Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120), and the quality system regulation (21 CFR part 820, OMB control number 0910–0073). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 9, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–19853 Filed 10–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0347]

Establishing a Docket for the Biological Products for Treatment of Rare Plasma Protein Disorders Public Workshop; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the opening of a docket to receive information and comments on the June 13 and 14, 2005, public workshop entitled ''Biological Products for Treatment of Rare Plasma Protein Disorders'' (the workshop). We are opening the docket to gather additional information from interested persons on the challenges in the development of products to treat rare plasma protein disorders and on current and future opportunities to facilitate development of such products. Interested persons may also submit comments on the workshop presentations and discussions, which we are also making available.

DATES: Submit written or electronic comments on the workshop, related regulatory and scientific issues, and comments on information submitted to the docket by other interested persons by April 4, 2006.

ADDRESSES: Submit written comments and information regarding the workshop to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852–1448. Submit electronic comments or information to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic and other access to the slide presentations from the workshop.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 6, 2005 (70 FR 24079), we published a notice to announce a public workshop entitled ''Biological Products for Treatment of Rare Plasma Protein Disorders.'' On June 13 and 14, 2005, we, in cosponsorship with the Office of Public Health and Science in the Department of Health and Human Services, held the workshop to facilitate the development of biological products used to treat patients with rare plasma protein disorders and to discuss related scientific and regulatory challenges. The following topics were discussed at the workshop:

- Patients' and physicians' perspective on the need for products to treat rare plasma protein disorders;
- The availability of registries and databases to identify patients for clinical trials;
- Differences between international and FDA regulatory approaches to the licensure of products for treating rare plasma protein diseases;
- Case studies describing the application of current FDA regulatory pathways to product development;
- Issues of product reimbursement; and
- Incentives for product development, such as the availability of small business and research grants, and orphan drug provisions.

The meeting concluded with proposals for advancing product development, and suggestions for future discussions on this topic. At the end of the workshop, we invited written comments to provide an opportunity for additional information and discussion of the issues.

We encourage interested persons to continue to provide information to this docket regarding:

- How to facilitate development of products used to treat rare plasma protein disorders,
- Comments on the workshop, and
- Comments on information submitted to the docket by other interested persons.

Information and comments submitted to the docket will assist us in determining the need for, and feasibility of, establishing new regulatory pathways and incentives for developing products to treat rare plasma protein disorders, among other issues.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the workshop and any additional information on the development of biological products for treatment of rare plasma protein disorders. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of this notice, the slide presentations from the workshop, and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the slide presentations at *http://www.fda.gov/cber/summaries.htm#biother*.

Dated: September 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–19852 Filed 10–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Migrant Health; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act

(Pub. L. 92–463), notice is hereby given of the following meeting:

Name: National Advisory Council on Migrant Health.

Date and Time: October 17, 2005, 1 p.m. to 4 p.m. (Eastern Time).

Place: Audio Conference Call, Phone: 1–866–727–1333, Password: 7822925.

Status: The meeting will be open to the public.

Agenda: The agenda includes an overview of the Council's general business activities, discussion of the Amended Charter and future activities of the Council.

Agenda items are subject to change as priorities indicate.

FOR FURTHER INFORMATION CONTACT: Anyone requiring information regarding the Council should contact Gladys Cate, Office of Minority and Special Populations, staff support to the National Advisory Council on Migrant Health, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 594–0367.

Dated: September 29, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–19867 Filed 10–3–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[USCG–2002–14134]

Port Pelican LLC Deepwater Port License Application; Fabrication Site Environmental Assessment

AGENCY: Coast Guard, DHS; Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Coast Guard and the Maritime Administration (MARAD) announce the cancellation of an Environmental Assessment (EA) that they previously planned as a follow-up to MARAD's approval of the license application for the Port Pelican LLC Deepwater Port in the Gulf of Mexico off Louisiana. The EA would have assessed the environmental impact of related shoreside fabrication site activities in Texas. The Coast Guard and MARAD are canceling the EA, due to Port Pelican LLC's decision to defer these fabrication site activities indefinitely.

