

that the “no go” policy would remain in effect until the agency develops more experience with the equipment. Consistent with the regulation, the FAA issued Advisory Circular (AC) 121–33B which restated the policy that “EMKs and AEDs are ‘no-go’ items and must be carried as indicated on the” MEL on January 12, 2006. The AC indicated that the air carrier may elect to carry redundant equipment to ensure that after use of the equipment in flight, the minimum required equipment is still on board the aircraft.

However, on April 12, 2006, the FAA issued Notice 8000.320, which allowed MMEL relief for EMKs and AEDs, despite the contrary statements in the rule and AC discussed earlier. The FAA allowed the MMEL relief based on data collected from major air carriers, beginning in 1998 that showed using an EMK on back-to-back flights was rare. The notice also determined that “a large number of passengers may be at more risk at a diversion airport than they would be if MMEL relief” was available allowing the aircraft to be dispatched to its intended destination. This notice, which reversed previous FAA policy as stated in the preamble to the 2001 final rule, was not published for public comment before its issuance. It was eventually cancelled after 12 months on April 12, 2007.

On April 18, 2006, soon after the release of Notice 8000.320, the FAA released PL–73, Revision 4, MMEL Relief for Emergency Medical Equipment. Consistent with Notice 8000.320, this revision granted limited dispatch authority for aircraft with EMKs, FAKs, and AEDs that did not meet the minimum requirements of 14 CFR § 121.803. PL–73, Revision 4 authorized an air carrier to complete up to three flight cycles (3 flights) without the required equipment allowing time for the air carrier to repair or replace emergency medical equipment. PL–73, Revision 4 remained in effect until June 15, 2011.

PL–73, Revision 5 was released on June 15, 2011. Revision 5 resulted from a review conducted by FAA Flight Standards Service, which concluded that the MMEL relief offered by revision 4 was not consistent with regulation and was counter to the FAA’s established position that EMKs and AEDs are “no-go” items. Revision 5 allows only one flight cycle (1 flight), in any situation, for an air carrier to obtain the minimum required emergency medical equipment on board the aircraft. However, upon review of the policy, the FAA concluded that revision 5, though more restrictive than revision 4, is still not consistent with the regulation nor does

it comply with the intent of the regulation as expressed in the preamble. Because revision 5 was a shift in the FAA’s stated policy, the public should have been notified and provided opportunity for comment before adopting the new policy.

The FAA’s position is that although the preamble to the rule is clear that EMKs and AEDs are “no go” items, as contemplated by that final rule. Our experience has led us to conclude that relief should be allowed in limited circumstances. However, it is foreseeable that required medical equipment may be used during a flight, and the pilot will divert the aircraft to a location where the utilized medical equipment cannot be replenished or replaced. Therefore, the FAA has determined that allowing the air carrier to conduct one flight so that the aircraft can fly to a location where supplies are available would allow passengers on such a flight to reach their destinations without adversely affecting safety. As discussed earlier, air carriers have presented statistical information about EMK usage on aircraft to the FAA, which indicates that once an EMK or AED is used during a flight, there is only a remote possibility that it would need to be used on the next flight.

Airlines for America (A4A) recently resubmitted that data along with an analysis of EMK use to support its position that three-flight relief would be acceptable. A4A’s analysis was based on the likelihood of using an EMK on the first successive flight and extrapolated that data to conclude the likelihood of using an EMK on three consecutive flights would be $1: 3.8 \times 10^{-13}$. The FAA evaluated A4A’s analysis and determined that the conclusion regarding use on three consecutive flights was not statistically valid. The FAA notes that A4A’s analysis failed to consider that the likelihood of needing to use an EMK on any of the three successive flights would be the same as needing it on the first flight. A4A’s letter has been placed in the docket associated with this notice.

The probability of needing an EMK does not decrease because an EMK was opened on the first flight. We believe, therefore, that the probability of needing the EMK on subsequent flights would be 5.5×10^{-5} to 7.8×10^{-5} (3 times as high as the one-flight case). Therefore, because there is a relatively low probability of needing the EMK on any particular flight, we are allowing one-flight relief to air carriers with an inoperative EMK or AED so that if the flight lands at a location where the equipment cannot be repaired or replenished, the airplane can move to a

location where such services are available. However, because the probability of needing to use an EMK on subsequent flights does not diminish, we do not believe that three-flight relief would be acceptable.

Issued in Washington, DC, on September 18, 2013.

