this notice, by the date listed in the **DATES** section of this notice. Individuals requiring sign language interpretation or other special accommodations should contact the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. In accordance with the Department of Health & Human Services standards, and an effort for the public to engage virtually in the open meetings, this APOE meeting will be available to view via live web streaming by visiting the link *www.cms.gov/live* during the designated time of the meeting.

FOR FURTHER INFORMATION CONTACT: Kirsten Knutson, (410) 786–5886. Additional information about the APOE is available on the Internet at: *http://www.cms.gov/Regulations-and Guidance/Guidance/FACA/APOE.html*. Press inquiries are handled through the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION: In accordance with section 10(a) of the Federal Advisory Committee Act (FACA), this notice announces a meeting of the Advisory Panel on Outreach and Education (APOE) (the Panel). Section 9(a)(2) of the Federal Advisory Committee Act authorizes the Secretary of Health and Human Services (the Secretary) to establish an advisory panel if the Secretary determines that the panel is ''in the public interest in connection with the performance of duties imposed . . . by law.'' Such duties are imposed by section 1804 of the Social Security Act (the Act), requiring the Secretary to provide informational materials to Medicare beneficiaries about the Medicare program, and section 1851(d) of the Act, requiring the Secretary to provide for ''activities . . . to broadly disseminate information to [M]edicare beneficiaries . . . on the coverage options provided under [Medicare Advantage] in order to promote an active, informed selection among such options.''

The Panel is also authorized by section 1114(f) of the Act (42 U.S.C. 1314(f)) and section 222 of the Public Health Service Act (42 U.S.C. 217a). The Secretary signed the charter establishing this Panel on January 21, 1999 (64 FR 7899, February 17, 1999) and approved the renewal of the charter on December 18, 2012 (78 FR 105, May, 31, 2013).

Pursuant to the amended charter, the Panel advises and makes recommendations to the Secretary of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services (CMS) concerning optimal strategies for the following:

- Developing and implementing education and outreach programs for individuals enrolled in, or eligible for, Health Insurance Marketplace, Medicare, Medicaid and the Children's Health Insurance Program (CHIP).
- Enhancing the federal government's effectiveness in informing Health Insurance Marketplace, Medicare, Medicaid and CHIP consumers, providers and stakeholders pursuant to education and outreach programs of issues regarding these and other health coverage programs, including the appropriate use of public-private partnerships to leverage the resources of the private sector in educating beneficiaries, providers and stakeholders.
- Expanding outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of Health Insurance Marketplace, Medicare, Medicaid and CHIP education programs.
- Assembling and sharing an information base of ''best practices'' for helping consumers evaluate health plan options.
- Building and leveraging existing community infrastructures for information, counseling and assistance.
- Drawing the program link between outreach and education, promoting consumer understanding of health care coverage choices and facilitating consumer selection/enrollment, which in turn support the overarching goal of improved access to quality care, including prevention services, envisioned under health care reform.

The current members of the Panel are: Joseph Baker, President, Medicare Rights Center; Philip Bergquist, Manager, Health Center Operations, CHIPRA Outreach & Enrollment Project and Director, Michigan Primary Care Association; Marjorie Cadogan, Executive Deputy Commissioner, Department of Social Services; Jonathan Dauphine, Senior Vice President, AARP; Barbara Ferrer, Executive Director, Boston Public Health Commission; Shelby Gonzales, Senior Health Outreach Associate, Center on Budget & Policy Priorities; Jan Henning, Benefits Counseling & Special Projects Coordinator, North Central Texas Council of Governments' Area Agency on Aging; Sandy Markwood, Chief Executive Officer, National Association of Area Agencies on Aging; Miriam Mobley-Smith, Dean, Chicago State University, College of Pharmacy; Ana Natale-Pereira, Associate Professor of Medicine, University of Medicine & Dentistry of New Jersey; Megan Padden, Vice President, Sentara Health Plans; Winston Wong, Medical Director, Community Benefit Director, Kaiser Permanente.

The agenda for the March 17, 2014 meeting will include the following:

- Welcome and Listening Session with CMS Leadership
- Recap of the Previous (September 16, 2013) Meeting
- Affordable Care Act Initiatives
- An Opportunity for Public Comment
- Meeting Summary, Review of Recommendations and Next Steps

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Individuals not wishing to make a presentation may submit written comments to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

Authority: Sec. 222 of the Public Health Service Act (42 U.S.C. 217a) and sec. 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR 102–3).

(Catalog of Federal Domestic Assistance Program No. 93.733, Medicare—Hospital Insurance Program; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 12, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–03909 Filed 2–21–14; 8:45 am]

BILLING CODE 4120–01–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 April 25, 2014.

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.

[FR Doc. 2014–03885 Filed 2–21–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0202]

Over-The-Counter Drug Monograph System—Past, Present, and Future; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a public hearing to obtain input on the Over-The-Counter (OTC) Drug Review (sometimes referred to as the OTC Monograph Process, OTC Monograph, or OTC Drug Review). The Agency would like input on how to improve or alter the current OTC Monograph Process for reviewing nonprescription drugs (sometimes referred to as OTC drugs) marketed under the OTC Drug Review. This public hearing is being held to obtain information and comments from the public on the strengths and weaknesses of the current OTC Monograph Process, and to obtain and discuss ideas about modifications or alternatives to this process.