III. Drug Products for Which Revised Draft Product-Specific BE Recommendations Are Available

FDA is announcing the availability of a revised draft guidance for industry on product-specific BE recommendations for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC BE RECOMMENDATIONS FOR DRUG PRODUCTS

B	Brimonidine tartrate (multiple reference listed drugs).
	Brimonidine tartrate; Brinzolamide.
	Brinzolamide.
	Budesonide.
C	Carbamazepine (multiple reference listed drugs and dosage forms).
	Ciprofloxacin; dexamethasone.
D	Dexmethylphenidate hydrochloride.
	Dextroamphetamine sulfate.
	Doxepin hydrochloride.
G	Gabapentin.
I	Isotretinoin.
M	Methylphenidate hydrochloride.
	Mirtazapine.
N	Nisoldipine.
P	Paliperidone.
T	Teriflunomide.

For a complete history of previously published **Federal Register** notices related to product-specific BE recommendations, go to *http://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft and revised draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These guidances represent the Agency's current thinking on product-specific design of BE studies to support ANDAs. They do not create or confer any rights for or on any person and do 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.

IV. Comments

Interested persons may submit either electronic comments on any of the specific BE recommendations posted on FDA's Web site 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. The guidances, notices, and 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*.

V. Electronic Access

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

Dated: March 3, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–05347 Filed 3–6–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0030]

Compounding of Human Drug Products Under the Federal Food, Drug, and Cosmetic Act; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of public docket.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to receive information, recommendations, and comments on matters related to the Agency's regulation of compounding of human drug products under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This docket is intended for general comments related to human drug compounding that are not specific to documents or issues that are the subject of other dockets.

DATES: Comments may be submitted to this docket at any time.

ADDRESSES: You may submit comments, identified by Docket No. [FDA–2015–N–0030], by any of the following methods.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written comments in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. [FDA–2015–N–0030]. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://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 Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Philantha Bowen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg.51, Rm. 5175, Silver Spring, MD 20993–0002, 301–796–2466.

SUPPLEMENTARY INFORMATION:

I. Background

Section 503A of the FD&C Act (21 U.S.C. 353a) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from the following three sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications). Previously, the conditions of section 503A of the FD&C Act also included restrictions on the advertising or promotion of the compounding of any particular drug, class of drug, or type of drug and the solicitation of prescriptions for compounded drugs. These provisions were challenged in court and held unconstitutional by the U.S. Supreme Court in 2002.[1]

On November 27, 2013, President Obama signed the Drug Quality and Security Act (DQSA) (Pub. L. 113–54), which contains important provisions relating to the oversight of human drug compounding. This new law removes from section 503A of the FD&C Act the provisions that had been held unconstitutional by the U.S. Supreme Court in 2002. By removing these provisions, the new law clarifies that section 503A of the FD&C Act applies nationwide. In addition, the DQSA adds a new section, 503B, to the FD&C Act (21 U.S.C. 353b) that creates a new category of ''outsourcing facilities''. Outsourcing facilities, as defined in section 503B of the FD&C Act, are facilities that meet certain conditions described in section 503B, including registration with FDA as an outsourcing facility. If these conditions are satisfied, a drug compounded for human use by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from three sections of the FD&C Act: (1) Section 502(f)(1), (2) section 505, and (3) section 582 (21 U.S.C. 360eee), but not section 501(a)(2)(B).

Since enactment of the DQSA, FDA has sought public comment on a number of specific human drug compounding issues and has published several **Federal Register** notices seeking public input. These have included notices inviting comment on the registration process and product reporting requirements for human drug compounding outsourcing facilities (78 FR 72899 and 78 FR 72897), requesting nominations for the list of drugs that present demonstrable difficulties for compounding (78 FR 72840), and seeking input on other specific matters. A complete list of the human drug compounding policy documents issued by the Agency for public comment can be found at *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/PharmacyCompounding/ucm166743.htm.* The Agency will continue to seek public comment on specific documents and issues through future **Federal Register** notices. The Agency recognizes, however, that it would be useful to have a docket available for submissions of any information related to human drug compounding that may be unrelated to the specific issues and documents published for public comment.

II. Establishment of a Docket

FDA is establishing a public docket so that anyone can share information, research, and ideas on any matters related to human drug compounding that are not specific to the documents or issues addressed in other dockets. This information will give the Agency insight into stakeholders' experiences and views regarding human drug compounding as the Agency works to implement sections 503A and 503B of the FD&C Act.

This docket will be open for comment simultaneously with a number of other dockets that are specific to particular human drug compounding documents or issues (see *http://www.fda.gov/drugs/*

[1] See *Thompson* v. *Western States Med. Ctr.,* 535 U.S. 357 (2002).