17. Meeting Summary and Attachment from the U.S.-EU Bivalve Molluscan Shellfish Equivalence Project. November 19–20, 2015. FDA Hillandale Building, Silver Spring, MD.
18. Commission Regulation (EU) 2015/2285 of 8 December 2015 Amending Annex II to Regulation (EC) No. 854/2004 of the European Parliament. Accessed online at *http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R2285&from=EN.*
19. Meeting Summary and Attachment from the U.S.-EU Bivalve Molluscan Shellfish Equivalence Project. September 19–20, 2016. FDA Center for Food Safety and Applied Nutrition, College Park, MD.
20. Bad Bug Book, *Foodborne Pathogenic Microorganisms and Natural Toxins.* Second Edition. FDA. 2012. Accessed online at *https://www.fda.gov/food/foodborneillnesscontaminants/causesofillnessbadbugbook/.*
21. Risk Assessment of *Vibrio vulnificus* in Raw Oysters, Interpretive Summary and Technical Report. World Health Organization/Food and Agriculture Organization of the United Nations. 2005. Accessed online at *http://www.who.int/foodsafety/publications/micro/mra8.pdf.*
22. Meeting Summary and Attachments from the U.S.-EU Molluscan Shellfish Equivalence Project. September 5–6, 2013. FDA White Oak Campus, Silver Spring, MD.
23. On-going Activities on Emerging Risks in the SCER Unit. Presentation at European Food Safety Authority (EFSA) 56th Advisory Forum Meeting. June 11–12, 2015. Accessed online at *https://www.efsa.europa.eu/sites/default/files/assets/af150611a-p9d.pdf.*

Dated: March 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–04772 Filed 3–8–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0410]

Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments'' that appeared in the **Federal Register** of February 22, 2018. The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Thursday, February 22, 2018 (83 FR 7727), in FR Doc. 2018–03603, on page 7727, the following correction is made:

1. On page 7727, in the first column, in the header of the document, the docket number is corrected to read ''FDA–2018–N–0410.''

Dated: March 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–04774 Filed 3–8–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–P–5946]

Determination That DORYX MPC (Doxycycline Hyclate), Delayed-Release Tablets, 60 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that DORYX MPC (doxycycline hyclate), delayed-release tablets, 60 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for DORYX MPC (doxycycline hyclate), delayed-release tablets, 60 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Aaron Young, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6217, Silver Spring, MD 20993–0002, 301–796–8083.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

DORYX MPC (doxycycline hyclate), delayed-release tablets, 60 mg, are the subject of NDA 50–795, held by Mayne Pharma International Pty Ltd., and initially approved on May 6, 2005. DORYX MPC is indicated for rickettsial infections; sexually transmitted infections; respiratory tract infections; specific bacterial infections; ophthalmic infections; anthrax, including inhalational anthrax (post-exposure); alternative treatment for selected infections when penicillin is contraindicated; adjunctive therapy in acute intestinal amebiasis and severe acne; and prophylaxis of malaria.

Mayne Pharma International Pty Ltd. has never marketed DORYX MPC (doxycycline hyclate), delayed-release tablets, 60 mg. In previous instances (see, *e.g.,* 72 FR 9763 (March 5, 2007) and 61 FR 25497 (May 21, 1996)), the Agency has determined that, for

purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Goodwin Procter LLP submitted a citizen petition dated September 26, 2017 (Docket No. FDA–2017–P–5946), under 21 CFR 10.30, requesting that the Agency determine whether DORYX MPC (doxycycline hyclate), delayed-release tablets, 60 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that DORYX MPC (doxycycline hyclate), delayed-release tablets, 60 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of DORYX MPC (doxycycline hyclate), delayed-release tablets, 60 mg, from sale. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list DORYX MPC (doxycycline hyclate), delayed-release tablets, 60 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to this drug product may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–04726 Filed 3–8–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Advisory Committee on Interdisciplinary, Community-Based Linkages

AGENCY: Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of meetings.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given that two orientation meetings are scheduled for the Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL). These meetings will be open to the public. Information about the ACICBL and the agenda for these meetings can be obtained by accessing the ACICBL website at: *https://www.hrsa.gov/advisory-committees/interdisciplinary-community-linkages/meetings/index.html.*

DATES: In order to accommodate the schedules of the ACICBL members, two orientation meetings will be held. The first meeting will be on March 15, 2018 from 11:00 a.m.–4:00 p.m., ET and the second meeting will be on March 27, 2018 from 12:00 p.m.–5:00 p.m., ET.

ADDRESSES: These meetings will be held via conference call/webinar.

- The teleconference call-in number is 1–800–619–2521, passcode: 9271697.
- The webinar link is *https://hrsa.connectsolutions.com/acicbl.*

FOR FURTHER INFORMATION CONTACT: Anyone requesting information regarding the ACICBL should contact Joan Weiss, Ph.D., RN, CRNP, FAAN, HRSA, in one of three ways: (1) Send a request to the following address: Joan Weiss, Ph.D., RN, CRNP, FAAN, Senior Advisor and Designated Federal Officer, Division of Medicine and Dentistry, HRSA, 5600 Fishers Lane, Room 15N39, Rockville, Maryland 20857; (2) call (301) 443–0430; or (3) send an email to *jweiss@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The ACICBL provides advice and recommendations on a broad range of issues relating to grant programs authorized by sections 750–760, Title VII, Part D of the Public Health Service Act. During the March 15, 2018 and March 27, 2018 meetings. ACICBL members will be oriented to the work of the Committee and identify potential topics to work on for 2018.

The ACICBL's reports are submitted to the Secretary of HHS; the Committee on Health, Education, Labor, and Pensions of the U.S. Senate; and the Committee on Energy and Commerce of the U.S. House of Representatives.

Members of the public will have the opportunity to provide comments. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to make oral comments or provide written comments to the ACICBL should be sent by March 13, 2018 for the March 15, 2018 meeting and by March 25, 2018 for the March 27, 2018 meeting.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–04815 Filed 3–8–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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: National Cancer Institute Special Emphasis Panel; NCI Pediatric Early Phase Clinical Trials Network (PEP–CTN).

Date: March 27, 2018.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W538, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Shamala K. Srinivas, Ph.D., Scientific Review Officer, Office of Referral, Review, and Program Coordination, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W530, Bethesda, MD 20892–9750, 240–276–6430, *ss537t@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; U01 SEP: Liquid Biopsy & Early Cancer Assessment.

Date: May 1, 2018.

Time: 10:00 a.m. to 5:00 p.m.