

IV. List of Recognized Standards

FDA maintains the Agency's current list of FDA Recognized Consensus Standards in a searchable database that may be accessed directly at FDA's Internet site at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>. FDA will incorporate the modifications and revisions described in this notice into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. FDA will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often if necessary. Beginning with Recognition List 033, FDA no longer announces minor revisions to the list of recognized consensus standards such as technical contact person, devices affected, processes affected, Code of Federal Regulations citations, and product codes.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation to standards@cdrh.fda.gov. To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

You may obtain a copy of "Guidance on the Recognition and Use of Consensus Standards" by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page, <http://www.fda.gov/MedicalDevices>, includes a link to standards-related documents including the guidance and the current list of recognized standards. After publication in the **Federal Register**, this notice

announcing "Modification to the List of Recognized Standards, Recognition List Number: 038" will be available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm>. You may access "Guidance on the Recognition and Use of Consensus Standards," and the searchable database for "FDA Recognized Consensus Standards" at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards>.

VII. Submission of Comments and Effective Date

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>. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 038. These modifications to the list of recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: January 22, 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-D-0198]

Current Good Manufacturing Practice Requirements for Combination Products; 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 a draft guidance for industry and FDA staff entitled "Current Good Manufacturing Practice Requirements for Combination Products." The guidance describes and explains the final rule on current good

manufacturing practice (CGMP) requirements for combination products, including presenting general considerations for CGMP compliance as well as analysis of hypothetical scenarios.

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 March 30, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Current Good Manufacturing Practice Requirements for Combination Products" to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request. 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993-0002, 301-796-8930.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled "Current Good Manufacturing Practice Requirements for Combination Products." The guidance provides background on combination products, including an overview of the final rule on CGMP requirements for combination products (78 FR 4307, January 22, 2013) (21 CFR part 4) and the role of the lead center and other Agency components with respect to combination product CGMP issues. The guidance addresses general considerations for CGMP requirements for combination products and the purpose and content of specific CGMP provisions addressed in part 4. The guidance also contains hypothetical scenarios intended to clarify how to

comply with certain CGMP requirements addressed in part 4 by presenting compliance considerations for specific types of combination products. Throughout the guidance, reference is made to other existing guidance and additional sources of information addressing CGMP requirements for drugs, devices, biological products, and human cells, tissues, and cellular and tissue-based products (HCT/Ps). Concurrent with publication of this draft guidance, FDA is withdrawing the draft guidance for industry and FDA staff entitled "Current Good Manufacturing Practice for Combination Products," which was issued in September 2004.

II. Significance of Guidance

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 CGMP requirements for combination 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 statute and regulations.

III. Paperwork Reduction Act

This draft 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). We note that the information collected under the underlying CGMP regulations for drugs, devices, and biological products, including current good tissue practices for HCT/Ps, found at 21 CFR parts 211, 820, 600 through 680, and 1271, have already been approved and are in effect. The provisions of part 211 are approved under the Office of Management and Budget (OMB) control number 0910–0139. The provisions of part 820 are approved under OMB control number 0910–0073. The provisions of parts 606, 640, and 660 are approved under OMB control number 0910–0116. The provisions of part 610 are approved under OMB control number 0910–0116 and OMB control number 0910–0338 (also for part 680). The provisions of part 1271, subparts C and D, are approved under OMB control number 0910–0543.

IV. 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>.

V. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126198.htm> or <http://www.regulations.gov>.

Dated: January 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1849]

Medical Devices and Clinical Trial Design for the Treatment or Improvement in the Appearance of Fungally-Infected Nails; 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 "Medical Devices and Clinical Trial Design for the Treatment or Improvement in the Appearance of Fungally-Infected Nails." This guidance is intended to provide recommendations when finalized regarding clinical trial design for medical devices intended either to provide improvement in the appearance of nails affected by onychomycosis or to treat onychomycosis (fungal nail infection). 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 April 27, 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 "Medical Devices and Clinical Trial Design for the Treatment or Improvement in the Appearance of Fungally-Infected Nails" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, 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: Neil Ogden, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G414, Silver Spring, MD 20993–0002, 301–796–6397.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled "Medical Devices and Clinical Trial Design for the Treatment or Improvement in the Appearance of Fungally-Infected Nails." This guidance is intended to provide recommendations when finalized regarding clinical trial design for medical devices intended either: (1) To provide improvement in the appearance of nails affected by onychomycosis, that is, to affect the structure/function of the nails or (2) to treat onychomycosis (fungal nail infection).

The FDA distinguishes these two conditions as target outcomes. The treatment of onychomycosis (an infectious disease) requires proof of stable elimination of the fungal organism, which is a medical endpoint. This outcome is distinct from outcomes limited to "temporary increase in clear nail" in nails which are fungally infected, which is considered an aesthetic endpoint, and does not connote successful eradication of fungal infection. The need for clinical performance data will be dependent on