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Withdrawal of Draft Guidance Documents Published Before December 31, 2013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SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of 47 draft guidance documents that published before December 31, 2013, and have never been finalized.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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 Number	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	FDA-2004-D-0420	10/28/2004

	Draft Guidance	Docket Number	Publication Date
	Cell Substitutes		
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	FDA-1998-N-0050	9/1/1992

	Draft Guidance	Docket Number	Publication Date
	Immunoglobulin System In Vitro Devices		
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	FDA-2009-D-0495	4/5/2010

	Draft Guidance	Docket Number	Publication Date
	Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief		
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
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	FDA-2002-D-0135	9/11/2002

	Draft Guidance	Docket Number	Publication Date
	Devices Derived from Bioengineered Plants for Use in Humans and Animals		
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.

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