4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0640]

Draft Guidance for Industry on Uncomplicated Gonorrhea: Developing Drugs for Treatment; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Uncomplicated Gonorrhea: Developing Drugs for Treatment." The purpose of this draft guidance is to assist sponsors in the development of new antibacterial drugs for the treatment of uncomplicated gonorrhea.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, 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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6244, Silver Spring, MD 20993-0002, 301-796-1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Uncomplicated Gonorrhea: Developing Drugs for Treatment." The purpose of this draft guidance is to assist sponsors in the development of new antibacterial drugs for the treatment of uncomplicated gonorrhea.

This draft guidance describes approaches for trial designs for the evaluation of new drugs for the treatment of uncomplicated gonorrhea. The draft guidance focuses on the noninferiority trial design and describes an efficacy endpoint for which there is a well-defined treatment effect. The draft guidance also provides the justification for the noninferiority margin. In addition, this guidance reflects recent developments in scientific information that pertain to drugs being developed for the treatment of uncomplicated gonorrhea.

Issuance of this draft guidance fulfills a portion of the requirements of Title VIII, section 804, of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144) that requires FDA to ". . . review and, as appropriate, revise not fewer than 3 guidance documents per year . . . for the conduct of clinical trials with respect to antibacterial and antifungal drugs . . . ."

In 1998, FDA published a draft guidance entitled "Uncomplicated Gonorrhea: Developing Drugs for Treatment" (1998 draft guidance). In a Federal Register notice dated August 7, 2013 (78 FR 48175), FDA announced an initiative in the Center for Drug Evaluation and Research involving the review of draft guidance documents issued before 2010 to determine their status and to decide whether those guidances should be withdrawn, revised, or finalized with only minor changes. In the August 7, 2013, Federal Register notice, FDA announced that the 1998 draft guidance, as well as other draft guidances, was being withdrawn (78 FR 48175). FDA is now issuing a new draft guidance that revises the recommendations in the 1998 draft guidance. Issuance of the new draft guidance constitutes a revision of a previously published draft guidance and fulfills a portion of the requirements of Public Law 112-144.

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 developing drugs for the treatment of uncomplicated gonorrhea. 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. The Paperwork Reduction Act of 1995

This draft 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 parts 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively.

III. 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.

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: June 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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