

**PART 39—AIRWORTHINESS  
DIRECTIVES**

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

**§ 39.13 [Amended]**

2. Section 39.13 is amended by adding the following new airworthiness directive:

96-18-03 Saab Aircraft AB: Amendment 39-9727. Docket 95-NM-243-AD.

*Applicability:* Model SAAB SF340A series airplanes, serial numbers -004 through -159 inclusive; and Model SAAB 340B series airplanes, serial numbers -160 through -379 inclusive; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

*Compliance:* Required as indicated, unless accomplished previously.

To prevent the movement of both power levers aft of the flight idle stop during flight, which could result in loss of power to both engines, as well as severe engine damage, accomplish the following:

(a) Within 12 months after the effective date of this AD, accomplish the requirements of paragraphs (a)(1), (a)(2), and (a)(3) of this AD.

Note 2: The actions specified in paragraphs (a)(1) and (a)(2) of this AD may be accomplished prior to, or in conjunction with, the accomplishment of the requirement of paragraph (a)(3) of this AD.

(1) Modify the electrical system of the flight idle stop in accordance with Saab Service Bulletin 340-76-031, Revision 04, dated February 25, 1996.

Note 3: Accomplishment of this modification prior to the effective date of this AD in accordance with previous revisions of Saab Service Bulletin 340-76-031 is considered acceptable for compliance with this paragraph.

(2) Install a control unit with a wheel spin-up signal in accordance with Saab Service Bulletin 340-32-100, Revision 02, dated March 25, 1996.

Note 4: Accomplishment of this installation prior to the effective date of this AD in accordance with previous revisions of Saab Service Bulletin 340-32-100 is considered acceptable for compliance with this paragraph.

(3) Install an automatic flight idle stop on the control quadrant in the flight

compartment in accordance with Saab Service Bulletin 340-76-032, Revision 03, dated March 25, 1996.

Note 5: Accomplishment of this installation prior to the effective date of this AD in accordance with previous revisions of Saab Service Bulletin 340-76-032 is considered acceptable for compliance with this paragraph.

Note 6: Paragraph 2.A. of the Accomplishment Instructions of Saab Service Bulletin 340-76-032 specifies procedures for removal of a mechanical beta stop mechanism from the airplane. Since installation of a mechanical beta stop mechanism was not previously required for all airplanes by AD, that mechanism may not have been installed on certain airplanes affected by this AD. In such cases, procedures for removal of the mechanical beta stop would not apply.

(b) In cases where the automatic flight idle (FI) stop has malfunctioned and/or use of the FI stop override has been necessary, the airplane may be operated for one revenue flight to a location where required maintenance/repair can be performed, provided that the FI stop system has been properly deactivated and placarded for flight crew awareness in accordance with the provisions of the FAA-approved Master Minimum Equipment List (M MEL).

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM-113.

Note 7: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM-113.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(e) The modification and installations shall be done in accordance with Saab Service Bulletin 340-76-031, Revision 04, dated February 25, 1996; Saab Service Bulletin 340-32-100, Revision 02, dated March 25, 1996; and Saab Service Bulletin 340-76-032, Revision 03, dated March 25, 1996. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from SAAB Aircraft AB, SAAB Aircraft Product Support, S-581.88, Linköping, Sweden. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on October 4, 1996.

Issued in Renton, Washington, on August 21, 1996.

Darrell M. Pederson,

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 96-22009 Filed 8-29-96; 8:45 am]

BILLING CODE 4910-13-U

**FEDERAL TRADE COMMISSION****16 CFR Part 307****Regulations Under the Comprehensive  
Smokeless Tobacco Health Education  
Act of 1986**

**AGENCY:** Federal Trade Commission.

**ACTION:** Final rule.

**SUMMARY:** The Comprehensive Smokeless Tobacco Health Education Act of 1986 ("Smokeless Tobacco Act") requires that all packaging and advertising for smokeless tobacco products display one of three health warnings in rotating sequence. On January 16, 1993, the Commission published a Notice of Proposed Rulemaking seeking public comment on a method for rotating the health warnings on promotional materials based on the date of dissemination of the materials. On February 14, 1995, the Commission published another Notice of Proposed Rulemaking seeking public comment on a proposal to permit rotation of warnings on utilitarian items based on either the date of order or the date of dissemination of the items, provided the production of such items is carried out in a manner consistent with customary business practices.

