and bringing to market pipeline products suggests that the divested products will be placed in the hands of a firm with the same ability and incentive to bring the products to market. As explained below, the Consent Agreement helps make that outcome more likely.

For two of the products that both Amneal and Impax currently market, generic desipramine hydrochloride tablets and felbamate tablets, Impax will assign its contract manufacturing agreements to ANI. For the third currently-marketed product, Amneal will supply ANI with generic ezetimibe and simvastatin IR tablets for two years with the option to extend for two additional years.

In four overlap markets in which Amneal has an on-market product and Impax has a product in development, Impax will divest its rights and assets to ANI rather than requiring Amneal to divest its on-market, in-house manufactured products. Each of these product markets has specific facts that warrant the divestiture of the Impax rights and assets rather than the Amneal product. Of note, three products—generic aspirin and dipyridamole ER capsules, generic methylphenidate hydrochloride ER tablets, and generic diclofenac sodium and misoprostol DR tablets—are more complicated to manufacture because they have extended or delayed release characteristics.

For generic aspirin and dipyridamole ER capsules, Amneal is the only manufacturer with a product on the market. Amneal manufactures this product in-house. Impax received FDA approval for its ANDA in 2017 and had expected to use a third-party manufacturer to launch its product. That manufacturer experienced some manufacturing difficulties and Impax had begun the process of developing the means to produce the product at its own facilities. With the divestiture, ANI will finalize the manufacturing process and expects to have the Impax drug on the market soon. Nevertheless, should ANI be unable to market its own version of this product by October 1, 2019, ANI has the option to source generic aspirin and dipyridamole ER capsules from Amneal until ANI obtains the necessary regulatory approvals or through March 1, 2021, whichever date is earlier. This ensures that ANI will be able to market a competing product near the time Impax likely would have had the product on market, and provides the incentive for ANI to manufacture and market its own product. An alternative divestiture of the Amneal product would involve more risk and could jeopardize the only generic product on the market.

The FDA approved Amneal's ANDA for generic methylphenidate hydrochloride ER tablets in February 2018. Impax also has an approved ANDA. Impax's product is contract manufactured, but the contract manufacturer needs to resolve manufacturing issues before it can resume manufacturing the product. It will be less risky for Impax to assign its manufacturing contract to ANI than to affect a technology transfer from Amneal for this complex product, and it will put the product in ANI's hands, which has the same ability and incentive as Impax to bring methylphenidate hydrochloride ER tablets to market. Thus, the proposed Order requires the divestiture of Impax's rights and assets to ANI.

For generic diclofenac sodium and misoprostol DR tablets, Amneal has an on-market in-house manufactured product, and Impax is partnered with Micro Labs to commercialize a competing product. Impax holds only marketing rights to the product; Micro Labs is responsible for development and manufacturing. Impax will transfer its marketing agreement with Micro Labs to ANI, and Micro Labs will manufacture the product for ANI for the current contract term.

For erythromycin tablets, Amneal launched its product in March 2018, and only one other competitor, Arbor Pharmaceuticals, is currently selling erythromycin tablets. Amneal manufactures the erythromycin tablets in-house. Impax is one of a few companies developing the product, and once approved, it plans to outsource the manufacturing. Here, the easier-to-divest product is the Impax drug in development. Thus, Commission staff considers it prudent to leave the in-house Amneal-manufactured product with the merged firm, an ongoing and viable competitor to Arbor. Further, Impax will transfer all of its assets related to its development of erythromycin tablets to ANI, which has the same ability and incentive to bring a competing third erythromycin tablet to market.

