

601.51), and any amendments to or annual reports on previously submitted DMFs or BPFs. This guidance also applies to submissions for drug/device combination products filed pursuant to section 505 of the FD&C Act or subsection (a) or (k) of section 351 of the PHS Act.

Section Technical Specification Documents Incorporated by Reference: Provides a list of documents incorporated by reference into this guidance and provides a complete listing of technical supportive files on the FDA eCTD Web page at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm>.

We also received a comment concerning the implementation timeline for the Portable Document Format (PDF) technical specification. As discussed in the guidance for industry "Providing Regulatory Submissions in Electronic Format—Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act," certain technical specifications are required no earlier than 2 years after the final guidance is published.

This guidance implements the electronic submission requirements of section 745A(a) of the FD&C Act by specifying the format for electronic submissions. All submissions submitted 24 months after the publication of this guidance must use the appropriate FDA-supported eCTD specifications for NDA, ANDA, and certain BLA submissions. Certain IND submissions must use the FDA-supported eCTD specifications for electronic submissions submitted 36 months after publication of this guidance.

In section 745A(a) of the FD&C Act, Congress granted explicit authorization to FDA to implement the statutory electronic submission requirements by specifying the format for such submissions in guidance. Because this guidance provides such requirements under section 745A(a) of the FD&C Act, indicated by the use of the words *must* or *required*, it is not subject to the usual restrictions in FDA's good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities. See 21 CFR 10.115(d).

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information 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 guidance pertains to sponsors and applicants

making regulatory submissions to FDA in electronic format for NDAs, ANDAs, BLAs, INDs, master files, and advertising and promotional labeling. The information collection discussed in the guidance is contained in our IND regulations (21 CFR part 312) and approved under OMB control number 0910–0014, our NDA regulations (including ANDAs) (21 CFR part 314) and approved under OMB control number 0910–0001, and our BLA regulations (21 CFR part 601) and approved under OMB control number 0910–0338.

Sponsors and applicants have been submitting NDAs, ANDAs, BLAs, INDs, and master files electronically since 2003, and the majority of these submissions are already received in electronic format. Under section 745A(a) of the FD&C Act, sponsors and applicants are required to file most of these submissions electronically. These requirements will be phased in over 2- and 3-year periods after the issuance of this guidance.

For some sponsors and applicants, there may be new costs, including capital costs or operating and maintenance costs, which would result from the requirements under FDASIA and this guidance, because some sponsors and applicants may have to upgrade eCTD specifications and/or change their method of submitting information to FDA. FDA estimates that, for some sponsors and applicants, the costs may be as follows:

- eCTD Publishing Software: \$25,000 to \$150,000
- Publishing Operations Support: \$50,000 to \$1 million
- Training: \$5,000 to \$50,000

III. Comments

Interested persons may submit either electronic comments to <http://www.regulations.gov> or written comments regarding this document 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 <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/>

GuidanceComplianceRegulatoryInformation/Guidances/default.htm, or <http://www.regulations.gov>.

Dated: April 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–10539 Filed 5–5–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1245]

Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System; Draft 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 draft guidance for industry entitled "Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System." This guidance provides recommendations for sponsors of investigational new drug applications (INDs), and applicants that submit new drug applications, abbreviated new drug applications (ANDAs), and supplements to these applications for immediate-release (IR) solid oral dosage forms, and who wish to request a waiver of in vivo bioavailability (BA) and/or bioequivalence (BE) studies.

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 July 6, 2015.

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, 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 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: Mehul Mehta, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-1573.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System." This guidance provides recommendations for sponsors and applicants who wish to request a waiver of in vivo BA and/or BE studies for IR solid oral dosage forms. These waivers are intended to apply to: (1) Subsequent in vivo BA or BE studies of formulations after the initial establishment of the in vivo BA of IR dosage forms during the IND period and (2) in vivo BE studies of IR dosage forms in ANDAs.

Regulations at 21 CFR part 320 address the requirements for BA and BE data for approval of drug applications and supplemental applications. Provision for waivers of in vivo BA/BE studies (biowaivers) under certain conditions is provided at § 320.22. This guidance updates the guidance for industry on "Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System," published in August 2000, and explains when biowaivers can be requested for IR solid oral dosage forms based on an approach termed the Biopharmaceutics Classification System (BCS). This guidance includes biowaiver extension to BCS class 3 drug products and additional modifications, such as criteria for high permeability and high solubility.

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 FDA's current thinking on waiver of in vivo bioavailability and bioequivalence studies for immediate-release solid oral dosage forms based on a BCS. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the

requirements of the applicable statutes and regulations.

II. 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>.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information 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 21 CFR part 314, including §§ 314.50 and 314.94, have been approved under OMB control number 0910-0001.

IV. 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: April 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-1419]

Withdrawal of Draft Guidance Documents Published Before December 31, 2013

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of 47 draft guidance documents that published before December 31, 2013, and have never been finalized. FDA is taking this action to improve the efficiency and transparency of the guidance development process.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), if you wish to submit comments on a specific withdrawal action in this notice, submit either electronic or written comments by June 5, 2015.

ADDRESSES: You may submit comments 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 submissions 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 Docket No. FDA-2015-N-1419 for this action. 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(s), 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, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lisa M. Helmanis, Regulations Policy and Management Staff, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3326, Silver Spring, MD 20993-0002, 301-796-9135, email: Lisa.Helmanis@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In September 2000, FDA codified its good guidance practices (GGPs). GGPs are FDA's policies and procedures for the development, issuance, and use of guidance documents. Level I guidance documents set forth initial interpretations of statutory or regulatory requirements, explain changes in interpretation of policies, or discuss complex scientific issues or highly controversial issues. The GGPs, generally, require that such guidances be issued in draft for public comment before they are finalized. FDA's guidance documents do not create