

Recent Concerns

Since the time petitioners first requested that other aircraft be excepted from the applicable FDR regulations, the FAA has learned of at least two circumstances that will affect the way exception requests are analyzed. First, after the initial exemptions were granted, the FAA was informed that operators of exempted aircraft actively sought out more aircraft of these models from overseas and brought them into the United States. Those operators already held exemptions from the FDR regulations for those models, and therefore, believed that those models should be included in their original exemptions. This situation weakens the argument for exception status in at least two ways. First, the greater number of aircraft allows the cost of retrofit to be spread across additional aircraft, reducing the per-aircraft retrofit cost. Second, it lessens any public interest argument an operator may have by increasing the number of aircraft allowed to operate without FDRs. The presence of FDRs has been well established as being in the public interest and an important source of information on accidents and incidents.

The FAA always intended exception status to be very limited. The agency was and remains concerned that older aircraft of which few are left operating under limited circumstances not be denied what use might be left in them. Large numbers of aircraft with considerable economic viability were never meant to be the subject of exception status. For this reason, the FAA will take into account all aircraft worldwide for any model submitted for exception status.

The second circumstance concerns the practice of routinely adding and removing the same aircraft from the registries of the United States and other countries for benefit. The language added to § 135.152 in 1988 was specific in its intent of capturing all aircraft that were brought onto the U.S. register after October 11, 1991, primarily to stop the continued importation of older aircraft that would not need FDRs if the rule had instead used a date of manufacture. In 1997, that provision was expanded to include aircraft that were added to U.S. operations specifications (under foreign registry) after that date. Some of these aircraft were affected by the information bulletin that the agency withdrew in 1997; it was only after withdrawal that the FAA learned that several operators were using the information bulletin, combined with the practice of swapping airplanes between registries, to gain a benefit. The information bulletin

presumed to grandfather any aircraft that had once been registered in the United States from the "brought on the U.S. register" language of § 135.152. Once that information bulletin was withdrawn as being in distinct conflict with the clear language and intent of the rule, the FAA indicated that all persons operating under it had 4 years to bring their aircraft into compliance. It was then that the FAA began to receive numerous requests for exception status. Operators are cautioned that all circumstances will be examined closely. Exception status will most likely *not* be proposed by the FAA when a significant number of any model is still operating. Nor does the fact that an aircraft model is no longer being manufactured automatically mean that exception status will be proposed.

The FAA has been sensitized to the situation that has resulted in distinct benefits being gained by some operators in manipulating the status of their aircraft while the FDR regulations were in flux. The loss of this benefit will not be considered in deciding whether an aircraft model is appropriate for relief from the FDR requirements. This is especially true for aircraft models that have never been brought into compliance with the regulations promulgated in 1988.

Conclusion

All operators are reminded that the compliance date for the 1997 regulations to upgrade FDRs is August 20, 2001. Similarly, aircraft that were affected by the withdrawal of the Flight Standards Information Bulletin in 1997 had the same 4 years to upgrade their aircraft to meet § 135.152. Given the considerable notice of these requirements provided by the final rule, the FAA does not intend to issue exemptions from that date except in the most limited, temporary circumstances, where fully justified. Request for exemption based on lack of installation data (i.e., no STC for their aircraft), parts availability, or generalized plans to retire aircraft will not be granted.

Issued in Washington, DC on May 31, 2001.

Nicholas Sabatini,

Director, Flight Standards Service.

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SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 270 and 275

[Release Nos. IC-24991 and IA-1945; File No. S7-06-01]

RIN 3235-A105

Electronic Recordkeeping by Investment Companies and Investment Advisers; Correction

AGENCY: Securities and Exchange Commission.

ACTION: Correction to final rule.

SUMMARY: This document contains a correction to the final rule, which was published on Wednesday, May 30, 2001 (66 FR 29224). This rule relates to electronic recordkeeping by investment companies and investment advisers. In FR Document No. 01-13526 beginning on page 29224 for Wednesday, May 30, 2001, the docket line contains an error. The docket line is correct as set forth above.

EFFECTIVE DATE: May 31, 2001.

FOR FURTHER INFORMATION CONTACT: Frances Sienkiewicz at (202) 942-7072.

Dated: May 31, 2001.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01-14218 Filed 6-5-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 00P-1275 and 00P-1276]

Food Labeling: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; notice of extension of period for issuance of final rule.

