

\$14,192 for other administrative expenses. In comparison, budgeted expenses for these items in 2008 were \$5,000 for compliance activities, \$61,000 for salaries, \$18,000 for research, and \$49,254 for other administrative expenses.

Decreases in management and administrative expenses are the result of management services, office rental fees and utilities being shared by the Committee and the California Date Administrative Committee (CDAC). In 2008, the Committee and the CDAC agreed to share management and administrative costs in order to streamline expenses for both programs. Additionally, the Committee recommended not renewing its budget for research in 2009 given that there were no pending research proposals at the time the budget was reviewed.

Prior to arriving at this budget, the Committee considered alternative expenditure and assessment rate levels, but ultimately decided that the recommended levels were reasonable to properly administer the order. The assessment rate recommended by the Committee was derived by the following formula: Anticipated 2009 expenses (\$77,692) plus the desired 2009 ending reserve (\$88,534), minus the 2009 beginning reserve (\$100,226) plus anticipated interest income (\$1,000), divided by the estimated 2009 shipments (6.5 million 18-pound lugs).

This rate should provide sufficient funds in combination with interest and reserve funds to meet the anticipated expenses of \$77,692 and result in a December 2009 ending reserve of \$88,534. This figure is about \$10,800 over the Committee's 2009 expenses. Section 925.41 of the order permits the Committee to maintain approximately one fiscal period's expenses in reserve. The Committee plans to continue using reserve funds to help meet its expenses and bring the reserve to a level lower than its expenses.

To calculate the percentage of grower revenue represented by the assessment rate for 2008, the assessment rate of \$0.02 per 18-pound lug is divided by the estimated average grower price (according to the NASS). This results in estimated assessment revenue for the 2008 season as a percentage of grower revenue of .245 percent (\$0.02 divided by \$8.16 per 18-pound lug). NASS data for 2009 is not yet available. However, applying the same calculations above using the average grower price for 2006–08 would result in estimated assessment revenue as a percentage of total grower revenue of .13 percent for the 2009 season (\$0.01 divided by \$7.77 per 18-pound lug). Thus, the assessment

revenue should be well below 1 percent of estimated grower revenue in 2009.

This rule continues in effect the action that decreased the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to producers. However, decreasing the assessment rate reduces the burden on handlers, and may reduce the burden on producers. In addition, the Committee's meeting was widely publicized throughout the grape production area and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the November 14, 2008, meeting was a public meeting and all entities, both large and small, were able to express views on this issue.

This action imposes no additional reporting or recordkeeping requirements on either small or large California grape handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

Comments on the interim final rule were required to be received on or before April 27, 2009. No comments were received. Therefore, for the reasons given in the interim final rule, we are adopting the interim final rule as a final rule, without change.

To view the interim final rule, go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=AMS-FV-08-0107>.

This action also affirms information contained in the interim final rule concerning Executive Orders 12866 and 12988, the Paperwork Reduction Act (44 U.S.C. Chapter 35), and the E-Gov Act (44 U.S.C. 101).

After consideration of all relevant material presented, it is found that finalizing the interim final rule, without change, as published in the **Federal Register** (74 FR 8141, February 24, 2009) will tend to effectuate the declared policy of the Act.

#### List of Subjects in 7 CFR Part 925

Grapes, Marketing agreements, Reporting and recordkeeping requirements.

#### PART 925—GRAPES GROWN IN A DESIGNATED AREA OF SOUTHEASTERN CALIFORNIA—[AMENDED]

■ Accordingly, the interim final rule amending 7 CFR part 925, which was published at 74 FR 8141 on February 24, 2009, is adopted as a final rule, without change.

Dated: July 20, 2009.

Rayne Pegg,

Administrator, Agricultural Marketing Service.

[FR Doc. E9–17602 Filed 7–23–09; 8:45 am]

BILLING CODE 3410–02–P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

##### 21 CFR Part 314

[Docket No. FDA–2009–N–0316]

##### New Drug Applications and Abbreviated New Drug Applications; Technical Amendment

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

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its new drug application (NDA) and abbreviated new drug application (ANDA) regulations to correct the address for the Orange Book Staff in the Office of Generic Drugs. This action is being taken to ensure accuracy and clarity in the agency's regulations.

**DATES:** This rule is effective July 24, 2009.

**FOR FURTHER INFORMATION CONTACT:** Olivia A. Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 51, rm. 6308, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3506.

**SUPPLEMENTARY INFORMATION:** FDA is amending its regulations in part 314 (21 CFR part 314) to correct the address for Orange Book Staff in the Office of Generic Drugs in §§ 314.52(a)(2), 314.53(f), and 314.95(a)(2).