Having considered all of the issues raised during the two public comment periods, the Commission is now amending the regulations governing utilitarian items and the regulations governing promotional materials to permit rotation based on either the date of order or the date of dissemination, provided the production of such items or materials is carried out in a manner consistent with customary business practices. This document contains the statement of basis and purpose and the text of the final regulations.

**EFFECTIVE DATE:** The effective date of these regulations will be September 30, 1996.

**ADDRESSES:** Requests for copies of the regulations and the statement of basis and purpose should be sent to Public Reference Branch, Room 130, Federal Trade Commission, 6th & Pennsylvania Ave. NW, Washington, DC 20580.

**FOR FURTHER INFORMATION CONTACT:** Phillip S. Priesman, Attorney, Division of Advertising Practices, Federal Trade

Commission, 6th & Pennsylvania Ave. NW, Washington, DC 20580. (202) 326-2484.

#### SUPPLEMENTARY INFORMATION:

##### Statement of Basis and Purpose

##### *I. Introduction*

Congress enacted the Comprehensive Smokeless Tobacco Health Education Act of 1986 for the express purpose of educating the public about the health consequences of using smokeless tobacco products. (Public Law No. 99-252, 100 Stat. 30 (1986), 15 U.S.C. 4401 *et seq.*). To achieve this end, the Act required the random display of three warnings on the packaging and the rotation of these warnings in the advertising of smokeless tobacco products.

Specifically, the Smokeless Tobacco Act mandated that one of the following three health warnings appear in the labeling and advertising (with the exception of outdoor billboard advertising) of smokeless tobacco products:

Warning: This product may cause mouth cancer.

Warning: This product may cause gum disease and tooth loss.

Warning: This product is not a safe alternative to cigarettes.

The Commission's original regulations applying the Act to promotional materials provided that "[a] satisfactory plan for point-of-sale and non-point-of-sale promotional materials \* \* \* could provide for rotation according to the time that the material is scheduled to be disseminated or the order date for the material." 51 Fed. Reg. 40005, 40023 (1986). Point-of-sale materials include shelf-talkers (a card or brochure attached to the shelf where the product is located in a retail outlet), rack header cards (cards identifying a particular smokeless brand on semi-circular racks displaying cans of snuff), and tear pads. Non-point-of-sale materials include direct mail circulars, coupons, leaflets and pamphlets.

The Commission's original regulations exempted utilitarian items from the regulations governing the rotation and display of the health warnings. The exemption for utilitarian items was challenged in court, and the court ultimately ordered the Commission to delete the exemption.<sup>1</sup> Accordingly, in 1991, the Commission issued final regulations setting out requirements for the rotation and display of health warnings on utilitarian items. During its consideration of the

1991 rulemaking proceeding, the Commission became concerned that companies could order a year's supply of utilitarian items at one time, and thereby display only one warning over an entire year. The Commission also was concerned that this apparent loophole could likewise apply to promotional materials. Thus, the Commission amended its regulations governing rotation of both promotional objects and utilitarian objects, and called for "rotation according to the date the materials or objects are disseminated." The Commission noted, however, that this could impose a hardship on a company that was unable to foresee its distribution schedule when placing the order. To alleviate this hardship, the rule also permitted rotational plans whereby each warning would be displayed on an equal number of objects comprising any given order. Under this option, for promotions lasting one year or longer, the company could distribute promotional materials or utilitarian items bearing the same warning for four months, and then switch to another warning. If the promotion was scheduled to last less than one year, the materials or items bearing the various warnings could be distributed randomly.

With regard to promotional materials, the Commission published this rule for additional public comment on January 16, 1993. The initial comment period was to expire on February 16, 1993, but the Commission extended the deadline until March 23, 1993. During this time, the Commission received five comments. Four of the comments were from manufacturers of smokeless tobacco products, and one was from a trade association representing the manufacturers.

On February 14, 1995, the Commission published a Notice of Proposed Rulemaking seeking comment on whether the requirements for rotating the health warnings on utilitarian items should be amended. The proposed rule permitted the rotation of warnings on utilitarian items according to either the date the item is ordered or the date of dissemination, provided that the production of the materials is carried out consistent with customary business practices. The Commission received four comments, all of which supported the proposed rule. All four comments were from manufacturers of smokeless tobacco products.