John S. Duncan,

Director, FAA Flight Standards Service.

[FR Doc. 2013–23522 Filed 9–26–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 501

[Docket No. FDA–2013–D–1088]

Guidance for Industry #223: Small Entity Compliance Guide—Declaring Color Additives in Animal Foods; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry #223 entitled “Small Entity Compliance Guide—Declaring Color Additives in Animal Foods.” This small entity compliance guide (SECG) aids industry in complying with the requirements of the final rule that published in the **Federal Register** of November 17, 2011. FDA issued the regulation in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act). Specifically, FDA amended its regulations regarding the declaration of certified color additives on the labels of animal food including animal feeds and pet foods.

DATES: The guidance is effective September 27, 2013. Submit either electronic or written comments on the SECG at any time.

ADDRESSES: Submit requests for single copies of the SECG to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

Submit electronic comments on the SECG to <http://www.regulations.gov>. Submit written comments to the

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Charlotte Conway, Center for Veterinary Medicine (HFV-228), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-8649; email: charlotte.conway@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of an SECG entitled "Small Entity Compliance Guide—Declaring Color Additives in Animal Foods." This SECG aids industry in complying with the requirements of the final rule published in the **Federal Register** of November 17, 2011 (76 FR 71248).

FDA has prepared this SECG in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121). This document is intended to provide guidance to small businesses on the requirements of the final rule, which implements a portion of the 1990 amendments. The 1990 amendments, among other things, provided for the declaration of certified color additives on the labels of human and animal food, including animal feeds and pet foods. The 1990 amendments also provided for the listing on food labels of the common or usual names of all color additives required to be certified by FDA. This regulation deals with the requirements associated with animal food only.

Before passage of the 1990 amendments, the FD&C Act provided that colorings could be declared collectively on food product labels using the term "colorings." The 2011 regulation requires that certified color additives be declared on labeling of animal food by their common or usual name, but color additives exempt from certification (e.g., caramel, paprika, and beet juice) may still be declared collectively. The rule makes these animal food regulations consistent with the regulations regarding the declaration of certified color additives on the labels of human food. The rule also suggests appropriate terminology for the declaration of noncertified color additives on the labels of animal food.

II. Significance of Guidance

FDA is issuing this SECG as a level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate

to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This SECG refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501-3520.) The collections of information in the regulation "Animal Food Labeling; Declaration of Certifiable Color Additives" (21 CFR 501.22(k)(1) and (2)) have been approved under OMB control number 0910-0721.

IV. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at <http://www.regulations.gov>.

V. Electronic Access

Persons with access to the Internet may obtain the SECG at either <http://www.fda.gov/cvm> or <http://www.regulations.gov>.

Dated: September 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-23560 Filed 9-26-13; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2013-0850]

Drawbridge Operation Regulation; Lake Pontchartrain, Near Slidell, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Norfolk Southern Railroad Bridge across Lake

Pontchartrain, mile 4.80, near Slidell, St. Tammany Parish, Louisiana. The deviation is necessary to replace worn joints on the north draw of the bridge. This deviation allows the bridge to remain closed to vessel traffic for six hours on three consecutive days.

DATES: This deviation is effective from 8 a.m. through 2 p.m. on October 8, 9 and 10, 2013.

ADDRESSES: The docket for this deviation, [USCG-2013-0850] is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this deviation. You may also visit 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.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Jim Wetherington, Coast Guard; telephone 504-671-2128, email james.r.wetherington@uscg.mil. If you have questions on viewing the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION: Norfolk Southern Corporation, the bridge owner, requested three, 6-hour closures for the Norfolk Southern RR Bridge over Lake Pontchartrain, Mile 4.80, near Slidell, St. Tammany Parish, LA. The bridge has a horizontal clearance of 105 feet and a vertical clearance of two feet, above Mean Sea Level, in the closed-to-navigation position and an unlimited vertical clearance in the open-to-navigation position.

The bridge opens on signal as per 33 CFR 117.5. The deviation period will be October 8, 9 and 10, 2013 from 8 a.m. through 2 p.m. each of those days. These closure periods will allow the replacement of the bridge joints as required in a normal maintenance cycle.

This waterway is used by both commercial and recreational vessel traffic. No previous coordination was made with the waterway users though the closure times were chosen to minimize the impact to these users.

Vessels able to pass through the bridge in the closed positions may do so at anytime. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners