U
Ulipristal acetate
W
Warfarin sodium

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

FDA is announcing revised draft product-specific BE recommendations for drug products containing the following active ingredients:

D
Desmopressin acetate
Diflunisal
Dipyridamole
H
Hydrochlorothiazide; lisinopril
Hydrochlorothiazide; losartan potassium
L
Liothyronine sodium
P
Phenoxybenzamine hydrochloride
Q
Quinine sulfate
R
Risedronate sodium
T
Tacrolimus
Thalidomide
Tinidazole

For a complete history of previously published **Federal Register** notices related to product-specific BE recommendations, please go to *http://www.regulations.gov* and enter docket number 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 to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments on any of the specific BE recommendations posted on FDA's Web site to *http://www.regulations.gov.* 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: December 11, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–30308 Filed 12–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1145]

Draft Guidance for Industry on Enrichment Strategies for Clinical Trials to Support Approval of Human Drugs and Biological Products; Availability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 entitled ''Enrichment Strategies for Clinical Trials to Support Approval of Human Drugs and Biological Products.'' The purpose of this document is to provide guidance to industry on enrichment strategies that can be used in clinical trials intended to support effectiveness and safety claims in new drug applications (NDAs) and biologics license applications (BLAs). This document defines several types of enrichment strategies, provides examples of various potential clinical trial designs, and discusses potential regulatory considerations when using enrichment strategies in clinical trials.

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 15, 2013.

ADDRESSES: Submit written requests for single copies of the draft 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 (1–800–835–4709 or 301–827–1800), or 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, or fax your request to 301–847–8149. 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 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: Robert Temple, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4212, Silver Spring, MD 20993–0003, 301–796–2270; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210; or Robert L. Becker, Center for Device and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5674, Silver Spring, MD 20993–0003, 301–796–5450.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Enrichment Strategies for Clinical Trials to Support Approval of Human Drugs and Biological Products.'' This document provides guidance to industry on enrichment strategies that can be used in clinical trials intended to support effectiveness and safety claims in new drug applications (NDAs) and biologics license applications (BLAs). Similar approaches could be used in clinical trials in earlier phases of drug development. As part of the reauthorization of the Prescription Drug User Fee Act (PDUFA IV), FDA committed to certain performance goals (see letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the

Congressional Record).[1] This draft guidance addresses one of these goals with the creation of a guidance document that addresses enriched trial designs. The guidance defines and discusses three enrichment strategies: Decreasing heterogeneity, predictive enrichment, and prognostic enrichment. The guidance also discusses general clinical trial design considerations, provides examples of potential clinical trial designs, and discusses regulatory considerations when using enrichment strategies.

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 clinical trial designs employing enrichment strategies to support approval of human drugs and biological products. 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. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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.

III. 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/default.htm*, *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm, or http://www.regulations.gov*.

Dated: November 20, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–30274 Filed 12–14–12; 8:45 am]

BILLING CODE 4160–01–P

[1] See ''Section A: PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 Through 2012'' (*http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm).*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1002]

Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Fifth Edition)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Questions and Answers Regarding Food Facility Registration (Fifth Edition).'' The guidance provides updated information pertaining to registration of human and animal food facilities under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA) on January 4, 2011.

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

ADDRESSES: Submit electronic comments on the 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. Submit written requests for single copies of the guidance to the Office of Compliance, Division of Field Programs and Guidance, Center for Food Safety and Applied Nutrition (HFS–615), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Amy Barringer, Center for Food Safety and Applied Nutrition (HFS–615), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1988.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Questions and Answers Regarding Food Facility Registration (Fifth Edition),'' which replaces the fourth edition of a guidance entitled ''Questions and Answers Regarding Registration of Food Facilities (Edition 4)'' issued in August 2004. The guidance provides updated information pertaining to the registration of food facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States.

On October 10, 2003, FDA issued an interim final rule (68 FR 58894) to implement amendments to the FD&C Act made by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Public Law 107–188). Section 415 of the FD&C Act (21 U.S.C. 350d) requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003. This guidance was developed to answer frequently asked questions relating to the registration requirements of section 415.

Section 102 of FSMA (Pub. L. 111–353), enacted on January 4, 2011, amended section 415 of the FD&C Act, in relevant part, to require facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States to submit additional registration information to FDA. This revised edition of the guidance includes new information relating to the FSMA amendments to section 415.

The first edition of this document was issued as level 2 guidance under § 10.115 (21 CFR 10.115) and was made available on FDA's Web site on December 4, 2003. The second, third, and fourth editions of this document were issued as level 1 guidance documents under § 10.115 and were made available on FDA's Web site on January 12, 2004, February 17, 2004, and August 2004, respectively. This revision (fifth edition) is being issued as a level 1 guidance and includes questions and answers relating to the FSMA amendments to section 415 of the FD&C Act. In addition, the guidance provides non-substantive revisions to clarify, delete, and renumber the questions and answers in edition 4.

This guidance is being issued consistent with FDA's good guidance practices regulation § 10.115 as a level 1 guidance. The Agency will accept comments at any time, but it is implementing this guidance immediately, in accordance with § 10.115(g)(2) because the Agency has determined that prior public participation is not feasible or appropriate.