##### *II. The Regulations*

The Commission's original regulations were written, for the most part, as creating safe harbors rather than imposing mandatory requirements for

compliance with the Smokeless Tobacco Act. The regulations issued in 1991 with respect to utilitarian items and promotional materials and those proposed again in 1993 regarding promotional materials removed the safe harbor provisions, and specified that the appropriate warning would be determined by the date the materials were scheduled for dissemination, with a limited option for random display. The comments the Commission received indicated that requiring rotation based on date of dissemination, even with the limited option for random display, was likely to impose additional, possibly significant, costs on smokeless tobacco manufacturers and their suppliers. Both the date of dissemination requirement and the more flexible date of order safe harbor appear likely to meet the chief benefit intended by the regulations: Providing a system for the rotation of health warnings as required by the Smokeless Tobacco Act. Consequently, the Commission is returning to the previous more flexible approach and specifying safe harbors for complying with the Smokeless Tobacco Act's warning requirements by amending the regulation governing utilitarian items, and retaining the present rotation schedule for promotional materials except for the amendment that such materials be produced in accordance with customary business practices. With these amendments, the regulations governing the rotation of warnings for utilitarian items will mirror those for promotional materials.

Given the practical constraints associated with the production and dissemination of utilitarian items and those for promotional materials, the Commission believes that the industry should be given some flexibility in conforming the rotation requirements to these types of advertising, while at the same time ensuring that the warnings rotate as required by the Smokeless Tobacco Act. If, however, there is a pattern of abuse or confusion suggesting that the safe harbors do not provide for adequate rotation of the warnings, the Commission will reconsider whether it is necessary to promulgate regulations providing less flexibility and more specificity. In particular, the Commission may reconsider whether to impose the mandatory date of dissemination requirement for the rotation of both utilitarian items and promotional materials.

##### *A. Comments Regarding the Rotation of Utilitarian Items*

The comments indicate that producing utilitarian items that comply with a rotation standard based upon

<sup>1</sup> *Public Citizen v. FTC*, 869 F.2d 1541 (D.C. Cir. 1989), *aff'd*, 588 F. Supp. 667 (D.D.C. 1988).

date of dissemination is expensive and imposes burdens on the smokeless tobacco manufacturers. According to one comment, the date of dissemination requirement is burdensome due to the difficulty of predicting the demand for any item in advance. This comment notes that such prediction is difficult both because methods of forecasting demand are imprecise and because premium promotions offering utilitarian items often change during the course of the promotion due to competitive conditions.<sup>2</sup> Several comments state that the date of dissemination requirement requires companies to order an excess supply of utilitarian items to ensure that the supply is not exhausted before the promotion ends.<sup>3</sup> These comments likewise state that the need to order an excess supply of items adds both warehousing and inventory costs (both in terms of manpower and facilities).<sup>4</sup> And, as inventory costs increase, so do freight costs, according to these comments. Another comment states that its inability to accurately forecast demand as well as the lead time needed to order items adds planning and administrative costs, including added costs of coordinating with suppliers, warehousing inventory, tracking inventory, and distributing items.<sup>5</sup>

#### B. Comments Regarding the Rotation of Promotional Materials

The comments from the smokeless tobacco manufacturers are similar to those for utilitarian items. The comments state that the companies exercise very little control over the actual rate or date of dissemination of promotional materials.<sup>6</sup> In addition, to comply with the proposed date of dissemination requirement, manufacturers would need to produce most of their materials in significantly larger quantities to ensure an adequate supply of materials with each of the warnings. This would increase their production expenses, as well as the cost of shipping, warehousing, and distributing the materials.<sup>7</sup> Several companies might also need to hire additional employees to handle the increased workload.<sup>8</sup> Further, much of

the additional burden would fall on the businesses that produce and supply the materials to the tobacco companies. While these businesses would likely pass on their increased costs to their customers, some of these suppliers might lack the resources to meet the increased production requirements, thus forcing them to lose a significant portion of their business.

According to some of the comments, the proposed regulations would also raise environmental issues by increasing the amount of waste generated in producing materials.<sup>9</sup> To comply with the proposed requirements, manufacturers of smokeless tobacco would need to order greater quantities of materials displaying each different warning label. Rather than being able to exhaust the existing supply of materials before re-ordering, companies would need to switch to materials printed with a different warning on the specified date, and throw out or otherwise destroy all of the remaining materials with the outdated warning. According to the comments, this would only add to the nation's growing environmental concerns.<sup>10</sup>