The proposed Order also requires Amneal to provide transitional services to ANI, Perrigo, and G&W to assist them in establishing their manufacturing capabilities and securing all of the necessary FDA approvals. These transitional services include technical assistance to manufacture the ten products at issue in substantially the same manner and quality employed or achieved by Impax. It also includes advice and training from knowledgeable employees of the parties. Under the proposed Consent Agreement, the Commission also will appoint an Interim Monitor.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Acquisition. If the Commission determines that ANI, Perrigo, and/or G&W are not acceptable acquirers, or that the manner of the divestitures is not acceptable, the proposed Order requires the parties to unwind the sale of rights to ANI, Perrigo, and/or G&W and then divest the affected products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2018–09546 Filed 5–3–18; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Health Statistics (BSC, NCHS)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), announces the following meeting for the Board of Scientific Counselors, National Center for Health Statistics (BSC, NCHS). This meeting is open to the public; however, visitors must be processed in accordance with established federal policies and procedures. For foreign nationals or non-U.S. citizens, pre-approval is required (please contact Gwen Mustaf, 301–458–4500, *glm4@cdc.gov,* or Charles Rothwell, (301) 458–4500, *cjr4@cdc.gov* at least 10 days in advance for requirements). All visitors are required to present a valid form of

picture identification issued by a state, federal or international government. As required by the Federal Property Management Regulations, all persons entering in or on Federal controlled property and their packages, briefcases, and other containers in their immediate possession are subject to being x-rayed and inspected. Federal law prohibits the knowing possession or the causing to be present of firearms, explosives and other dangerous weapons and illegal substances. The meeting room accommodates approximately 78 people.

DATES: The meeting will be held on June 19, 2018, 11:00 a.m.–5:30 p.m., EDT, and June 20, 2018, 8:30 a.m.–1:00 p.m., EDT.

ADDRESSES: NCHS Headquarters, 3311 Toledo Road, Hyattsville, Maryland 20782.

FOR FURTHER INFORMATION CONTACT: Charles J. Rothwell, Director, NCHS/CDC, 3311 Toledo Road, Room 2627, Hyattsville, Maryland 20782, telephone (301) 458–4500, email *cjr4@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: This committee is charged with providing advice and making recommendations to the Secretary, Department of Health and Human Services; the Director, CDC; and the Director, NCHS, regarding the scientific and technical program goals and objectives, strategies, and priorities of NCHS.

Matters to be Considered: Day One meeting agenda includes: Welcome remarks by NCHS leadership; update on Selected NCHS OPIOID Related Projects; update on Health, United States 2017 and Beyond; Day Two meeting agenda includes: Update on Visualizing the National Health Interview Survey Early Release Program: A New Online Dynamic Report; and an update on National Health and Nutrition Examination Survey 2013: The Future is Now. Requests to make oral presentations should be submitted in writing to the contact person listed below. All requests must contain the name, address, telephone number, and organizational affiliation of the presenter. Written comments should not exceed five single-spaced typed pages in length and must be received by June 4, 2018. Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Claudette Grant,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2018–09473 Filed 5–3–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC–2018–0024; Docket Number NIOSH–302]

Draft—National Occupational Research Agenda for Respiratory Health; Extension of Comment Period

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice and extension of comment period.

SUMMARY: On March 15, 2018 the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), published a notice in the **Federal Register** [83 FR 11537] announcing the availability of a draft NORA Agenda entitled National Occupational Research Agenda for Respiratory Health for public comment. Written comments were to be received by May 14, 2018. In response to a request from an interested party, NIOSH is extending the public comment period to July 13, 2018.

FOR FURTHER INFORMATION CONTACT: Emily Novicki *NORACoordinator@cdc.gov*), National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Mailstop E–20, 1600 Clifton Road NE, Atlanta, GA 30329, phone (404) 498–2581 (not a toll free number).

ADDRESSES: You may submit comments, identified by CDC–2018–0024 and Docket Number NIOSH–302, by either of the following two methods:

- *Federal eRulemaking Portal: http://www.regulations.gov* Follow the instructions for submitting comments.
- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226–1998.

Dated: April 25, 2018.

Frank J. Hearl,

Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2018–09442 Filed 5–3–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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, and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—Funding Opportunity Announcement (FOA), PAR 16–098, Cooperative Research Agreements to the World Trade Center Health Program (U01).

Date: June 25, 2018.

Times: 1:00 p.m.–4:00 p.m. EDT.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Nina Turner, Ph.D., Scientific Review Officer, CDC/NIOSH, 1095 Willowdale Road, Mailstop G905, Morgantown, West Virginia 26505, Telephone: (304) 285–5975.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Claudette Grant,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2018–09475 Filed 5–3–18; 8:45 am]

BILLING CODE 4163–18–P