

The decision to impose this freeze is procedural in nature, and therefore is not subject to the notice and comment and effective date requirements of the Administrative Procedure Act, 5 U.S.C. 553(b)(A), (d). Moreover, the Media Bureau finds that there is good cause for not delaying the effect of these procedures until 30 days after publication in the **Federal Register**. Such a delay would be impractical, unnecessary, and contrary to the public interest because it would undercut the purposes of the freeze.

This action is taken by the Chief, Media Bureau pursuant to authority delegated by 47 CFR 0.283 of the Commission's rules.

Federal Communications Commission.

**Barbara Kreisman,**

*Chief, Video Division, Media Bureau.*

[FR Doc. 2018-00286 Filed 1-9-18; 8:45 am]

**BILLING CODE 6712-01-P**

## FEDERAL MARITIME COMMISSION

### Notice of Agreement Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may submit comments on the agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. A copy of the agreement is available through the Commission's website ([www.fmc.gov](http://www.fmc.gov)) or by contacting the Office of Agreements at (202)-523-5793 or [tradeanalysis@fmc.gov](mailto:tradeanalysis@fmc.gov).

*Agreement No.:* 201200-001.

*Title:* Houston Marine Terminal Operators/Freight Handlers Agreement.

*Parties:* Ceres Gulf Inc.; Cooper/Ports America LLC; and SSA Gulf, Inc.

*Filing Party:* Shareen Larmond; West Gulf Maritime Association; 1717 Turning Basin Drive, Suite 200; Houston, Texas 77029.

*Synopsis:* The amendment updates the membership of the Agreement and makes other administrative changes.

By Order of the Federal Maritime Commission.

Dated: January 5, 2018.

**Rachel E. Dickon,**

*Assistant Secretary.*

[FR Doc. 2018-00289 Filed 1-9-18; 8:45 am]

**BILLING CODE 6731-AA-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[CDC-2013-0015; Docket Number NIOSH 237-A]

#### National Framework for Personal Protective Equipment Conformity Assessment—Infrastructure

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of availability.

**SUMMARY:** NIOSH announces the availability of the following publication: National Framework for Personal Protective Equipment Conformity Assessment—Infrastructure.

**DATES:** The technical report was published on November 17, 2017.

**ADDRESSES:** This document may be obtained at the following link: <https://www.cdc.gov/niosh/docs/2018-102/default.html>.

**FOR FURTHER INFORMATION CONTACT:** Maryann M. D'Alessandro, NIOSH, National Personal Protective Technology Laboratory, 626 Cochran Mill Road, Building 20, Pittsburgh, PA 15236, email address: [bpj5@cdc.gov](mailto:bpj5@cdc.gov), (412) 386-6111 (not a toll free number).

**SUPPLEMENTARY INFORMATION:** In May 2011, NIOSH published a notice in the **Federal Register** [76 FR 28791] requesting comments on the recommendations issued by the Institute of Medicine in a report they electronically published in November 2010, titled, "Certifying Personal Protective Technologies." In August 2013, NIOSH published a notice in the **Federal Register** [78 FR 49524] requesting comments on the draft NIOSH response to the Institute of Medicine recommendations, and announcing a public meeting which was held on September 17, 2013. In response to a request, NIOSH extended the public comment period to December 2, 2013. All comments received were reviewed and addressed where appropriate.

**John Howard,**

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.*

[FR Doc. 2018-00252 Filed 1-9-18; 8:45 am]

**BILLING CODE 4163-19-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0085]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, we, or Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by February 9, 2018.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0629. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics

*OMB Control Number 0910-0629—Extension*

This information collection supports the Agency guidance document entitled, "Guidance for Industry: Cooperative Manufacturing for Licensed Biologics" (available at: <https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/ucm069908.pdf>). The guidance

document provides information concerning cooperative manufacturing arrangements applicable to biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262). The guidance addresses several types of manufacturing arrangements (*i.e.*, short supply arrangements, divided manufacturing arrangements, shared manufacturing arrangements, and contract manufacturing arrangements) and describes certain reporting and recordkeeping responsibilities associated with these arrangements, including the following: (1) Notification of all important proposed changes to production and facilities; (2) notification of results of tests and investigations regarding or possibly impacting the product; (3) notification of products manufactured in a contract facility; and (4) standard operating procedures.