SUMMARY: The Food and Drug Administration (FDA) is extending to July 25, 2001, the period for issuance of a final rule in response to its interim final rule of September 8, 2000, entitled "Food Labeling: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease." FDA's regulations require the agency to issue a notice of such extension if it finds, for cause, that it is unable to issue a final rule within 270 days from the date of publication of the

interim final rule. The complexity of the issues raised by the comments to the interim final rule and the lack of agency resources to complete the final rule within the specified 270 days have persuaded the agency of the need to extend the deadline to publish the final rule.

FOR FURTHER INFORMATION CONTACT:

James E. Hoadley, Center for Food Safety and Applied Nutrition (HFS-832), 200 C St. SW., Washington, DC 20204, 202-205-5372.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of May 22, 1997 (62 FR 28230), FDA published a final rule amending § 101.70 (21 CFR 101.70) of its regulations to provide a timeframe in which it will issue, in rulemakings on health claims, final rules announcing whether it will authorize the use of the claim at issue and to provide for extensions of that timeframe for cause. In that final rule, FDA adopted § 101.70(j)(4)(i), which provides that within 270 days of the date of publication of a proposal to authorize a health claim, the agency will publish a final rule that either authorizes the use of a health claim or explains why the agency has decided not to authorize one. FDA also adopted § 101.70(j)(4)(ii), which provides that, for cause, the agency may extend, no more than twice, the period in which it will publish a final rule and that each such extension will be for no more than 90 days. This regulation further requires that FDA publish a notice of any such extension in the *Federal Register*, and that it explain in that notice the basis for the extension, the length of the extension, and the date by which the final rule will be published (§ 101.70(j)(4)(ii)).

In the *Federal Register* of May 14, 1998 (63 FR 26717), FDA published a final rule that, in part, amended § 101.70 in response to section 302 of the Food and Drug Administration Modernization Act of 1997 (FDAMA). Section 302 of FDAMA amended section 403(r)(4)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(4)(A)(i)) to provide, in part, that if FDA initiates rulemaking in response to a health claim petition, the agency must complete the rulemaking within 540 days of receipt of the petition. If FDA does not meet the 540-day deadline, FDAMA requires FDA to provide the relevant House and Senate legislative committees with the reasons for failing to do so. Accordingly, FDA amended § 101.70(j)(4)(ii) to state that any extensions of the final rule deadline in health claim rulemakings shall not cause the deadline to exceed 540 days from receipt of the petition. FDA noted

that, depending upon how much time the agency uses to file a petition and publish a proposed rule in response to it, the agency may be limited to only one extension under § 101.70(j)(4)(ii), and the extension may be limited to fewer than 90 days (63 FR 26717 at 26718).

In the *Federal Register* of September 8, 2000 (65 FR 54686), FDA published an interim final rule adding 21 CFR 101.83 to authorize the use, on food labels and in food labeling, of health claims on the association between plant sterol/stanol esters and reduced risk of coronary heart disease (CHD) (plant sterol/stanol esters interim final rule). The act, as amended by FDAMA, authorizes FDA to make proposed health claim regulations effective upon publication pending consideration of public comment and publication of a final regulation, if the agency determines that such action is necessary for public health reasons (see section 403(r)(7) of the act). The legislative history of FDAMA indicates that such proposed regulations should be issued as interim final rules (H. Conf. Rept. 105-399, at 98 (1997)). Because the plant sterol/stanol esters interim final rule was issued under FDA's authority to make a proposed rule effective upon publication (see 65 FR 54685 at 54713), it was subject to the deadline for proposed rules in § 101.70(j)(3). Likewise, the final rule deadline in § 101.70(j)(4) applies to this rulemaking.

In the plant sterol/stanol esters interim final rule, the agency presented the rationale for a health claim on this food-disease relationship under the standard in section 403(r)(3)(B)(i) of the act and 21 CFR 101.14(c) of FDA's regulations. The agency concluded that, based on the totality of the publicly available scientific evidence, plant sterol/stanol esters may reduce the risk of CHD. The interim final rule specified the daily intake levels of plant sterol and stanol esters associated with reduced risk of CHD, the categories of foods eligible to bear the plant sterol/stanol esters health claim, and analytical methods for assessing compliance with qualifying criteria for the claim.

The comments received in response to the plant sterol/stanol esters interim final rule raised numerous complex issues. For example, we received many comments urging the agency to broaden the categories of foods eligible to bear the plant sterol/stanol esters health claim. Many comments also argued that the daily intake level for plant stanol esters should be the same as for plant sterol esters. Another group of comments requested that FDA allow

foods containing the nonesterified form of plant sterols/stanols to bear the health claim.

