Synopsis: The agreement would authorize the parties to charter space from one another in the trade between the U.S. and Europe, the Middle East and Asia.

Agreement No.: 012382.

Title: Crowley/King Ocean Space Charter Agreement.

Parties: Crowley Caribbean Services, LLC and King Ocean Services Limited, Inc.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor; 1200 19th Street NW., Washington, DC 20036.

Synopsis: The agreement would authorize King Ocean to charter space to Crowley in the trade between the U.S. East Coast on the one hand and Aruba, Bonaire and Curacao on the other hand.

By Order of the Federal Maritime Commission.

Dated: December 29, 2015.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2015–33083 Filed 1–4–16; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Meeting Notice

December 30, 2015.

TIME AND DATE: 10:00 a.m., Wednesday, January 13, 2016.

PLACE: The Richard V. Backley Hearing Room, Room 511N, 1331 Pennsylvania Avenue NW., Washington, DC 20004 (enter from F Street entrance).

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will hear oral argument in the matter *Secretary of Labor* v. *Hibbing Taconite Company,* Docket Nos. LAKE 2013–231–RM, *et al.* (Issues include whether the Judge erred in upholding failure to abate orders.)

Any person attending this oral argument who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and 2706.160(d).

CONTACT PERSON FOR MORE INFO: Emogene Johnson (202) 434–9935/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

Sarah L. Stewart,

Deputy General Counsel.

[FR Doc. 2015–33203 Filed 12–31–15; 11:15 am]

BILLING CODE 6735–01–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Meeting Notice

December 30, 2015.

TIME AND DATE: 10:00 a.m., Thursday, January 14, 2016

PLACE: The Richard V. Backley Hearing Room, Room 511N, 1331 Pennsylvania Avenue NW., Washington, DC 20004 (enter from F Street entrance).

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following in open session: *Secretary of Labor* v. *Hibbing Taconite Company,* Docket Nos. LAKE 2013–231–RM, et al. (Issues include whether the Judge erred in upholding failure to abate orders.)

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and 2706.160(d).

CONTACT PERSON FOR MORE INFO: Emogene Johnson (202) 434–9935/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

Sarah L. Stewart,

Deputy General Counsel.

[FR Doc. 2015–33201 Filed 12–31–15; 11:15 am]

BILLING CODE 6735–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0256 (Formerly 2007D–0089)]

Agency Information Collection Activities: Proposed Collection; Comment Request; Draft Guidance for Industry and Review Staff on Target Product Profile—A Strategic Development Process Tool

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements contained in the draft guidance for industry and review staff entitled ''Target Product Profile—A Strategic Development Process Tool.''

DATES: Submit either electronic or written comments on the collection of information by March 7, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2007–D–0256 (formerly 2007D–0089) for ''Agency Information Collection Activities: Proposed Collection; Comment Request; Draft Guidance for Industry and Review Staff on Target Product Profile—A Strategic Development Process Tool.'' Received

comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520) Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, in the **Federal Register** of March 30, 2007 (72 FR 15141), FDA published a notice of availability of the draft guidance document with a 60-day notice requesting public comment on the collection of information. In response to a request by OMB, FDA is republishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The draft guidance is intended to provide sponsors and FDA review staff with information regarding target product profiles (TPPs). A TPP can be prepared by a sponsor and then shared voluntarily with the appropriate FDA review staff to facilitate communication regarding a particular drug development program. A Clinical Development Working Group recommended use of a template that provides a summary of drug labeling concepts to focus discussions and aid in the understanding between sponsors and FDA. The resulting TPP is a format for a summary of a drug development program described in terms of labeling concepts. With the TPP, a sponsor specifies the labeling concepts that are the goals of the drug development program, documents the specific studies that are intended to support the labeling concepts, and then uses the TPP to assist in a constructive dialogue with FDA. The draft guidance describes the purpose of a TPP, its advantages, and its optimal use. It also provides information on how to complete a TPP and relates case studies that demonstrate a TPP's usefulness.

