

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requesting that the Agency determine whether DORYX MPC (doxycycline hyclate), delayed-release tablets, 60 mg, were withdrawn from sale for reasons of safety or effectiveness.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time, FDA has determined under § 314.161 that DORYX MPC (doxycycline hyclate), delayed-release tablets, 60 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness.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 We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.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.

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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.

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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.