CDER2014170
2014-673

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products; 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 "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 new chemical entity (NCE) exclusivity statutory and regulatory provisions as they apply to certain fixed-combination drug products (fixed combinations). As described in the guidance, 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 in a single-ingredient drug product or in certain fixed-combinations. This guidance finalizes the draft guidance issued in February 2014.

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

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, 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 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: 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 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. Section 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 historically interpreted the term "drug" as it appears in the first sub-clause of the statutory provisions and in the definition of "new chemical entity" in its regulation to mean "drug product." This resulted in a fixed-combination not being eligible for 5-year NCE exclusivity if it contained any drug substance that contained an active moiety that had been previously approved

by the Agency, even if the fixed-combination also contained another drug substance that contained 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 guidance sets forth the Agency's revised interpretation regarding the eligibility for 5-year NCE exclusivity of certain fixed-combinations. Under the revised interpretation, the term "drug" in the relevant provisions is interpreted to mean "drug substance" or "active ingredient," and not "drug product." Accordingly, a drug product is eligible for 5-year NCE exclusivity provided that it contains a 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., one that contains no previously approved active moiety) to be eligible for 5-year NCE exclusivity, regardless of whether it is approved in a single-ingredient drug product, in a fixed-combination with another drug substance that contains no other previously approved active moiety, or in a fixed-combination with another drug substance that contains a previously approved active moiety.

In the Federal Register of February 24, 2014 (79 FR 10167), this guidance was published as a draft guidance. We have carefully reviewed and considered the comments that were received on the draft guidance. We have made editorial changes primarily for clarification.

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 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 parts 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: October 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-24597 Filed 10/15/2014 at 8:45 am; Publication Date: 10/16/2014]