#### C. Commission Conclusions

Based on its review of these comments, the Commission believes it is appropriate to adopt a rotation method that allows rotation to be based on either the date of order or the date of dissemination, as long as "the production of such materials is carried out in a manner consistent with customary business practices." Such a method will fulfill the purpose of the Smokeless Tobacco Act and prevent manufacturers from circumventing the rotation requirement without imposing a substantial hardship on the manufacturers and their suppliers. Almost all of the members of the industry have demonstrated their ability to comply with a rotation requirement based on the date of order by submitting rotational plans that follow this schedule. Moreover, the addition of the requirement that production be based upon business considerations will ensure that permitting rotation based on date of order will not frustrate the Act's requirement that the warnings rotate. The inclusion of this "caveat" is intended to inhibit bulk-ordering by companies to avoid any one particular warning.<sup>11</sup>

<sup>20</sup> (March 18, 1993); Conwood at 5 (March 16, 1993); Pinkerton at 4 (March 17, 1993); Helme at 2 (March 5, 1993).

<sup>9</sup> Comment of Conwood at 6 (March 16, 1993).

<sup>10</sup> *Id.*

<sup>11</sup> Such bulk-ordering was raised as a concern during the Commission's 1991 rulemaking

Some comments suggest that the Commission could lessen the burden on the smokeless tobacco manufacturers by allowing for the random simultaneous display of the various warnings on promotional materials. The Smokeless Tobacco Act and the Commission's regulations specifically permit random simultaneous display for packaging. However, the Smokeless Tobacco Act expressly provided for different methods of assuring the rotation of the three warnings for packaging and advertising. On packaging, the Act specifies that the warnings be displayed randomly in as equal a number of times as possible. In advertising, however, the Act mandates the rotation of the three warnings in alternating sequence every four months. While random simultaneous display may meet the Act's directives applicable to packaging, it generally would not appear to satisfy the prescribed rotation in alternating sequence in advertising. The Commission, therefore, concludes that the regulations should not provide for random simultaneous display of either utilitarian items or promotional materials.<sup>12</sup>

Thus, the Commission's final regulations provide that the rotation of the health warnings on utilitarian items and promotional materials may be based upon either the date of order or the date of dissemination of the materials, provided that the items or materials are produced in accordance with customary business practices.

#### III. Regulatory Flexibility Act

When the Commission first promulgated the smokeless tobacco regulations, the agency certified that the Regulatory Flexibility Act's requirement for regulatory analysis was not applicable because the regulation did

regarding the rotation of warnings on smokeless tobacco utilitarian items. 56 FR 11653, 11659 (1991).

<sup>12</sup> In 1985, the Commission reached a similar conclusion with respect to the rotation of warnings on *cigarette packaging*. The Comprehensive Smoking Education Act ("Cigarette Act") specified that the four statutory health warnings had to rotate quarterly. 15 U.S.C. 1331(c). Pursuant to the Cigarette Act, the cigarette companies submitted a rotational warning plan that called for the random simultaneous display of the warnings on cigarette packages. The Commission rejected this proposal, notifying the companies and the relevant committees of Congress of its action. Subsequently, the Congress amended the rotational warning requirements of the Cigarette Act to allow simultaneous rotation on packaging only for those cigarette companies that sold less than one-fourth of one percent of all cigarettes sold in the United States. The Nurse Education Amendments of 1985, Pub. L. 99-92, 99 Stat. 393, 402-403 (1985). The same Congress later enacted the Smokeless Tobacco Act, with its different rotational warning schemes for smokeless tobacco packages and for smokeless tobacco advertisements.

<sup>2</sup> Comment of Pinkerton at 5 (April 17, 1995).

<sup>3</sup> Comments of Conwood at 3 (April 17, 1995); Pinkerton at 6 (April 17, 1995).

<sup>4</sup> Comment of Pinkerton at 6 (April 17, 1995).

<sup>5</sup> Comment of United States Tobacco Co. at 9 (April 11, 1995).

<sup>6</sup> Comments of Conwood at 2-3 (April 17, 1993); Smokeless Tobacco Council at 3 (March 18, 1993); Pinkerton at 5 (March 17, 1993).

<sup>7</sup> Comments of Helme at 2 (March 5, 1993); United States Tobacco Co. at 10-11 (March 18, 1993); Pinkerton at 3-4 (March 17, 1993).

<sup>8</sup> Comments of Smokeless Tobacco Council at 6 (March 18, 1993); United States Tobacco Co. at 18-

not appear to have a significant economic impact on a substantial number of small entities. 51 FR 40005, 40014 (1986). In its subsequent Notice, the Commission noted that the proposed amendments did not change the regulations sufficient to alter its previous "no impact" determination; nonetheless, to ensure that no substantial impact was being overlooked, the Commission requested public comment on the effect of the proposed regulations on costs, profitability, competitiveness, and employment in small entities. 54 FR 31541 (1989).