#### 1. Notification of All Important Proposed Changes to Production and Facilities

Each licensed manufacturer in a divided manufacturing arrangement or shared manufacturing arrangement must notify the appropriate FDA Center regarding proposed changes in the manufacture, testing, or specifications of its product, in accordance with § 601.12 (21 CFR 601.12). In the guidance, we recommend that each licensed manufacturer that proposes such a change should also inform other participating licensed manufacturer(s) of the proposed change.

For contract manufacturing arrangements, we recommend that the contract manufacturer should share with the license manufacturer all important proposed changes to production and facilities (including introduction of new products or at inspection). The license holder is responsible for reporting these changes to FDA (§ 601.12).

#### 2. Notification of Results of Tests and Investigations Regarding or Possibly Impacting the Product

In the guidance, we recommend the following for contract manufacturing arrangements:

- The contract manufacturer should fully inform the license manufacturer of the results of all tests and investigations regarding or possibly having an impact on the product; and
- The license manufacturer should obtain assurance from the contractor that any FDA list of inspectional observations will be shared with the license manufacturer to allow

evaluation of its impact on the purity, potency, and safety of the license manufacturer's product.

#### 3. Notification of Products Manufactured in a Contract Facility

In the guidance, we recommend for contract manufacturing arrangements that a license manufacturer cross reference a contract manufacturing facility's master files only in circumstances involving certain proprietary information of the contract manufacturer, such as a list of all products manufactured in a contract facility. In this situation, the license manufacturer should be kept informed of the types or categories of all products manufactured in the contract facility.

#### 4. Standard Operating Procedures

In the guidance, we remind the license manufacturer that the license manufacturer assumes responsibility for compliance with the applicable product and establishment standards (21 CFR 600.3(t)). Therefore, if the license manufacturer enters into an agreement with a contract manufacturing facility, the license manufacturer must ensure that the facility complies with the applicable standards. An agreement between a license manufacturer and a contract manufacturing facility normally includes procedures to regularly assess the contract manufacturing facility's compliance. These procedures may include, but are not limited to, review of records and manufacturing deviations and defects, and periodic audits.

For shared manufacturing arrangements, each manufacturer must submit a separate biologics license application describing the manufacturing facilities and operations applicable to the preparation of that manufacturer's biological substance or product (§ 601.2(a)). In the guidance, we state that we expect the manufacturer that prepares, or is responsible for the preparation of, the product in final form for commercial distribution to assume primary responsibility for providing data demonstrating the safety, purity, and potency of the final product. We also state that we expect the licensed finished product manufacturer to be primarily responsible for any postapproval obligations, such as postmarketing clinical trials, additional product stability studies, complaint handling, recalls, postmarket reporting of the dissemination of advertising and promotional labeling materials as required under § 601.12(f)(4), and adverse experience reporting. We recommend that the final product manufacturer establish a procedure with

the other participating manufacturer(s) to obtain information in these areas.

*Description of Respondents:* Respondents to the information collection are participating licensed manufacturers, final product manufacturers, and contract manufacturers associated with cooperative manufacturing arrangements subject to the associated regulations discussed in the guidance.

In the **Federal Register** of August 7, 2017 (82 FR 36797), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received no comments.

*Burden Estimate:* We believe that the information collection provisions in the guidance do not create a new burden for respondents. We believe the reporting and recordkeeping provisions are part of usual and customary business practices. Licensed manufacturers would have contractual agreements with participating licensed manufacturers, final product manufacturers, and contract manufacturers, as applicable for the type of cooperative manufacturing arrangement, to address all these information collection provisions.

The guidance also refers to previously approved collections of information found in FDA regulations at parts 201, 207, 211, 600, 601, 606, 607, 610, 660, 801, 803, 807, 809, and 820 (21 CFR parts 201, 207, 211, 600, 601, 606, 607, 610, 660, 801, 803, 807, 809, and 820). The collections of information in parts 606 and 610 have been approved under OMB control numbers 0910-0116, 0910-0458, and 0910-0206; part 600 has been approved under OMB control numbers 0910-0308 and 0910-0458; parts 601 and 660 have been approved under OMB control number 0910-0338; part 803 has been approved under OMB control number 0910-0437; part 211 has been approved under OMB control number 0910-0139; part 820 has been approved under OMB control number 0910-0073; parts 207, 607, and 807 have been approved under OMB control numbers 0910-0045, 0910-0052, and 0910-0625; and parts 201, 801, and 809 have been approved under OMB control numbers 0910-0537, 0910-0572, and 0910-0485.

Dated: January 4, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-00238 Filed 1-9-18; 8:45 am]

**BILLING CODE 4164-01-P**