TABLE 3—SIGNIFICANT DISCIPLINARY ACTION REPORT BURDEN [1]—Continued

| Significant disciplinary actions | Number of respondents | Number of responses per respondent | Total responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Total | | | | | 26 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 4—OTHER VOLUNTARY REPORTS BURDEN [1]

| Other voluntary reports | Number of respondents | Number of responses per respondent | Total responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Wholesale distributors | 5 | 1 | 5 | 0.25 hour (15 minutes). | 1.25 |
| 3PLs | 1 | 1 | 1 | 0.25 hour (15 minutes). | 0.25 |
| Total | | | | | 1.50 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

*F. Capital Costs*

There are no capital costs associated with this collection and reporting of information if the FDA-provided Web portal is used for reporting.

## III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

## IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.regulations.gov.*

Dated: December 3, 2014.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2014–28711 Filed 12–8–14; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–N–0001]**

### Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Endocrinologic and Metabolic Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on January 12, 2015, from 8 a.m. to 5 p.m.

*Location:* College Park Marriott Hotel and Conference Center, Potomac Ballroom, 3501 University Blvd. East, Hyattsville, MD 20783. The conference center's telephone number is 301–985–7300.

*Contact Person:* Stephanie L. Begansky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *EMDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* The committee will discuss the safety and efficacy of new drug application (NDA) 022517, proposed trade name NOCDURNA (established name: desmopressin), orally disintegrating sublingual tablets submitted by Ferring Pharmaceuticals, Inc. The proposed indication is treatment of nocturia due to nocturnal polyuria in adults who awaken two or more times each night to void.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before December 26, 2014.

Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 17, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 18, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Stephanie L. Begansky (see Contact Person) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 2, 2014.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2014–28702 Filed 12–8–14; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Office of the Director Notice of Charter Renewal

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102–3.65(a), notice is hereby given that the Charter for the Board of Regents of the National Library of Medicine (BOR) was renewed for an additional two-year period on November 20, 2014.

It is determined that the BOR is in the public interest in connection with the performance of duties imposed on the Department of Health and Human Services by law, and that these duties can best be performed through the advice and counsel of this group.

Inquires may be directed to Jennifer S. Spaeth, Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail Code 4875), Telephone (301) 496–2123, or *spaethj@od.nih.gov.*

Dated: December 3, 2014.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2014–28750 Filed 12–8–14; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**FOR FURTHER INFORMATION CONTACT:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

**SUPPLEMENTARY INFORMATION:** Technology descriptions follow.

**Vaccine for Protection Against *Shigella sonnei* Disease**

Description of Technology: Shigellosis is a global human health problem. Transmission usually occurs by contaminated food and water or through person-to-person contact. The bacterium is highly infectious by the oral route, and ingestion of as few as 10 organisms can cause an infection in volunteers. An estimated 200 million people worldwide suffer from shigellosis, with more than 650,000 associated deaths annually. A recent CDC estimate indicates the occurrence of over 440,000 annual shigellosis cases in the United States alone, approximately eighty percent (80%) of which are caused by *Shigella sonnei. Shigella sonnei* is more active in developed countries. *Shigella* infections are typically treated with a course of antibiotics. However, due to the emergence of multidrug resistant *Shigella* strains, a safe and effective vaccine is highly desirable. No vaccines against *Shigella* infection currently exist. Immunity to *Shigellae* is mediated largely by immune responses directed against the serotype specific O-polysaccharide. Claimed in the invention are compositions and methods for inducing an immunoprotective response against *S. sonnei.* Specifically, an attenuated bacteria capable of expressing an *S. sonnei* antigen comprised of the *S. sonnei* form I O-polysaccharide expressed from the *S. sonnei* rfb/rfc gene cluster is claimed. The inventors have shown that the claimed vaccine compositions showed one hundred percent (100%) protection against parenteral challenge with virulent *S. sonnei* in mice.

Potential Commercial Applications:

- Shigella/Typhoid vaccine for travelers, military
- Shigella/Typhoid vaccine for developing countries
- Shigella/Typhoid diagnostics

Competitive Advantages:

- Low cost of production
- Temperature stable formulation
- Safety/efficacy of Ty21a established in humans

Development Stage: In vivo data available (animal)

Inventors: Dennis J. Kopecko (FDA), De Qi Xu (NIDCR), John O. Cisar (NICHD)

Publication: Kopecko DJ, et al. Molecular cloning and characterization of genes for Shigella sonnei form I O polysaccharide: proposed biosynthetic pathway and stable expression in a live salmonella vaccine vector. Infect Immun. 2002 Aug;70(8):4414–23. [PMID: 12117952]