the design and use of the device. This guidance is intended to provide information related to both indications, when the device is applied to nails with confirmed fungal infection.

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This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on clinical trial design for the treatment or improvement in the appearance of fungally infected nails. 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. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. Persons unable to download an electronic copy of “Medical Devices and Clinical Trial Design for the Treatment or Improvement in the Appearance of Fungally-Infected Nails” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1400009 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This 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). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information regarding adverse events have been approved under OMB control number 0910–0471; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

The labeling recommendations of this draft guidance are not subject to review by the Office of Management and Budget because they do not constitute a “collection of information” under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, the recommended labeling is a “public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public.” (see 5 CFR 1320.3(c)(2)).

V. 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

Dated: January 21, 2015.

Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2015–01407 Filed 1–26–15; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


International Conference on Harmonisation; S10 Photosafety Evaluation of Pharmaceuticals; 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 guidance for industry entitled “S10 Photosafety Evaluation of Pharmaceuticals.” The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This guidance outlines details on when photosafety testing is warranted and on possible assessment strategies; it should be read in conjunction with the ICH M3(R2) guidance, section XIV(14) Photosafety Testing. The purpose of the guidance is to recommend international standards for photosafety assessment and to harmonize such assessments that support human clinical trials and marketing authorization for pharmaceuticals. This guidance finalizes the draft guidance issued on February 4, 2013.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the 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: Regarding the guidance: Abigail Jacobs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6474, Silver Spring, MD 20993–0002; Regarding the ICH: Michelle Limoli, Center for Drug Evaluation and Research, International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1174, Silver Spring, MD 20993–0002, 301–796–8377.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory Agencies.

ICH was organized to provide an opportunity for tripartite harmonization
supplements the ICH M3(R2) guidance, which: (1) Provides certain information regarding timing of photosafety testing relative to clinical development and (2) recommends that an initial assessment of photoreactive potential be conducted and, if appropriate, an experimental evaluation be undertaken before exposure of large numbers of subjects.

The guidance describes a flexible, integrated process that involves photochemical characteristics, data from nonclinical studies, and human safety information. Although the strategy is flexible and the options selected are the developer’s choice, characterization of the ultraviolet-visible absorption spectrum is recommended as the initial assessment and can obviate any further photosafety evaluation. Results of the evaluation determine the need for risk minimization measures to prevent adverse events in humans.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on this topic. 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 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. Electronic Access
