

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**

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## 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**

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## 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](mailto: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**

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## 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.

Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2017-P-5124 for "Medical Devices; Exemption From Premarket Notification: OTC Denture Repair Kits." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993-0002, 301-796-6527.

#### SUPPLEMENTARY INFORMATION:

##### I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (1976 amendments) (Pub. L. 94-295), as

amended by the Safe Medical Devices Act of 1990 (Pub. L. 101-629), devices are to be classified into class I (general controls) if there is information showing that the general controls of the FD&C Act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the FD&C Act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices), are classified through the premarket notification process under section 510(k) of the FD&C Act (21 U.S.C. 360(k)). Section 510(k) of the FD&C Act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is "substantially equivalent" within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105-115). Section 206 of FDAMA, in part, added new section 510(m) to the FD&C Act. Section 510(m)(1) of the FD&C Act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the FD&C Act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the FD&C Act provides that, 1 day after the date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section, as amended by the 21st Century Cures Act (Pub. L. 114–255), requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 60-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

## II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the Agency issued on February 19, 1998, entitled "Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff." That guidance is available through the internet at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf> or by sending an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive a copy of the document. Please use the document number 159 to identify the guidance you are requesting.

## III. Proposed Class II Device Exemptions

FDA has received the following petition requesting an exemption from premarket notification for a class II device: Paul Hyman, Hyman, Phelps & McNamara, PC, 700 13th St. NW., Suite 1200, Washington, DC 20005–5929, for OTC denture repair kits, classified under 21 CFR 872.3570.

## IV. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 807, subpart E, regarding premarket notification submissions,

have been approved under OMB control number 0910–0120.

Dated: November 9, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017–25065 Filed 11–17–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Request for Public Comment: 60 Day Notice for Extension of the Indian Health Service Loan Repayment Program

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice and request for comments. Request for extension of approval.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to take this opportunity to comment on the information collection Office of Management and Budget (OMB) Control Number 0917–0014, titled, "IHS Loan Repayment Program (LRP)."

This previously approved information collection project was last published in the **Federal Register** (80 FR 23558) on April 28, 2015, and allowed 60 and 30 days for public comment. No public comment was received in response to the notices. This notice announces our intent to submit this collection, which expires July 31, 2018, to OMB for approval of an extension and solicit comments on specific aspects for the proposed information collection.

A copy of the draft supporting statement is available at [www.regulations.gov](http://www.regulations.gov) (see Docket ID IHS\_FRDOC\_0001).

**DATES:** Consideration will be given to all comments received by January 19, 2018.

**ADDRESSES:** Submit comments to Jackie Santiago by one of the following methods:

- *Mail:* Jackie Santiago, Chief, Loan Repayment Program, 5600 Fishers Lane, Mail Stop: 11E53A, Rockville, MD 20857.
- *Phone:* 301–443–2486.
- *Email:* [Jackie.Santiago@ihs.gov](mailto:Jackie.Santiago@ihs.gov).
- *Fax:* 301–443–4815.

Comments submitted in response to this notice will be made available to the public by publishing them in the 30 day **Federal Register** notice for this information collection. For this reason, please do not include information of a confidential nature, such as sensitive

personal information or proprietary information. If comments are submitted via email, the email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

**FOR FURTHER INFORMATION CONTACT:** To request additional information, please contact Evonne Bennett-Barnes, Information Collection Clearance Officer at: [Evonne.Bennett-Barnes@ihs.gov](mailto:Evonne.Bennett-Barnes@ihs.gov) or 301–443–4750.

**SUPPLEMENTARY INFORMATION:** The IHS is submitting the proposed information collection to OMB for review, as required by section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995. This notice is soliciting comments from members of the public and affected agencies as required by 44 U.S.C. 3506(c)(2)(A) concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques of other forms of information technology, *e.g.*, permitting electronic submission of responses.

*Title:* 0917–0014, "Indian Health Service Loan Repayment Program."

*Type of Information Collection Request:* Three year extension approval of this information collection.

*OMB Control Number:* 0917–0014.

*Forms:* Educational and Professional Background, Financial Information, and General Applicant Information (*i.e.* all forms are part of the LRP application). The LRP application is available in an electronically fillable and fileable format.

*Need and Use of Information Collection:* The IHS LRP identifies health professionals with pre-existing financial obligations for education expenses that meet program criteria and who are qualified and willing to serve at, often remote, IHS health care facilities. Under the program, eligible