4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.FDA-2013-D-1675]

Draft Guidance for Industry on New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products." This draft guidance sets forth a change in the Agency's interpretation of the 5-year new chemical entity (NCE) exclusivity statutory and regulatory provisions as they apply to certain fixed-combination drug products (fixed combinations). If the guidance is finalized, a drug product will be eligible for 5-year NCE exclusivity if it contains a drug substance that meets the definition of "new chemical entity," regardless of whether that drug substance is approved alone or in certain fixed-combinations.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration,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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: Nisha Shah, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993-0002, 301-796-4455; or Jay Sitlani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6272, Silver Spring, MD 20993-0002, 301-796-5202.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products." This guidance sets forth a change in the Agency's interpretation of the 5-year NCE exclusivity provisions as they apply to certain fixed-combinations. Sections 505(c)(3)(E)(ii) and (j)(5)(F)(ii) of the Food, Drug, and Cosmetic Act and 21 CFR 314.108, among other provisions, establish the scheme under which a drug product is eligible for 5-year NCE exclusivity. The Agency currently interprets the term "drug" as it appears in the first subclause of the statutory provisions and in the definition of "new chemical entity" in its regulation to mean "drug product." This results in a fixed-combination not being eligible for 5-year NCE exclusivity if it contains any

drug substance that contains an active moiety that had been previously approved by the Agency, even if the fixed-combination also contains another drug substance that contains a previously unapproved active moiety.

The Agency recognizes, however, that fixed-combinations have become increasingly prevalent in certain therapeutic areas and that these products play an important role in optimizing adherence to dosing regimens and improving patient outcomes. Therefore, to further incentivize the development of fixed-combinations containing previously unapproved active moieties, the Agency is revising its existing interpretation regarding the eligibility for 5-year NCE exclusivity of certain fixed-combinations. Under the revised interpretation, the term "drug" in the relevant provisions would be interpreted to mean "drug substance" or "active ingredient," and not "drug product." Accordingly, a drug product would be eligible for 5-year NCE exclusivity provided that it contains any drug substance that contains no active moiety that has been previously approved. This will permit a drug substance that meets the definition of new chemical entity (i.e., it contains no previously approved active moiety) to be eligible for 5-year NCE exclusivity, even when it is approved in a fixed-combination with another drug substance that contains a previously approved active moiety.

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 5-year NCE exclusivity for certain fixed-combinations. 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. The 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 collection of information in 21 CFR part 314 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: February 19, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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