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