DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces a meeting for the initial review of applications in response to Funding Opportunity Announcement (FOA) GH16–007, Operations Research (Implementation Science) for Strengthening Global Health Protection Implementation.

Times and Dates: 9:00 a.m.–2:00 p.m., EDT, Panel A, August 8, 2016 (Closed); 9:00 a.m.–2:00 p.m., EDT, Panel B, August 9, 2016 (Closed); 9:00 a.m.–2:00 p.m., EDT, Panel C, August 10, 2016 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to FOA GH–007 Operations Research (Implementation Science) for Strengthening Global Health Protection Implementation.

Contact Person for More Information: Hylan Shoob, Scientific Review Officer, Center for Global Health (CGH) Science Office, CGH, CDC, 1600 Clifton Road NE., Mailstop D–69, Atlanta, Georgia 30033, Telephone: (404) 639–4796.

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.

Catherine Ramadei,

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

[FR Doc. 2016–16582 Filed 7–13–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Requests for Nominations of Candidates and Suggested Meeting Topics for the Clinical Laboratory Improvement Advisory Committee (CLIAC)

Correction: This notice was published in the **Federal Register** on June 7, 2016, 81 FR 36543. The Request for Candidates should read as follows:

Request For Candidates: Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to accomplishing CLIAC's objectives. Nominees will be selected by the HHS Secretary or designee from authorities knowledgeable across the fields of microbiology (including bacteriology, mycobacteriology, mycology, parasitology, and virology), immunology (including histocompatibility), chemistry, hematology, pathology (including histopathology and cytology), or genetic testing (including cytogenetics); representatives from the fields of medical technology, public health, and clinical practice; and consumer representatives. Members may be invited to serve for terms of up to four years.

The U.S. Department of Health and Human Services policy stipulates that Committee membership be balanced in terms of points of view represented, and the committee's function. Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government. Current participation on federal workgroups or prior experience serving on a federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships. Committee members are Special Government Employees, requiring the filing of financial disclosure reports at the beginning and annually during their terms. CDC reviews potential candidates for CLIAC membership each year, and provides a slate of nominees for consideration to the Secretary of HHS for final selection. HHS notifies selected candidates of their appointment near the start of the term in July, or as soon as the HHS selection process is completed. Note that the need for different expertise varies from year to year and a candidate who is not selected in one year may be reconsidered in a subsequent year.

Candidates should submit the following items to be considered for nomination. The deadline for receipt of materials for the 2017 term is August 1, 2016:

- Current *curriculum vitae,* including complete contact information (name, affiliation, mailing address, telephone number, email address).
- Letter(s) of recommendation from person(s) not employed by the U.S. Department of Health and Human Services.

FOR FURTHER INFORMATION CONTACT: Nancy Anderson, Chief, Laboratory Practice Standards Branch, Division of Laboratory Systems, Center for Surveillance, Epidemiology and Laboratory Services, Office of Public Health Scientific Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop F–11, Atlanta, Georgia 30329–4018; telephone (404) 498–2741; or via email at *NAnderson@cdc.gov.*

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.

Catherine Ramadei,

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

[FR Doc. 2016–16580 Filed 7–13–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

In accordance with sction 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces a meeting for the initial review of applications in response to Funding Opportunity Announcement (FOA) CK17–1701, Emerging Infections Programs.

Time and Date: 10:00 a.m.–5:00 p.m., EDT, August 30–31, 2016 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5 U.S.C., and the determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''Emerging Infections Programs'', FOA CK17–1701.

Contact Person for More Information: Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road NE., Mailstop E60, Atlanta, Georgia 30333, Telephone: (404) 718–8833.

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.

Catherine Ramadei,

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

[FR Doc. 2016–16581 Filed 7–13–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–P–4224]

Determination That PARAFON FORTE DSC (Chlorzoxazone) Tablets, 500 Milligrams, Was 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 PARAFON FORTE DSC (chlorzoxazone) tablets, 500 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and this determination will allow FDA to continue to approve ANDAs for chlorzoxane tablets, 500 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: David Faranda, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–8767.

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 (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.

PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, is the subject of NDA 011529, held by Janssen Research & Development, LLC, and initially approved on August 15, 1958. PARAFON FORTE DSC is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions.

PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, is listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Flamingo Pharmaceuticals Ltd. submitted a citizen petition dated November 7, 2015 (Docket No. FDA–2015–P–4224), under 21 CFR 10.30, requesting that the Agency determine whether PARAFON FORTE DSC (chlorzoxazone) tablets, 500 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 PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PARAFON FORTE DSC (chlorzoxazone) tablets, 500 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 PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, 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: July 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–16635 Filed 7–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1678]

The Food and Drug Administration Foods and Veterinary Medicine Program's Strategic Plan for Fiscal Years 2016–2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice and request for comments.