Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.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FDA is announcing the availability of a draft guidance for industry entitled ''Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on waiver of in vivo bioavailability and bioequivalence studies for immediate-release solid oral dosage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.

[FR Doc. 2015–10479 Filed 5–5–15; 8:45 am]

BILLING CODE 4164–01–P

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

legally enforceable rights or responsibilities and do not legally bind the public or FDA.

A key component of the GGPs is ensuring transparency during guidance development and issuance. In 2011, as part of the Agency's Transparency Initiative, FDA reviewed and set forth best practices for facilitating early stakeholder input, efficiency, and transparency in the Agency's processes, including GGPs.

In recent years, FDA's guidance workload has increased due to requests from the public for guidance to clarify specific issues and statutorily mandated guidances. Many of these draft guidances were not finalized most often because of higher priorities and resource issues. However, over the years, because of new information, scientific developments, and emerging technologies, a number of draft guidances have become outdated and therefore, should be withdrawn.

II. Withdrawal of Guidances

FDA is withdrawing the following 47 guidance documents.

Draft guidance	Docket No.	Publication date
1. Draft Guidance for Industry: Platelet Testing and Evaluation of Platelet Substitute Products	FDA–1998–D–0680	5/20/1999
2. Draft Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Intimate Contacts.	FDA–1999–D–0045	2/11/2002
3. Draft Guidance for Industry: Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Blood Cell Substitutes.	FDA–2004–D–0420	10/28/2004
4. Draft Guidance for Industry: Validation of Growth-Based Rapid Microbiological Methods for Sterility Testing of Cellular and Gene Therapy Products.	FDA–2008–D–0055	2/11/2008
5. Draft Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components for Transfusion and Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).	FDA–2009–D–0137	3/26/2009
6. Accelerated Approval Products—Submission of Promotional Materials	FDA–1999–D–0752	3/26/1999
7. Providing Regulatory Submissions in Electronic Format—Prescription Drug Advertising and Promotional Labeling.	FDA–2001–D–0169	1/1/2001
8. Comparability Protocols—Protein Drug Products and Biological Products—Chemistry, Manufacturing, and Controls Information.	FDA–2003–D–0355	9/5/2003
9. Providing Regulatory Submissions in Electronic Format—General Considerations	FDA–2003–D–0429	10/1/2003
10. ''Help-Seeking'' and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms.	FDA–2004–D–0500	1/26/2004
11. Notification to FDA of Issues that May Result in a Prescription Drug or Biological Product Shortage.	FDA–2012–D–0140	2/21/2012
12. Assessing the Safety and Effectiveness of Home-Use In Vitro Diagnostic Devices: Draft Points to Consider Regarding Labeling and Premarket Submissions.	FDA–1998–N–0050	10/5/1988
13. 510(k) Submission of Lymphocyte Immunophenotyping IVDs Using Monoclonal Antibodies	FDA–1998–N–0050 FDA–2013–N–0046	9/26/1991
14. 510(k) Submission of Immunoglobulins A, G, M, D, and E Immunoglobulin System In Vitro Devices.	FDA–1998–N–0050	9/1/1992
15. Draft Guidance for Preparation of PMA Applications for Testicular Prostheses	FDA–1998–N–0050	3/16/1993
16. Emergency Resuscitator Guidance	FDA–1998–N–0050	4/14/1993
17. 510(k) Submission Requirements for Peak Flow Meters	FDA–1998–N–0050	1/3/1994
18. Reviewer Guidance on Face Masks and Shield for CPR	FDA–1998–N–0050	3/16/1994
19. Reviewer Guidance for Ventilators	FDA–1998–N–0050	7/1/1995
20. Testing MR Interaction with Aneurysm Clips	FDA–1998–N–0050	5/22/1996
21. A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems	FDA–1997–D–0423	2/7/1997
22. Review Criteria Assessment of Portable Blood Glucose Monitoring In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase or Hexokinase Methodology.	FDA–2006–P–0022–0003	2/28/1997
23. Distribution and Public Availability of Premarket Approval Application Summary of Safety and Effectiveness Data Packages (P97–1).	FDA–1998–N–0050–0002	10/10/1997
24. Premarket Submissions and Labeling Recommendations for Drugs of Abuse Screening Tests	FDA–2003–D–0373	12/2/2003
25. Class II Special Controls Guidance Document: Tinnitus Masker Devices	FDA–2005–D–0085	11/8/2005
26. Class II Special Controls Guidance Document: Absorbable Hemostatic Device	FDA–2006–D–0356	10/31/2006
27. Class II Special Controls Guidance Document: Tissue Expander	FDA–2008–D–0603	12/22/2008
28. Heart Valves: Investigational Device Exemption and Premarket Approval Applications	FDA–2009–D–0559	1/20/2010
29. Class II Special Controls Guidance Document: Electroconductive Media	FDA–2009–D–0495	4/5/2010
30. Class II Special Controls Guidance Document: Cutaneous Electrode	FDA–2009–D–0495	4/5/2010
31. Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief.	FDA–2009–D–0495	4/5/2010
32. Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator with Limited Output for Pain Relief.	FDA–2009–D–0495	4/5/2010
33. Class II Special Controls Guidance Document: Transcutaneous Electrical Stimulator for Aesthetic Purposes.	FDA–2009–D–0495	4/5/2010
34. Class II Special Controls Guidance Document: Transcutaneous Electrical Stimulator with Limited Output for Aesthetic Purposes.	FDA–2009–D–0495	4/5/2010
35. Class II Special Controls Guidance Document: Powered Muscle Stimulator for Rehabilitation	FDA–2009–D–0495	4/5/2010
36. Class II Special Controls Guidance Document: Powered Muscle Stimulator with Limited Output for Rehabilitation.	FDA–2009–D–0495	4/5/2010
37. Class II Special Controls Guidance Document: Powered Muscle Stimulator for Muscle Conditioning.	FDA–2009–D–0495	4/5/2010
38. Class II Special Controls Guidance Document: Powered Muscle Stimulator with Limited Output for Muscle Conditioning.	FDA–2009–D–0495	4/5/2010
39. Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief Intended for Over the Counter Use.	FDA–2009–D–0495	4/5/2010