The complex issues raised by these comments warrant significant attention and the expenditure of significant staff resources. Unfortunately, the Office of Nutritional Products, Labeling, and Dietary Supplements (ONPLDS) within FDA's Center for Food Safety and Applied Nutrition has had to focus a large part of its health claim review resources on litigation-related work since the issuance of the plant sterol/stanol esters interim final rule. (ONPLDS is also the office responsible for reviewing all health claim petitions.) FDA's review of these comments, therefore, has been hampered by a lack of staff available to examine the scientific evidence pertaining to these complex issues. Accordingly, an extension of time to complete the plant sterol/stanol esters final rule is needed.

To publish a final rule regarding a health claim for plant sterol/stanol esters and CHD within 270 days of the date of publication of the interim final rule, which was on September 8, 2000, the agency would have to publish the final rule on or before June 5, 2001. However, because of the need to provide for additional time for agency staff to evaluate the issues raised by the comments on the plant sterol/stanol esters interim final rule, FDA hereby gives notice that there is cause to extend the deadline for publication of the final rule by 50 days. FDA will, therefore, publish a final rule in response to the interim final rule on or before July 25, 2001.

The new deadline of July 25, 2001, falls within the 540-day limit set by the statute. As noted above, section 403(r)(4)(A)(i) of the act requires FDA to complete health claim rulemakings within 540 days of the receipt of the petition. Since the current rulemaking involves two separate health claim petitions, submitted by Lipton and McNeil Consumer Healthcare, that have been combined into one rulemaking, the agency will consider the date of receipt of the earlier petition for purposes of calculating the deadline. Lipton submitted its health claim petition on February 1, 2000; McNeil submitted its petition on February 15, 2000. Publication of a final rule on or before July 25, 2001, will allow the agency to complete this rulemaking within 540 days of the receipt of the earlier (Lipton's) petition.

Dated: May 31, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-14285 Filed 6-5-01; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD07-01-042]

RIN 2115-AE46

Special Local Regulations; Gulf of Mexico, Sarasota, Florida

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily modifying the special local regulation for the Suncoast Offshore Challenge in Sarasota, FL. The sponsor of the event recently changed the event date. These regulations are needed to provide for the safety of life on navigable waters during the event.

DATES: This rule is effective from 10 a.m. June 30, 2001 to 5 p.m. June 30, 2001.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket CGD07-01-042 and are available for inspection or copying at Commander, Coast Guard Group St. Petersburg, 600 8th Avenue, S.E., St. Petersburg, FL 33701, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LTJG Steven Stewart, Coast Guard Group St. Petersburg, Florida at (727) 824-7553.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Publishing an NPRM is unnecessary and contrary to public safety interests because immediate action is needed to protect the public and because this temporary rule modifies an existing published regulation.

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**. This is because entry into the regulated area will only be prohibited

for approximately six hours on the day of the event, and traffic will be able to safely pass around the race area. Additionally, delaying the effective date would be contrary to the public interest because it is needed on the day of the event in order to protect the safety of the race participants and the general public.

Background and Purpose

The Suncoast Offshore Racing Association is sponsoring a sanctioned American Power Boat Association Offshore Event, with approximately 100 power boats, ranging in length from 21 to 50 feet participating in the 2001 Suncoast Offshore Challenge. The race will take place in the Gulf of Mexico off Sarasota, FL on June 30, 2001. There will also be approximately two hundred (200) spectator craft. A Special Local Regulation exists at 33 C.F.R. 100.719 for this event, which is usually held in July. However, the sponsor changed the date for this year. These regulations are intended to promote safe navigation on the waters of Sarasota Bay by controlling the traffic entering, exiting, and traveling within the regulated area.

Regulatory Evaluation

This regulation is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. The Office of Management and Budget has exempted it from review under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. Entry into the regulated area is prohibited for only approximately seven hours on the day of the event and traffic can safely pass around the race area.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

This special local regulation will not have a significant economic impact on a substantial number of small entities

for the following reasons. This regulation will only be in effect a total of one day, for six hours on the day of the event. Further traffic can safely pass around the regulated area.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-221), we want to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking process. If the rule will affect your small business, organization, or government jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** for assistance in understanding this rule. We also have a point of contact for commenting on actions by employees of the Coast Guard. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247).

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

Federalism

We have analyzed this rule under Executive Order 13132 and have determined that this rule does not have implications for federalism under that order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those unfunded mandate costs. This rule will not impose an unfunded mandate.