#### List of Subjects in 21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under

authority delegated to the Commissioner of Food and Drugs, 21 CFR part 314 is amended as follows:

**PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG**

■ 1. The authority citation for 21 CFR part 314 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 371, 374, 379e.

**§ 314.52 [Amended]**

■ 2. Section 314.52 is amended in paragraph (a)(2) by removing “at the address identified on FDA’s Web site (<http://www.fda.gov/cder/ogd>)” and by adding in its place “7500 Standish Pl., Rockville, MD 20855”.

**§ 314.53 [Amended]**

■ 3. Section 314.53 is amended in paragraph (f) by removing “at the address identified on FDA’s Web site (<http://www.fda.gov/cder/ogd>)” and by adding in its place “7500 Standish Pl., Rockville, MD 20855”.

**§ 314.95 [Amended]**

■ 4. Section 314.95 is amended in paragraph (a)(2) by removing “at the address identified on FDA’s Web site (<http://www.fda.gov/cder/ogd>)” and by adding in its place “7500 Standish Pl., Rockville, MD 20855”.

Dated: July 17, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9–17680 Filed 7–23–09; 8:45 am]

**BILLING CODE 4160–01–S**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 100**

[Docket No. USCG–2009–0659]

**RIN 1625–AA08**

**Special Local Regulations for Marine Events; Port Huron to Mackinac Island Sail Race**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard will enforce a special local regulation for the annual Port Huron to Mackinac Island Sail Race. This action is necessary to safely control vessel movements in the vicinity of the race starting point and provide for the safety of the general boating public and commercial shipping. During this

period, no person or vessel may enter the regulated area without the permission of the Coast Guard Patrol Commander (“PATCOM”).

**DATES:** This rule is effective from 9 a.m. through 4 p.m. on July 25, 2009.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket USCG–2009–0659 and are available online by going to <http://www.regulations.gov>, selecting the Advanced Docket Search option on the right side of the screen, inserting USCG–2009–0659 in the Docket ID box, pressing Enter, and then clicking on the item in the Docket ID column. They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions concerning this temporary rule, call or e-mail Mr. Frank Jennings, Jr., Enforcement Branch, Ninth Coast Guard District, 1240 East 9th Street, Cleveland, OH, via e-mail at: [frank.t.jennings@uscg.mil](mailto:frank.t.jennings@uscg.mil) or by phone at: (216) 902–6094. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

**SUPPLEMENTARY INFORMATION:**

**Regulatory Information**

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the special local regulation pertaining to this annual race was previously published in the Code of Federal Regulations, but inadvertently removed during the most recent revision to 33 CFR 100.901. Because this is an annual race, held in the same location, local maritime interests are already familiar with the provisions of these regulations. Based on the late discovery of the missing permanent rule, the hazards associated with marine regattas within Port Huron and the short amount of

time until the event, delaying publication of this regulation would be contrary to the public interest.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The special local regulation pertaining to this annual race was previously published in the Code of Federal Regulations, but inadvertently removed during the most recent revision to 33 CFR 100.901. Because this is an annual race, held in the same location, local maritime interests are already familiar with the provisions of these regulations. Delaying this rule would be contrary to the public interest of ensuring the safety of spectators and vessels during this operation and immediate action is necessary to prevent possible loss of life or property.

**Background and Purpose**

Special local regulations are necessary to safely control vessel movements in the vicinity of the race starting point and provide for the safety of the general boating public and commercial shipping. The Captain of the Port Detroit has determined that the start of the Port Huron to Mackinac Island Sail Race does pose significant risks to public safety and property. The likely combination of congested waterways, vessels engaged in a regatta, and fast currents could easily result in serious injuries or fatalities.

**Discussion of Rule**

The Coast Guard will enforce special local regulations for the annual Port Huron to Mackinac Sail Race from 9 a.m. until 4 p.m. on July 25, 2009. The special local regulations apply to the waters of the Black River, St. Clair River and lower Lake Huron from:

Latitude	Longitude
42°58.8' N .....	082°26' W, to
42°58.4' N .....	082°24.8' W, thence northward along the International Boundary to
43°02.8' N .....	082°23.8' W, to
43°02.8' N .....	082°26.8' W, thence southward along the U.S. shoreline to
42°58.9' N .....	082°26' W, thence to
42°58.8' N .....	082°26' W.

[DATUM: NAD 1983].

In order to ensure the safety of spectators and participating vessels, the special local regulations will be in effect for the day of the start of the event. The Coast Guard will patrol the race area under the direction of a designated Coast Guard Patrol Commander