Sponsors are not required to submit a TPP. The TPP does not represent an implicit or explicit obligation on the sponsor's part to pursue all stated goals. Submission of a TPP summary does not constrain the sponsor to submit draft labeling in a new drug application (NDA) or biologics license application (BLA) that is identical to the TPP. The TPP is part of the proprietary investigational new drug application (IND) file.

The TPP is organized according to the key sections of the drug labeling and links drug development activities to specific concepts intended for inclusion in the drug labeling. The TPP is not a long summary. Generally, the TPP is shorter than the ultimate annotated draft labeling because it captures only a summary of the drug development activities and labeling concepts. Early TPPs can be brief depending on the status of the drug's development process.

The Target Product Profile Template in Appendix C of the draft guidance details the suggested information to be included in each section of the TPP. The TPP includes information from each discipline comprising an NDA/BLA. Within each discipline, the TPP briefly summarizes the specific studies that will supply the evidence for each conclusion that is a labeling concept. A TPP is organized according to key sections in the drug's labeling. Typical key sections are:

- Indications and Usage
- Dosage and Administration
- Dosage Forms and Strengths
- Contraindications
- Warnings and Precautions
- Adverse Reactions
- Drug Interactions
- Use in Specific Populations
- Drug Abuse and Dependence
- Overdosage
- Description
- Clinical Pharmacology
- Nonclinical Toxicology
- Clinical Studies
- References
- How Supplied/Storage and Handling
- Patient Counseling Information

Description of Respondents: Sponsors of applications seeking FDA approval to perform clinical investigations of a human drug before applying for marketing approval of the drug from FDA.

Burden Estimate: FDA estimates that sponsors of approximately 10 percent of the number of active INDs submitted to FDA annually would prepare and submit TPPs. This would equal

approximately 132 TPPs per year. Based on data received from the Pharmaceutical Research and Manufacturers of America, we estimate that approximately 20 sponsors would submit TPPs and that each TPP would take approximately 20 hours to prepare and submit to FDA. Based on the previous methodology and assumptions, the following table provides an estimate of the annual reporting burden for the voluntary submission of TPPs under the draft guidance. FDA requests comments on this analysis of information collection burdens.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Target Product Profiles (TPPs)	20	6.6	132	20	2,640

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

Dated: December 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–33127 Filed 1–4–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Advisory Committee; Food Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Food Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Food Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the December 18, 2017.

DATES: Authority for the Food Advisory Committee will expire on December 18, 2017, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Karen Strambler, Center for Food Safety and Applied Nutrition, Office of Regulations, Policy, and Social Sciences, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2589, *karen.strambler@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Food Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

I. Objectives and Scope of Activities

The Food Advisory Committee (the Committee) advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

II. Description of Duties

The Committee reviews and evaluates emerging food safety, nutrition, and other food- or cosmetic-related health issues that FDA considers of primary importance for its food and cosmetics programs. The Committee may be charged with reviewing and evaluating available data and making recommendations on matters such as those relating to: (1) Broad scientific and technical food- or cosmetic-related issues; (2) the safety of food ingredients and new foods; (3) labeling of foods and cosmetics; (4) nutrient needs and nutritional adequacy; and (5) safe exposure limits for food contaminants. The Committee may also be asked to provide advice and make recommendations on ways of communicating to the public the potential risks associated with these issues and on approaches that might be considered for addressing the issues.

III. Membership and Designation

The Committee shall consist of a core of 15 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of physical sciences, biological and life sciences, food science, risk assessment, nutrition, food technology, molecular biology, epidemiology, and other relevant scientific and technical disciplines. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include two technically qualified member(s), selected by the Commissioner or designee, who are identified with consumer interests and are recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include two non-voting member(s) who are identified with industry interests.

Further information regarding the most recent charter and other information can be found at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/ucm120646.htm* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: December 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–33171 Filed 1–4–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Minority Health

AGENCY: Office of Minority Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (DHHS) is hereby giving notice that the Advisory Committee on