customs brokers, freight forwarders, logistics companies, trucking and drayage companies, VOCCs, port authorities, and MTOs.

The many responses to the Petition illustrate the complexity of issues surrounding ocean container shipping and marine terminal operations.

Given the importance of this issue, its complexity, and the public interest indicated by the number and quality of comments submitted in response to the Petition, the Commission will hold public hearings to further explore the issues raised by the Petition and address specific questions. Commentary and answers to these questions will be helpful to the Commission as it determines its next steps with regard to Petition P4–16.

By the Commission.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2017–25016 Filed 11–17–17; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Sunshine Act; Notice of Board Member Meeting

Agenda

November 28, 2017, 8:30 a.m. (In-Person).

Open Session

1. Approval of the minutes for the October 23, 2017 Board Member Meeting
2. Monthly Reports
   (a) Participant Activity
   (b) Investment Performance
   (c) Legislative Report
3. Quarterly Reports
   (d) Metrics
   (e) Project Activity
4. Capital Market and L Fund Annual Asset Allocation Review
5. TSP Investment Option Benchmark Study
6. 2018 Proposed Internal Audit Schedule
7. Enterprise Risk Framework and Dashboard
8. Blended Retirement Update
9. IT Update

Closed Session

Information covered under 5 U.S.C. 552b (c)(6) and (c)(9)(B).

Adjourn.

CONTACT PERSON FOR MORE INFORMATION: Kimberly Weaver, Director, Office of External Affairs, (202) 942–1640.

Dated: November 16, 2017.

Megan Grumbine,

General Counsel,

Federal Retirement Thrift Investment Board.

[FR Doc. 2017–25184 Filed 11–16–17; 4:15 pm]

BILLING CODE 6760–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4853]

Receipt of Notice That a Patent Infringement Complaint Was Filed Against a Biosimilar Applicant

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing notice that an applicant for a proposed biosimilar product notified FDA that a patent infringement action was filed in connection with the applicant's biologics license application (BLA). Under the Public Health Service Act (PHS Act), an applicant for a proposed biosimilar product or interchangeable product must notify FDA within 30 days after the applicant was served with a complaint in a patent infringement action described under the PHS Act. FDA is required to publish notice of the complaint in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Daniel Orr, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6246, Silver Spring, MD 20993–0002, 240–402–0979, *daniel.orr@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) was enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111–148) on March 23, 2010. The BPCI Act amended the PHS Act and created an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product. Section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, describes the requirements for a BLA for a proposed biosimilar product or a proposed interchangeable product (351(k) BLA). Section 351(l) of the PHS Act, also added by the BPCI Act, describes certain procedures for exchanging patent information and resolving patent disputes between a 351(k) BLA applicant and the holder of the BLA reference product. If a 351(k) applicant is served with a complaint for a patent infringement described in section 351(l)(6) of the PHS Act, the applicant is required to provide FDA with notice and a copy of the complaint within 30 days of service. FDA is required to publish notice of a complaint received under section 351(l)(6)(C) of the PHS Act in the **Federal Register**.

FDA received notice of the following complaint under section 351(l)(6)(C) of the PHS Act: *Janssen Biotech, Inc.* v. *Celltrion Healthcare Co. Ltd., et al.,* 17–cv–11008 (D. Mass., filed May 31, 2017).

FDA has only a ministerial role in publishing notice of a complaint received under section 351(l)(6)(C) of the PHS Act, and does not perform a substantive review of the complaint.

Dated: November 14, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–25070 Filed 11–17–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–P–5124]

Medical Devices; Exemption From Premarket Notification: Over-the-Counter Denture Repair Kits

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that it has received a petition requesting exemption from the premarket notification requirements for over-the-counter (OTC) denture repair kits. These devices consist of material, such as a resin monomer system of powder and liquid glues, which is intended to be applied permanently to a denture to mend cracks or breaks. FDA is publishing this notice to obtain comments in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit either electronic or written comments by January 19, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 19, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 19, 2018.