
**Proposed Effective Date:** 11/1/2018.
**Location:** [https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/334](https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/334).
**Agreement No.:** 011353–038.
**Agreement Name:** The Credit Agreement.
**Parties:** Dole Ocean Cargo Express, LLC; King Ocean Services Limited; Crowley Latin American Services, LLC; Seaboard Marine Ltd.; and Seaboard Marine of Florida, Inc.
**Filing Party:** Wayne Rohde; Cozen O’Connor.
**Synopsis:** The amendment adds Dole Ocean Cargo Express, LLC as a party to the Agreement, replacing Dole Ocean Cargo Express, Inc.

**Proposed Effective Date:** 11/1/2018.
**Location:** [https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/1728](https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/1728).
**Agreement No.:** 011790–003.
**Agreement Name:** Dole Ocean Cargo Express/King Ocean Services Limited Space Charter Agreement.
**Parties:** Dole Ocean Cargo Express, LLC and King Ocean Services Limited.
**Filing Party:** Wayne Rohde; Cozen O’Connor.
**Synopsis:** The amendment removes Dole Ocean Cargo Express, Inc. as a party to the Agreement and replaces it with Dole Ocean Cargo Express, LLC.

**Proposed Effective Date:** 11/1/2018.
**Location:** [https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/639](https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/639).
**Agreement No.:** 011842–002.
**Agreement Name:** Crowley/Dole Space Charter and Sailing Agreement.
**Parties:** Dole Ocean Cargo Express, LLC and Crowley Latin America Services, LLC.
**Filing Party:** Wayne Rohde; Cozen O’Connor.
**Synopsis:** The amendment removes Dole Ocean Cargo Express, Inc. as a party to the Agreement and replaces it with Dole Ocean Cargo Express, LLC.

**Proposed Effective Date:** 11/2/2018.
**Location:** [https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/569](https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/569).
**Agreement No.:** 201277.
**Agreement Name:** CMA CGM/Maersk Line TRIDENT/PAD2 Service Space Charter Agreement.
**Parties:** CMA CGM S.A. and Maersk Line A/S.
**Filing Party:** Wayne Rohde; Cozen O’Connor.
**Synopsis:** The Agreement authorizes Maersk Line to charter space to CMA CGM on its TRIDENT/PAD2 service in the trade between ports on the Atlantic Coast of the United States and ports in Australia, New Zealand, Colombia and Panama. The parties request expedited review.

**Proposed Effective Date:** 11/3/2018.
**Location:** [https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/16297](https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/16297).
**Dated:** September 20, 2018.
**Rachel E. Dickon.**
**Secretary.**

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

2. **Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).**
3. **Call the Reports Clearance Office at (410) 786–1326.**

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by November 26, 2018.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways:

1. **Electronically.** You may send your comments electronically to [http://www.regulations.gov](http://www.regulations.gov). Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. **By regular mail.** You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection’s supporting statement and associated materials (see **ADDRESSES**).
Information Collection

1. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medicaid Program; Eligibility Changes under the Affordable Care Act of 2010; Use: The eligibility systems are essential to the goal of increasing coverage in insurance affordability programs while reducing administrative burden on states and consumers. The electronic transmission and automation of data transfers are key elements in managing the expected insurance affordability program caseload that started in 2014. Accomplishing the same work without these information collection requirements would not be feasible. Form Number: CMS–10410 (OMB control number 0938–1147); Frequency: Occasionally; Affected Public: Individuals or Households, and State, Local, and Tribal Governments; Number of Respondents: 25,500,096; Total Annual Responses: 25,500,333; Total Annual Hours: 21,276,302. (For policy questions regarding this collection contact Stephanie Bell at 410–786–0617).


William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3306]

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee. The general function of the committees is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document. DATES: The meeting will be held on November 2, 2018, from 8 a.m. to 5 p.m. ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (RM. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm406555.htm.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2018–N–3306. The docket will close on October 31, 2018. Submit either electronic or written comments on this public meeting by October 31, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 31, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of October 31, 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.

Comments received on or before October 18, 2018, will be provided to the committees. Comments received after that date will be taken into consideration by FDA. You may submit comments as follows:

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–2018–N–3306 for “Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.” 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.” FDA 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