

alternatives were not adopted. Thus it has satisfied its mandate under the RFA.

### 3. The Air Tour Providers Have Not Demonstrated That the Weighing of the Interests Favors a Stay

The FAA, in enacting these rules is carrying out the statutory mandate set forth in Public Law 100-91—to substantially restore natural quiet in the GCNP. It has been 12 years since the enactment of this legislation and the FAA has attempted to work with the Air Tour Providers, the Indian Tribes, the environmental groups and the National Park Service to come to a resolution with regard to the means of substantially restoring natural quiet. The FAA believes that this rule achieves the proper balance that Congress sought in adopting Public Law 100-91 between the interests of the Air Tour Providers and those of the environmental interests and makes significant gains in substantial restoration of natural quiet. See 65 FR 17713. This balance is evidenced by the fact that the government has been sued in the District of Columbia Circuit Court of Appeals for the United States by one party (Air Tour Providers) claiming the government has done too much in effecting the goal of Public Law 100-91 and by another party (Grand Canyon Trust, *et al.*) claiming the government has not gone far enough in fulfilling the statutory mandate. The Air Tour Providers have not demonstrated why their interests outweigh the interest expressed by Congress in passing Public Law 100-91.

### D. Conclusion

Given that the Air Tour Providers cannot prevail under either the public interest test followed by the Department of Transportation, or the *Washington Metropolitan* test followed by the Circuit Court, the FAA hereby denies the Air Tour Providers' Motion to Stay the final rules.

Issued in Washington, DC on October 3, 2000.

**Jane F. Garvey,**  
*Administrator.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 25

[Docket No. 00N-0085]

#### National Environmental Policy Act; Food Contact Substance Notification System; Confirmation of Effective Date

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

**ACTION:** Direct final rule; confirmation of effective date.

**SUMMARY:** The Food and Drug Administration (FDA) is confirming the effective date of August 24, 2000, for the direct final rule (DFR) that appeared in the **Federal Register** of May 11, 2000 (65 FR 30352). The DFR amended FDA's regulations on environmental impact considerations. This document confirms the effective date of the DFR.

**DATES:** Effective date confirmed: August 24, 2000.

**FOR FURTHER INFORMATION CONTACT:** Mitchell A. Cheeseman, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3083.

**SUPPLEMENTARY INFORMATION:** In a DFR published in the **Federal Register** of May 11, 2000 (65 FR 30352), FDA amended its regulations on environmental impact considerations as part of the agency's implementation of the FDA Modernization Act (FDAMA) of 1997. FDAMA amended the Federal Food, Drug, and Cosmetic Act (the act) by establishing a notification process for authorizing new uses of food additives that are food contact substances. The DFR amended the regulations in 21 CFR 25.20 to add to the list of those actions that require an environmental assessment allowing a notification submitted under section 409(h) of the act (21 U.S.C. 348(h)) to become effective and in 21 CFR 25.32(i), (j), (k), (q), and (r) to expand the existing categorical exclusions from the requirement of an environmental assessment to include allowing a notification submitted under section 409(h) of the act to become effective.

FDA solicited comments concerning the DFR for a 75-day period ending July 25, 2000. FDA stated that the effective date of the DFR would be on August 24, 2000, 30 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period.

FDA received only one comment (from a trade association) on the DFR,

which reiterated the association's views presented in response to an agency public meeting held prior to the initiation of this rulemaking. FDA has determined that the received comment is not a significant adverse comment for several reasons. First, in the preamble to the DFR, FDA referenced the association's prior submission and addressed its substance. Second, the comment does not dispute (or even directly address) the analysis presented in the DFR. It raises no new arguments and provides no new information for the agency's consideration. Finally, the association expressly characterizes the comment as not a "significant adverse comment" and supports the rule becoming effective as drafted.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the amendments issued thereby became effective August 24, 2000.

Dated: October 3, 2000.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF TRANSPORTATION

### Coast Guard

#### 33 CFR Part 117

[CGD11-00-009]

#### Drawbridge Operation Regulations; Mokelumne River, CA

**AGENCY:** Coast Guard, DOT.

**ACTION:** Notice of temporary deviation from regulations.

**SUMMARY:** The Commander, Eleventh Coast Guard District has approved a temporary deviation to the regulations governing the opening of the Millers Ferry swing bridge, mile 12.1, over the Mokelumne River at Walnut Grove, CA. The approval specifies that the bridge need not open for vessel traffic from 8 p.m. to 6 a.m., October 9 through October 13, 2000. The purpose of this deviation is to allow Sacramento County to perform essential maintenance on the bridge.

**DATES:** Effective period of the deviation is 8 p.m., October 9, 2000 through 6 a.m., October 14, 2000.

**FOR FURTHER INFORMATION CONTACT:** Mr. David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District, Building 50-6, Coast Guard Island, Alameda, CA 94501-5100, phone (510) 437-3516.