

Application No.	Drug	Applicant
NDA 006002 .....	Aralen Hydrochloride (chloroquine hydrochloride (HCl)) Injection, Equivalent to (EQ) 40 milligram (mg) base/milliliter (mL); Aralen (chloroquine phosphate) Tablets, EQ 300 mg base.	Sanofi-Aventis, U.S., LLC, 55 Corporate Dr., Bridgewater, NJ 08807.
NDA 008107 .....	Leucovorin calcium for Injection USP, EQ 60 mg base/vial for solution, oral; EQ 3 mg base/mL injection; EQ 50 mg base/vial injection; EQ 100 mg base/vial injection; EQ 350 mg base/vial injection.	Hospira Inc., Subsidiary of Pfizer Inc., 235 East 42nd St., New York, NY 10017.
NDA 009321 .....	Cholografin Meglumine (iodipamide meglumine) Injection, 10.3% and 52% (cholografin sodium, 20%).	Bracco Diagnostics, Inc., 259 Prospect Plains Rd., Monroe Township, NJ 08831.
NDA 017566 .....	Brevicon (ethinyl estradiol; norethindrone) Tablets, 0.035 mg/0.5 mg (21-Day Regimen).	Allergan Pharmaceuticals International, Ltd., c/o Allergan Sales, LLC, 2525 Dupont Dr., Irvine, CA 92612.
NDA 018181 .....	Mycelex (clotrimazole) Topical Solution, 1% .....	Bayer HealthCare LLC, 100 Bayer Blvd., 100 Bayer Rd., Pittsburgh, PA 15205.
NDA 018182 .....	Mycelex-7 (clotrimazole) Tablets, 100 mg .....	Do.
NDA 018183 .....	Mycelex (clotrimazole) Topical Cream, 1% .....	Do.
NDA 018230 .....	Mycelex-7 (clotrimazole) Topical Vaginal Cream, 1%.	Do.
NDA 018856 .....	D-Xylose (xylose) Powder, 25 grams (g)/bottle ...	Lyne Laboratories, 10 Burke Dr., Brockton, MA 02301.
NDA 018874 .....	Calcijex (calcitriol) Injection, 0.001 mg/mL and 0.002 mg/mL.	AbbVie, Inc., 1 North Waukegan Rd., North Chicago, IL 60064.
NDA 020214 .....	Zemuron (rocuronium bromide) Injection, 50 mg/5 mL (10 mg/mL); 10 mg/mL (10 mg/mL); 100 mg/10 mL (10 mg/mL).	Organon USA Inc., Subsidiary of Merck & Co., Inc., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
NDA 020389 .....	Mycelex-7 Combination Pack (clotrimazole) Topical Vaginal Cream and Tablets, 1%, 100 mg.	Bayer HealthCare LLC.
NDA 020528 .....	Mavik (trandolapril) Tablets, 1 mg, 2 mg, and 4 mg.	AbbVie, Inc.
NDA 020738 .....	Teveten (eprosartan mesylate) Tablets, 300 mg, 400 mg, and 600 mg.	Do.
NDA 020863 .....	Pletal (cilostazol) Tablets, 50 mg and 100 mg ....	Otsuka Pharmaceutical Development and Commercialization, Subsidiary of Otsuka Pharmaceutical Company, Ltd., 2440 Research Blvd., Rockville, MD 20850.
NDA 021268 .....	Teveten HCT (eprosartan mesylate and hydrochlorothiazide) Tablets, 600/12.5 mg and 600/25 mg.	AbbVie, Inc.
NDA 021410 .....	Avandamet (rosiglitazone maleate and metformin hydrochloride (HCl)) Tablets, 500 mg EQ 1 mg base; 500 mg EQ 2 mg base; 500 mg EQ 4 mg base; 1 g EQ 2 mg base; 1 g EQ 4 mg base.	GlaxoSmithKline, 1250 South Collegeville Rd., Collegeville, PA 19426.
NDA 021511 .....	Copegus (ribavirin) Tablets, 200 mg and 400 mg	Hoffmann La-Roche, Inc., Subsidiary of Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080.
NDA 021700 .....	Avandaryl (glimepiride and rosiglitazone maleate) Tablets, 1 mg/4 mg; 2 mg/4 mg; 2 mg/8 mg; 4 mg/4 mg; 4 mg/8 mg.	SB Pharmco Puerto Rico Inc., Subsidiary of GlaxoSmithKline, 1250 South Collegeville Rd., Collegeville, PA 19426.
NDA 205123 .....	Olysio (simeprevir sodium) Capsules, EQ 150 mg base.	Janssen Pharmaceuticals, Inc., 1000 U.S. Rte. 202 South, Raritan, NJ 08869.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of November 19, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on November 19, 2018 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: October 15, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-22805 Filed 10-18-18; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood 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 Heart, Lung, and Blood Institute Special Emphasis Panel;

Using Stem Cells to Better Understand Heart Failure.

*Date:* November 2, 2018.

*Time:* 8:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Crystal City Hilton Crystal City, 2399 Jefferson Davis Hwy., Arlington, VA 22202.

*Contact Person:* David A. Wilson, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7204, Bethesda, MD 20892-7924, 301-435-0299, [wilsonda2@nhlbi.nih.gov](mailto:wilsonda2@nhlbi.nih.gov).

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel; Bold New Bioengineering Methods and Approaches for Heart, Lung, Blood and Sleep Disorders and Diseases (R21).

*Date:* November 2, 2018.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Westin Grand, 2350 M Street NW, Washington, DC 20037.

*Contact Person:* Susan Wohler Sunnarborg, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892, [susan.sunnarborg@nih.gov](mailto:susan.sunnarborg@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 15, 2018.

**Ronald J. Livingston, Jr.,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-22760 Filed 10-18-18; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2018-0877]

### National Maritime Security Advisory Committee; Meeting

**AGENCY:** U.S. Coast Guard, Department of Homeland Security.

**ACTION:** Notice of Federal Advisory Committee meeting.

**SUMMARY:** The National Maritime Security Advisory Committee will meet in Houston, Texas, to review and discuss various issues relating to national maritime security. All meetings will be open to the public.

**DATES:**

*Meetings.* The Committee will meet on Tuesday, November 6, 2018, from 12:00 noon to 5 p.m. and on

Wednesday, November 7, 2018, from 8 a.m. to 1 p.m. These meetings may close early if all business is finished.

*Comments and supporting documentation.* To ensure your comments are reviewed by Committee members before the meetings, submit your written comments no later than November 1, 2018.

**ADDRESSES:** The meeting will be held at the Double Tree Hilton Hotel by Houston Hobby Airport, 8181 Airport Boulevard, Houston, TX 77061, [HoustonHobbyAirport.DoubleTree.com](http://HoustonHobbyAirport.DoubleTree.com).

This meeting will be broadcast via a web enabled interactive online format and teleconference line. To participate via teleconference, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section no later than November 1, 2018. Additionally, if you would like to participate in this meeting via the online web format, please log onto <https://share.dhs.gov/nmsac/> and follow the online instructions to register for this meeting. If you encounter technical difficulties, contact Mr. Ryan Owens at 202-302-6565.

For information on facilities or services for individuals with disabilities, or to request special assistance at the meetings, contact the individual listed in **FOR FURTHER INFORMATION CONTACT** below as soon as possible.

Written comments must be submitted using the Federal eRulemaking Portal: <http://www.regulations.gov>. If you encounter technical difficulties, contact the individual in the **FOR FURTHER INFORMATION CONTACT** section of this document.

*Instructions:* You are free to submit comments at any time, including orally at the meetings, but if you want Committee members to review your comment before the meetings, please submit your comments no later than November 1, 2018. We are particularly interested in comments on the issues in the “Agenda” section below. You must include “Department of Homeland Security” and the docket number [USCG-2018-0877]. Comments received will be posted without alteration at <http://www.regulations.gov> including any personal information provided. For more information about privacy and the docket, review the Privacy and Security Notice for the Federal Docket Management System at <https://www.regulations.gov/privacyNotice>.

*Docket Search:* For access to the docket or to read documents or comments related to this notice, go to <http://www.regulations.gov>, and use docket number “USCG-2018-0877” in

the “Search” box, press Enter, and then click on the item you wish to view.

**FOR FURTHER INFORMATION CONTACT:** Mr. Ryan Owens, Alternate Designated Federal Officer of the National Maritime Security Advisory Committee, 2703 Martin Luther King Jr. Avenue SE, Washington, DC 20593, Stop 7581, Washington, DC 20593-7581; telephone 202-372-1108 or email [ryan.f.owens@uscg.mil](mailto:ryan.f.owens@uscg.mil).

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is in compliance with the *Federal Advisory Committee Act*, Title 5, United States Code, Appendix. The National Maritime Security Advisory Committee operates under the authority of 46 U.S.C. 70112.

The National Maritime Security Advisory Committee provides advice, consults with, and makes recommendations to the Secretary of Homeland Security, via the Commandant of the Coast Guard, on matters relating to national maritime security.

### Agenda

#### Day 1

The Committee will meet to review, discuss and formulate recommendations on the following issues:

(1) Cyber Security Update. Members will receive an update from the U.S. Coast Guard concerning the draft Cyber Security Navigation and Vessel Inspection Circular and other Cyber Security matters related to the Marine Transportation System.

(2) Unmanned Aircraft Systems. The Committee will receive an update from the U.S. Coast Guard concerning the threat of Unmanned Aircraft Systems and the efforts of the U.S. Coast Guard to provide guidance to the maritime industry in addressing the concern these aircraft pose to critical infrastructure.

(3) Port of Houston Maritime Security Review. The Committee will receive a brief on the current state of maritime security at the Port of Houston.

(4) Public Comment period.

#### Day 2

The Committee will meet to review, discuss and formulate recommendations on the following issues:

(1) Member Report. The Committee members will each provide an update on the security developments in each of the respective member’s representative segment.

(2) Customs-Trade Partnership Against Terrorism. The Committee will receive an update on efforts of from Customs and Border Protection to revise the security requirements of the program.