ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0865.

Title: Wireless Telecommunications Bureau Universal Licensing System Recordkeeping and Third Party Disclosure Requirements.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, Individuals or households, Not-for-profit institutions, and State, Local or Tribal Government.

Number of Respondents and Responses: 84,048 respondents; 84,050 responses.

Estimated Time per Response: .166 hours (10 minutes)—4 hours.

Frequency of Response: Recordkeeping and third-party disclosure requirements; on occasion reporting requirement.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in 47 U.S.C. 154(i) and 309(j).

Total Annual Burden: 116,306 hours.

Annual Cost Burden: No cost.

Needs and Uses: The Commission will submit this information collection to the Office of Management and Budget (OMB) as an extension after this 60-day comment period to obtain the full three-year clearance from them.

The purpose of this information collection is to continually streamline and simplify processes for wireless applicants and licensees, who previously used a myriad of forms for various wireless services and types of requests, in order to provide the Commission information that has been collected in separate databases, each for a different group of services. Such processes have resulted in unreliable reporting, duplicate filings for the same licensees/applicants, and higher cost burdens to licensees/applicants. By streamlining the Universal Licensing System (ULS), the Commission eliminates the filing of duplicative applications for wireless carriers; increases the accuracy and reliability of licensing information; and enables all wireless applicants and licensees to file all licensing-related applications and other filings electronically, thus increasing the speed and efficiency of the application process. The ULS also benefits wireless applicants/licensees by reducing the cost of preparing applications, and speeds up the licensing process in that the Commission can introduce new entrants more quickly into this already competitive industry. Finally, ULS enhances the availability of licensing information to the public, which has access to all publicly available wireless licensing information on-line, including maps depicting a licensee's geographic service area.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–04595 Filed 3–6–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

[Docket No. 22–35]

M.E. Dey & Co., Inc. Complainant v. Hapag-Lloyd AG and Hapag-Lloyd (America) LLC, Respondents; Notice of Filing of Amended Complaint and Assignment

Served: March 1, 2023

Notice is given that an Amended Complaint has been filed with the Federal Maritime Commission (Commission) by M.E. Dey & Co., Inc. hereinafter ''Complainant,'' against Hapag-Lloyd AG and Hapag-Lloyd (America) LLC. (hereinafter ''Respondents''). Complainant states that it is organized and existing under the laws of Wisconsin a non-vessel-operating common carrier with a principal place of business in Milwaukee, Wisconsin. Complainant identifies the Hapag-Lloyd AG is a global ocean carrier with headquarters in Hamburg, Germany, and Hapag-Lloyd (America) LLC as a United States subsidiary and agent of Hapag AG located in Atlanta, Georgia.

Complainant alleges that Respondents violated 46 U.S.C. 41102(c) and 41104(a)(14) regarding their practices and the billing and payment of charges on the shipments of cargo, including demurrage and rail storage charges and the failure to provide chassis. An answer to the complaint is due to be filed with the Commission within twenty-five (25) days after the date of service. The full text of the complaint can be found in the Commission's Electronic Reading Room at *https://www2.fmc.gov/readingroom/proceeding/22-35/.*

This proceeding has been assigned to Office of Administrative Law Judges. The initial decision of the presiding officer in this proceeding shall be issued by December 26, 2023, and the final decision of the Commission shall be issued by July 10, 2024.

William Cody, Secretary.

[FR Doc. 2023–04596 Filed 3–6–23; 8:45 am]

BILLING CODE 6730–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0008]

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will take place virtually on April 20, 2023, from 9 a.m. to 6 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions, including information regarding special accommodations due to a disability, may be accessed at: *https://www.fda.gov/advisory-committees/about-advisory-committees/common-questions-and-answers-about-fda-advisory-committee-meetings.*

FOR FURTHER INFORMATION CONTACT: Akinola Awojope, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993–0002, *Akinola.Awojope@fda.hhs.gov,* 301–636–0512, 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 website at *https://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 the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On April 20, 2023, the committee will discuss, make recommendations, and vote on clinical information related to the De Novo request for the NUsurface Meniscus Implant sponsored by Active Implants, Inc. The device is a polymeric disc-shaped device implanted in the medial compartment of the knee to distribute load between the distal femur and proximal tibia and is intended to improve pain and function in the medial compartment of a knee in which the medial meniscus has been resected.

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 website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down and select the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

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 April 4, 2023. Oral presentations from the public will be scheduled on April 20, 2023, between approximately 1 p.m. and 2 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include 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 March 27, 2023. 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 March 28, 2023.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett at *Artair.Mallett@fda.hhs.gov* or 301–796–9638 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://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: March 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04561 Filed 3–6–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2022–P–2752 and FDA–2022–P–3125]

Determination That Lithium Citrate Oral Solution, 8 Milliequivalents/5 Milliliters, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that lithium citrate oral solution, 8 milliequivalents (mEq)/5 milliliters (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Caitlin Callahan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6240, Silver Spring, MD 20993–0002, 240–402–4318, *Caitlin.Callahan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Lithium citrate oral solution, 8 mEq/5 mL, is the subject of NDA 018421, held by Hikma Pharmaceuticals USA Inc., and initially approved on December 23, 1980.[1] Lithium citrate oral

[1] In their citizen petitions, petitioners Saptalis Pharmaceuticals LLC, and Hyman, Phelps & McNamara, P.C., refer to this drug product, respectively, as ''Lithium Citrate Syrup EQ 300 mg Carbonate/5mL'' and ''Lithium Citrate Oral Syrup,

Continued