FOR FURTHER INFORMATION CONTACT: If you have questions about the Port Pelican LLC Deepwater Port project, contact LCDR Derek Dostie, Deepwater Ports Standards Division, United States Coast Guard at (202) 267–0662 or *ddostie@comdt.uscg.mil.*

SUPPLEMENTARY INFORMATION: On November 14, 2003, the Maritime Administrator issued a Record of Decision (ROD) approving the application of Port Pelican LLC for a license to construct and operate a liquefied natural gas deepwater port on the Outer Continental Shelf, in the Gulf of Mexico approximately 36 miles south-southwest of Freshwater City, LA.

As indicated in the deepwater port?s final Environmental Impact Statement (notice of availability, 68 FR 52048, August. 29, 2003) and in the ROD, the deepwater port would use concrete structures prefabricated at a shoreside site and approval of the deepwater port license application was conditioned on Coast Guard and MARAD issuance of a supplemental National Environmental Policy Act of 1969 (NEPA) document to assess the impact of the shoreside fabrication site activities. On June 25, 2004, the Coast Guard and MARAD announced their intent to prepare that EA.

Port Pelican LLC has now informed the Coast Guard and MARAD that it will not pursue its plans for the Port Aransas site at this time, and therefore the Coast Guard and MARAD are canceling their plans for the supplemental EA. The Coast Guard and MARAD will publicly announce resumption of NEPA document preparation should Port Pelican LLC elect to resume its plans for shoreside fabrication activities.

Dated: September 23, 2005.

Howard L. Hime,

Acting Director of Standards, Marine Safety, Security, Ports and Environmental Protection, U.S. Coast Guard.

H. Keith Lesnick,

Senior Transportation Specialist, Deepwater Ports Program Manager, U.S. Maritime Administration.

[FR Doc. 05–19854 Filed 10–3–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2005–22541]

Merchant Mariner Credentials: Temporary Procedures; Hurricane Katrina

AGENCY: Coast Guard, DHS.

ACTION: Notice of Fee Waiver.

SUMMARY: On August 29, 2005, Hurricane Katrina devastated the coastlines of Louisiana, Mississippi, and Alabama. The Regional Examination Center (REC) at New Orleans, which serves 14% of mariners nation-wide and reflects about 29,000 mariners in those three states, was completely flooded, destroying vital records and equipment, and rendering the facility temporarily inoperable. Since mariners in the area may also have lost their credentials in the storm and subsequent flooding, the Coast Guard is hereby implementing temporary measures to relieve some hardship on mariners in the Gulf coast area who need replacement credentials.

DATES: This Notice is effective October 4, 2005.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call Mr. Donald J. Kerlin, Deputy Director, Coast Guard National Maritime Center (NMC), (202) 493–1006.

SUPPLEMENTARY INFORMATION: Mariners whose homes of record are in the states of Louisiana, Mississippi or Alabama as confirmed by the Coast Guard's merchant mariner licensing and documentation system (MMLD), and have lost their merchant mariner's document (MMD), merchant mariner's license, or certificate of registry (COR) (collectively referred to as ''credentials'') may apply at any REC to receive a duplicate credential that will bear the same expiration date and qualifications as the original credential that was lost. Until February 28, 2006, the fee usually charged for the issuance of duplicate credentials, will be waived. Additionally, any mariner who applied for a duplicate credential between August 29, 2005 and the publication of this Notice, and paid any fee may apply for a refund at the issuing REC. This waiver only applies to duplicate credentials that replace credentials held before the hurricane. It does not apply to routine renewals or transactions that enhance the mariner's authority (raises of grade). Also, all other provisions and requirements in Title 46, Code of Federal Regulations (46 CFR) 10.219 and 12.02–23 still apply.

Since REC New Orleans is expected to remain closed for approximately six months or more, additional resources are being allocated to RECs Memphis, Houston, Miami and Charleston. Mariners may also seek help at any of the other 12 RECs around the country, a list of which appears at 46 CFR 10.105 and 12.01–7. You may also call Mr. Kerlin for assistance at the number