Draft guidance	Docket No.	Publication date
40. Recommended Warning for Surgeon's Gloves and Patient Examination Gloves	FDA–2011–D–0030	2/7/2011
41. Class II Special Controls Guidance Document: In Vitro Diagnostic Devices for Bacillus spp. Detection.	FDA–2011–D–0102	5/18/2011
42. Use of Antibiotic Resistance Marker Genes in Transgenic Plants	FDA–1998–N–0050	9/4/1998
43. Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals.	FDA–2002–D–0135	9/11/2002
44. Preliminary Timetable for the Review of Applications for Modified Risk Tobacco Products under the Federal Food, Drug, and Cosmetic Act.	FDA–2009–D–0563	11/27/2009
45. Guidance for Industry: Regulatory Procedures Manual—Chapter 9, Subchapter: Guidance Concerning Recommending Customs' Seizure and Destruction of Imported Human and Animal Food That has Not Been Reconditioned; Draft Guidance.	FDA–1998–N–0050	11/5/2002
46. Submission of Laboratory Packages By Accredited Laboratories	FDA–2008–D–0510	1/2009
47. Guidance for the Public and FDA Staff on Convening Advisory Committee Meetings	FDA–2008–D–0417	8/1/2008

Dated: April 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–10477 Filed 5–5–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1376]

Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices.'' This draft guidance is being issued to explain the circumstances in which it may be appropriate to leverage existing clinical data to support pediatric device indications in premarket approval applications (PMAs) and humanitarian device exemptions (HDEs). The draft guidance also describes the approach that FDA would use to determine whether extrapolation is appropriate in medical devices, and the factors that would be considered within a statistical model for extrapolation. Extrapolation may be appropriate when the course of the disease or condition and the effects of the device are sufficiently similar in adults and pediatric patients and the adult data are of high quality for borrowing. This draft guidance is not final nor is it in effect at this time.

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 of 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 August 4, 2015.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jacqueline Francis, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993–0002, 301–796–6405; or Stephen Ripley, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Section 520(m)(6)(E)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j) defines pediatric device patients as persons aged 21 or younger at the time of their diagnosis or treatment (*i.e.,* from birth through the 21st year of life, up to but not including the 22d birthday). Pediatric subpopulations are defined in section 520(m)(6)(E)(ii) (and adopted by reference in section 515A(c) of the FD&C Act (21 U.S.C. 360e)) to be neonates, infants, children, and adolescents.

In an attempt to promote pediatric medical device development, CDRH published a final guidance document in 2004 entitled ''Premarket Assessment of Pediatric Medical Devices'' (Ref. 1). This 2004 document indicates that data can be extrapolated to support effectiveness and, on a limited basis, safety for premarket approval applications (PMAs) when consistent with scientific principles. Congress was aware of this 2004 document when it passed the Food and Drug Administration Amendments Act of 2007 (FDAAA). Title III of FDAAA is the Pediatric Medical Device Safety and Improvement Act (PMDSIA). The FDAAA specifically authorized the use of adult data to demonstrate pediatric effectiveness. While safety exploration is not discussed in PMDSIA, FDA believes that there are specific cases where it will be appropriate to consider extrapolation of existing clinical safety data to support or enhance evidence for pediatric indications. FDA seeks comment on the appropriateness of extrapolating from adult clinical data to support medical device safety in pediatric patients.

FDA aims to increase the availability of safe and effective pediatric devices while ensuring that the approval of these devices is based on valid scientific evidence. Extrapolation of adult data for pediatric use may benefit pediatric patients by making it possible for devices to be approved for pediatric-specific indications and labeling, even when there is little or no existing pediatric data. Extrapolation facilitates the use of available relevant data by making optimal use of what is already known about device effects in other