DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number NIOSH 278]

Request for Nominations of Candidates To Serve on the Board of Scientific Counselors (BSC), National Institute for Occupational Safety and Health (NIOSH)

The Centers for Disease Control and Prevention (CDC) is soliciting nominations for possible membership on the BSC, NIOSH.

The BSC, NIOSH consists of 15 experts in fields related to occupational safety and health. The members are selected by the Secretary of the U.S. Department of Health and Human Services (HHS). The board advises the NIOSH Director on occupational safety and health research and prevention programs. The board also provides advice on standards of scientific excellence, current needs in the field of occupational safety and health, and the applicability and dissemination of research findings. This advice may take the form of reports or verbal communications to the NIOSH Director during BSC meetings. Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishment of the board's mission. More information is available on the NIOSH BSC Web site: *http://www.cdc.gov/niosh/BSC/default.html.*

Nominees will be selected based on expertise in occupational safety and health fields, such as occupational medicine, occupational nursing, industrial hygiene, occupational safety and health engineering, toxicology, chemistry, safety and health education, ergonomics, epidemiology, biostatistics, and psychology. Members may be invited to serve for terms of two to four years. Selected nominees would begin service on the BSC, NIOSH in January 2018.

The U.S. Department of Health and Human Services policy stipulates that committee membership shall 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 or federally registered lobbyists. 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. Board 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 the Board membership each year, and provides a slate of nominees for consideration to the Secretary of HHS for final selection.

Candidates should submit the following items:

- Current *curriculum vitae,* including complete contact information (name, affiliation, mailing address, telephone number, email address)
- A letter of recommendation stating the qualifications of the candidate.

Nominations must be submitted (postmarked or electronically received) by January 31, 2017.

Submissions must be electronic or by mail. Submissions should reference docket 278. Electronic submissions: You may electronically submit nominations, including attachments, to *nioshdocket@cdc.gov.*

Attachments in Microsoft Word are preferred. Regular, Express, or Overnight Mail: Written nominations may be submitted (one original and two copies) to the following address only: NIOSH Docket 278, c/o Richie Dickerson, Committee Management Specialist, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS: E–20, Atlanta, Georgia 30329. Telephone and facsimile submissions cannot be accepted.

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. 2016–30522 Filed 12–19–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–4320]

Sun Pharmaceutical Industries, Inc.; Withdrawal of Approval of 28 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 28 abbreviated new drug applications held by Sun Pharmaceutical Industries, Inc. (Sun Pharmaceutical), U.S. Agent for Sun Pharmaceutical Industries Limited, 270 Prospect Plains Rd., Cranbury, NJ 08512. The drug products are no longer marketed, and Sun Pharmaceutical has requested that the approval of the applications be withdrawn.

DATES: January 19, 2017.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: The applications listed in the table in this document are no longer marketed, and Sun Pharmaceutical has requested that FDA withdraw approval of the applications. The company has also, by its request, waived its opportunity for a hearing.

Application No.	Drug
065007	Cephalexin Capsules USP, Equivalent to (EQ) 250 milligrams (mg) base and EQ 500 mg base.
065016	Amoxicillin Capsules USP, 250 mg and 500 mg.
065021	Amoxicillin Tablets USP (Chewable), 125 mg and 250 mg.
065059	Amoxicillin Tablets USP, 500 mg and 875 mg.
065060	Amoxicillin Tablets USP (Chewable), 200 mg and 400 mg.
065081	Cephalexin for Oral Suspension USP, EQ 125 mg base/5 milliliters (mL) and EQ 250 mg base/5 mL.
065082	Cefpodoxime Proxetil for Oral Suspension USP, EQ 50 mg base/5 mL and EQ 100 mg base/5 mL.
065083	Cefpodoxime Proxetil Tablets USP, EQ 100 mg base and EQ 200 mg base.

Application No.	Drug
065102	Amoxicillin and Clavulanate Potassium Tablets USP, 875 mg/EQ 125 mg base.
065109	Amoxicillin and Clavulanate Potassium Tablets USP, 500 mg/EQ 125 mg base.
065113	Amoxicillin for Oral Suspension USP, 200 mg/5 mL and 400 mg/5 mL.
065115	Cefadroxil for Oral Suspension USP, EQ 125 mg base/5 mL, EQ 250 mg base/5 mL, and EQ 500 mg base/5 mL.
065118	Cefuroxime Axetil Tablets USP, EQ 125 mg base, EQ 250 mg base, and EQ 500 mg base.
065132	Amoxicillin and Clavulanate Potassium for Oral Suspension USP, 200 mg/EQ 28.5 mg base per 5 mL and 400 mg/EQ 57 mg base per 5 mL.
065161	Amoxicillin and Clavulanate Potassium Tablets USP (Chewable), 200 mg/EQ 28.5 mg base and 400 mg/EQ 57 mg base.
065207	Amoxicillin and Clavulanate Potassium for Oral Suspension USP, 600 mg/EQ 42.9 mg base per 5 mL.
065323	Cefuroxime Axetil for Oral Suspension USP, EQ 125 mg base/5 mL and EQ 250 mg base/5 mL.
074975	Acyclovir Capsules USP, 200 mg.
074980	Acyclovir Tablets USP, 400 mg and 800 mg.
075132	Ranitidine Tablets USP, EQ 75 mg base.
075439	Ranitidine Tablets USP, EQ 150 mg base and EQ 300 mg base.
076041	Sotret (isotretinoin) Capsules USP, 10 mg, 20 mg, and 40 mg.
076285	Simvastatin Tablets USP, 5 mg, 10 mg, 20 mg, 40 mg, and 80 mg.
076332	Fluconazole for Oral Suspension, 10 mg/mL and 40 mg/mL.
076409	Nefazodone Hydrochloride Tablets USP, 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg.
076503	Sotret (isotretinoin) Capsules USP, 30 mg.
076606	Gabapentin Capsules USP, 100 mg, 300 mg, and 400 mg.
076739	Fosinopril Sodium and Hydrochlorothiazide Tablets USP, 10 mg/12.5 mg and 20 mg/12.5 mg.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn, effective January 19, 2017.

Dated: December 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–30623 Filed 12–19–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0969]

Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Zika Virus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for an in vitro diagnostic device for detection of the Zika virus in response to the Zika virus outbreak in the Americas. FDA issued this Authorization under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by Abbott Molecular, Inc. The Authorization contains, among other things, conditions on the emergency use of the authorized in vitro diagnostic device. The Authorization follows the February 26, 2016, determination by the Secretary of Health and Human Services (HHS) that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus. On the basis of such determination, the Secretary of HHS declared on February 26, 2016, that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under the FD&C Act. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of November 21, 2016.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Carmen Maher, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4347, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help assure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military