

■ 5. Section 114.13 is revised to read as follows:

**§ 114.13 Determination of the expiration dating period of a product.**

An expiration dating period determined by the stability of each of its fractions shall be assigned to each product. Stability shall be determined with a stability-indicating assay that can detect changes over time in the pertinent properties of the product. Stability criteria include the specifications for potency at release, potency throughout the dating period, and the length of the dating period. When tested at any time during the dating period, the potency of the product shall not be less than the minimum specified in the filed Outline of Production. Prior to licensure, the licensee shall propose an expiration dating period for the product based on preliminary data available about the stability of each of its fractions. If the preliminary stability data are acceptable, the product may be licensed with the provision that the proposed expiration dating period must be confirmed by conducting a real-time stability study with a stability-indicating assay as follows:

(a) In the case of a newly licensed product with acceptable preliminary stability data and the real-time stability study is not conducted in animals, at least three production serials of the product shall be selected and tested during the proposed dating period. Each serial shall be tested beginning on the day of filling into final containers or the date of final formulation specified in the filed Outline of Production, and at the following intervals:

- (1) Every 3 months during the first year of storage,
- (2) Every 6 months during the second year of storage, and
- (3) Annually thereafter throughout the proposed dating period.

(b) In the case of a newly licensed product with acceptable preliminary stability data and the real-time stability study is conducted in animals, at least three production serials shall be tested as follows:

- (1) One test per serial shall be conducted beginning on the day of filling into final containers or the date of final formulation specified in the filed Outline of Production.
- (2) One test per serial shall be conducted at the end of the proposed dating period.
- (3) One test per serial shall be conducted between the initial and final test, but at a different interval for each serial.

(c) In the case of a newly licensed product, and licensed products whose stability studies were completed prior to **[Effective date of final rule]**, a real-time stability study conducted with a stability-indicating assay in accordance with paragraphs (a) or (b) of this section shall be completed in support of changes to one of the stability criteria or for major changes to the potency test.

(d) In the case of a licensed product with an unconfirmed expiration dating period that is tested in animals with a test that is not a stability-indicating assay, the following shall apply:

(1) Testing involving the use of a non-stability-indicating assay specified in the filed Outline of Production to confirm the expiration dating period for such product shall be completed by **[Date 42 months after effective date of the final rule]**, or

(2) Subsequent to **[Date 42 months after effective date of the final rule]**, such testing to confirm expiration dating shall be completed with a stability-indicating assay. Products not meeting the requirement to confirm the expiration dating with a stability-indicating assay shall be withheld from the market.

(e) At the completion of the real-time stability study to confirm or change expiration dating, the data shall be submitted to Animal and Plant Health Inspection Service for approval for filing and the approved for filing date shall be specified in section VI of the filed Outline of Production at the next revision.

(f) For products licensed subsequent to **[Effective date of the final rule]**, the licensee or permittee shall submit a plan to monitor the stability of the product and the suitability of its dating period that includes regularly testing serials for potency with a stability-indicating assay during and at the end of dating.

Done in Washington, DC, this 3<sup>rd</sup> day of September 2010.

**John Ferrell,**

*Deputy Under Secretary for Marketing and Regulatory Programs.*

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**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 167**

**[Docket No. USCG-2010-0785]**

**Port Access Route Study: The Approaches to San Francisco**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of public meetings; request for comments.

**SUMMARY:** The Coast Guard announces a public meeting to receive comments on the study entitled "Port Access Route Study: Off San Francisco" that was published in the **Federal Register** on Thursday, December 10, 2009. As stated in that document, the Coast Guard is conducting a Port Access Route Study (PARS) to evaluate the continued applicability of and the potential need for modifications to the current vessel routing in the approaches to San Francisco.

**DATES:** A Public meeting will be held on Wednesday, October 20, 2010 from 6:30 p.m. to 8:30 p.m. to provide an opportunity for oral comments. Written comments and related material may also be submitted to Coast Guard personnel specified at the meetings.

**ADDRESSES:** The October 20, 2010 public meeting will be held at the Executive Inn and Suites at 1755 Embarcadero, Oakland, California. Visitor parking is available in the lots outside the hotel.

**FOR FURTHER INFORMATION CONTACT:** If you have questions concerning the meeting or the study, please call or e-mail LTJG Lucas Mancini, Coast Guard; telephone 510-437-3801, e-mail [Lucas.W.Mancini@uscg.mil](mailto:Lucas.W.Mancini@uscg.mil). If you have questions on viewing the docket call Ms. Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

**SUPPLEMENTARY INFORMATION:**

**Background and Purpose**

We published a notice of study in the **Federal Register** on December 10, 2009 (74 FR 65543), entitled "Port Access Route Study: Off San Francisco" in which we did not state a plan to hold a public meeting. We have decided to hold a meeting in order to give the public and waterway users a chance to comment in person.

In the notice of PARS, we discussed our intent to help reduce the risk of marine casualties and increase the efficiency of vessel traffic in the study region. Our goal is to assess whether the current vessel routing system is effective

in its predictability of vessel movements, which may decrease the potential for collisions, oil spills, and other events that could threaten the marine environment.

