Dated: October 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–24599 Filed 10–15–14; 8:45 am]

BILLING CODE 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 This guidance finalizes the draft guidance issued in February 2014.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 10–15–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Public Conference—Vitamin D: Moving Toward Evidence-Based Decision Making for Primary Care

SUMMARY: A conference to identify issues surrounding evidence-based decision making for vitamin D in primary care will be held December 2–3, 2014, on the main campus of the National Institutes of Health (NIH) in Bethesda, Maryland. It will also be broadcast as a webinar. The conference discussions will serve to highlight research gaps as well as data and methodological needs relevant to reducing uncertainties surrounding vitamin D in primary care practice. All persons are invited to attend, especially clinical educators, those who develop clinical recommendations, health care providers and researchers. Persons wishing to attend are required to register in advance of the conference.

DATES: December 2–3, 2014; 8:00 to 5:00 p.m. (Eastern Time) on first day and 8:00 to noon on second day.

ADDRESSES: National Institutes of Health, William H. Natcher Building; Natcher Conference Center, Building 45. Bethesda, Maryland, 20892.

FOR FURTHER INFORMATION CONTACT: Ms. Cindy Rooney, Office of Dietary Supplements, National Institutes of Health, 6100 Executive Boulevard, Room 3B01, Bethesda, MD 20892–7523, Email: *rooneyc@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The conference is sponsored by the NIH Office of Dietary Supplements along with co-sponsors from 10 federal agencies. Information about the conference agenda, registration procedures, and webinar arrangements can be found at: *https://events-support.com/events/Vitamin_D_Primary_Care.*

Through its Vitamin D Initiative, the National Institutes of Health (NIH) Office of Dietary Supplements (ODS) leads several efforts to advance scientific understanding of vitamin D and health: *http://ods.od.nih.gov/Research/VitaminD.aspx.*

Dated: October 8, 2014.

Lawrence A. Tabak,

Principal Deputy Director, NIH.

[FR Doc. 2014–24455 Filed 10–15–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Nephrology.

Date: October 27, 2014.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Mushtaq A Khan, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2176, MSC 7818, Bethesda, MD 20892, 301–435–1778, *khanm@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Pain.

Date: November 4–5, 2014.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: John Bishop, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892, (301) 408–9664, *bishopj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business PAR Panel: Safe and Effective Instruments and Devices for Use in Neonatal and Pediatric Care Settings.

Date: November 6, 2014.

Time: 11:00 a.m. to 5:00 p.m..

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: John Firrell, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5118, MSC 7854, Bethesda, MD 20892, 301–435–2598, *firrellj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowship: Surgical Sciences, Biomedical Imaging and Bioengineering.

Date: November 7, 2014.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Weihua Luo, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5114, MSC 7854, Bethesda, MD 20892, 301–435–1170, *luow@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Respiratory Sciences.

Date: November 13–14, 2014.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Yuanna Cheng, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, MSC 7814, Bethesda, MD 20892, (301) 435–1195, *Chengy5@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Molecular and Therapeutic Genetics.

Date: November 13, 2014.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ronald Adkins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2206, MSC 7890, Bethesda, MD 20892, 301–435–4511, *ronald.adkins@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Digestive Sciences.

Date: November 14, 2014.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion,4300 Military Road NW., Washington, DC 20015.

Contact Person: Martha Garcia, Ph.D., Scientific Reviewer Officer, Center for Scientific Review, National Institutes of