You may view the notice of PARS in our online docket, in addition to comments submitted thus far by going to <http://www.regulations.gov>. Once there, insert "USCG-2009-0576" in the "keyword" box and click "search." If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

We encourage you to participate in this study by submitting comments at the meeting either orally or in writing. If you bring written comments to the meeting, you may submit them to Coast Guard personnel specified at the meeting to receive written comments. These comments will be posted to our online public docket. All comments received will be posted without change to <http://www.regulations.gov> and will include any personal information you have provided.

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

#### Information on Service for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the public meeting, contact LTJG Lucas Mancini at the telephone number or e-mail address indicated under the **FOR FURTHER INFORMATION CONTACT** section of this notice.

#### Public Meeting

The Coast Guard will hold a public meeting regarding its Port Access Route Study in the Approaches to San Francisco on Wednesday October 20, 2010 from 7 p.m. to 9 p.m. at the Executive Inn and Suites located at 1755 Embarcadero, Oakland California, telephone 510-536-6633. We will provide a written summary of the

meeting and additional comments received at the meeting in the docket.

Dated: September 2, 2010.

**S.P. Metruck,**

*Captain, U.S. Coast Guard, Acting Commander, Eleventh Coast Guard District.*

[FR Doc. 2010-23176 Filed 9-16-10; 8:45 am]

**BILLING CODE 9110-04-P**

## POSTAL SERVICE

### 39 CFR Part 111

#### Express Mail Open and Distribute and Priority Mail Open and Distribute

**AGENCY:** Postal Service™.

**ACTION:** Proposed rule.

**SUMMARY:** The Postal Service proposes to revise *Mailing Standards of the United States Postal Service*, Domestic Mail Manual (DMM®) 705.16 to require the use of a single-ply address label containing a service barcode with unique Service Type Code "723" or a "DB" prefix along with new Tag 257, Tag 267, or Label 257S, on all Express Mail® Open and Distribute containers. The Postal Service also proposes to revise the service commitment for Express Mail Open and Distribute as a guaranteed end of day product; and to add a five-pound minimum weight requirement for Express Mail Open and Distribute and Priority Mail® Open and Distribute sacks.

**DATES:** Submit comments on or before October 18, 2010.

**ADDRESSES:** Mail or deliver written comments to the Manager, Mailing Standards, U.S. Postal Service, 475 L'Enfant Plaza, SW., Room 4446, Washington, DC 20260-4446. Copies of all written comments will be available for inspection and photocopying between 9 a.m. and 4 p.m., Monday through Friday, at the Postal Service Headquarters Library, 475 L'Enfant Plaza, SW., 11th Floor North, Washington, DC 20260-0004. E-mail comments, containing the name and address of the commenter, may be sent to: [MailingStandards@usps.gov](mailto:MailingStandards@usps.gov), with a subject line of "Open and Distribute Changes Comments." Faxed comments are not accepted.

#### FOR FURTHER INFORMATION CONTACT:

Jewelyn Harrington at 202-268-7648 or Garry Rodriguez at 202-268-7281.

#### SUPPLEMENTARY INFORMATION:

##### Express Mail

Express Mail Open and Distribute service is designed to provide mailers with expedited service to destination delivery units and other mail processing

facilities. Currently, Express Mail Open and Distribute service follows the same mailing requirements and delivery standards as Express Mail service.

The requirement to use the Express Mail Label 11 series with a 13-digit barcode prevents the Postal Service from differentiating between Express Mail and Express Mail Open and Distribute products.

The delivery standards for Express Mail service are intended for residential/business customers and as a result are delivered by 12 noon or 3 p.m. Express Mail Open and Distribute is a product that is delivered to a processing facility or delivery unit for further processing of the contents.

To account for the Express Mail Open and Distribute product, the Postal Service is proposing to require mailers to place a single-ply address label with a service barcode on all Express Mail Open and Distribute containers and to submit an electronic file. The service barcode is required to be a USS 128 or Code 39 barcode with a "DB" prefix, or concatenated GS1-128 (eVS approved mailers) symbology with a unique Service Type Code (STC) "723". The text, "USPS SCAN ON ARRIVAL," must appear above the barcode. This scan information is exclusive to the Open and Distribute service and will assist in facilitating correct scan behavior.

This proposed requirement is in accordance with instructions for barcode specifications, electronic file format and testing, and the certification process in Publication 91, *Confirmation Services Technical Guide*.

The Postal Service also proposes to replace Tag 157 with Tag 257 (DDU), Tag 267 (SCF, NDC), and Label 257S (DDU), to assist in the verification of the arrival at the destination facility for all Express Mail Open and Distribute containers.

Generally, the Postal Service processing window is 12 noon to 6 a.m. The window to dispatch mail from plants to delivery units is from 4 a.m. to 9 a.m. To better align the Express Mail Open and Distribute product with processing and dispatch windows, without loss of service, we are proposing to change the service commitment to end of day (11:59 p.m.).

#### Express Mail and Priority Mail

In addition, processing facilities currently receive Express Mail Open and Distribute and Priority Mail Open and Distribute sacks containing mail that weighs less than five pounds, making it difficult to identify that the sack contains mail.

The handling of low volume sacks in plants has been identified as