Two of the comments received during the comment period for promotional materials discussed the effect that regulations requiring rotation based upon date of dissemination would have on small businesses. The Smokeless Tobacco Council noted that smaller smokeless tobacco manufacturers may be unable to absorb any additional production costs, and may eliminate their promotional programs. The Smokeless Tobacco Council and Conwood Tobacco Company noted that small suppliers may be unable to make the necessary adjustments. No other comments on burden were received during the 1993 comment period for promotional materials and no comments on burden were received during the 1995 comment period for utilitarian items. By permitting rotation based upon date of order or date of dissemination, the final regulations will avoid any of these potential burdens on small entities. Thus, the Commission certifies that the amendments will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. § 605(b) (1982).

#### IV. Effective Date

During the comment period concerning the proposed regulations for promotional items, the Commission received two comments requesting that if the Commission adopts a requirement that promotional items rotate according to the date of dissemination, the Commission include a grandfather clause delaying the effective date of the rule for at least two years from publication of the final rule, to enable companies to use up their existing inventory of materials, and to allow suppliers time to make the necessary adjustments.<sup>13</sup> The Commission, however, does not believe that any grandfather period is necessary given the flexibility permitted by the amended

regulations. In addition, the Commission notes that the major smokeless tobacco manufacturers have all previously filed plans calling for rotation based on date of order, one of the permitted methods of rotation under the amended regulations. However, the Commission will provide thirty (30) days for companies to come into compliance with these amendments. Thus, the effective date for the regulations governing the date that serves as the basis for rotating warnings on promotional materials is thirty (30) days from the date of publication of the final rule.

#### List of Subjects in 16 CFR Part 307

Health warnings, Smokeless tobacco, Trade practices.

Accordingly, Part 307 of 16 CFR Chapter I is amended as follows:

#### **PART 307—REGULATIONS UNDER THE COMPREHENSIVE SMOKELESS TOBACCO HEALTH EDUCATION ACT OF 1986**

1. The authority for Part 307 continues to read as follows:

Authority: 15 U.S.C. 4401 *et seq.*

2. Section 307.12(b) is revised to read as follows:

#### **§ 307.12 Rotation, display, and dissemination of warning statements in smokeless tobacco advertising.**

\* \* \* \* \*

(b) Each manufacturer, packager, or importer of a smokeless tobacco product must submit a plan to the Commission or its designated representative that ensures that the three warning statements are rotated every four (4) months in alternating sequence. There may be more than one system, however, that complies with the Act and these regulations. For example, a plan may require all brands to display the same warning during each four-month period or require each brand to display a different warning during a given four-month period. A plan shall describe the method of rotation and shall include a list of the designated warnings for each four-month period during the first year for each brand. A plan shall describe the method that will be used to ensure the proper rotation in different advertising media in sufficient detail to ensure compliance with the Act and these regulations, although a number of different methods may satisfy these requirements. For example, a satisfactory plan for advertising in newspapers, magazines, or other periodicals could provide for rotation according to either the cover or closing date of the publication. A satisfactory

plan for posters and placards, other than billboard advertising, could provide for rotation according to either the scheduled or the actual appearance of the advertising. A satisfactory plan for point-of-sale and non-point-of-sale promotional materials such as leaflets, pamphlets, coupons, direct mail circulars, paperback book inserts, or non-print items, or for utilitarian objects, could provide for rotation according to the date the materials or objects are ordered by the smokeless tobacco manufacturer, or the date the objects or materials are scheduled to be disseminated, provided that the production of such materials or objects is carried out in a manner consistent with customary business practices.

\* \* \* \* \*

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 96-22221 Filed 8-29-96; 8:45 am]

BILLING CODE 6750-01-P

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

#### **Food and Drug Administration**

#### **21 CFR Part 184**

[Docket No. 85G-0335]

#### **Direct Food Substances Affirmed as Generally Recognized as Safe; Enzyme-Modified Lecithin**

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its regulations to affirm that the use of enzyme-modified lecithin as a direct human food ingredient is generally recognized as safe (GRAS). This action is in response to a petition filed by Kyowa Hakko Kogyo Co., Ltd.

**DATES:** Effective August 30, 1996. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of two publications listed in new § 184.1063, effective August 30, 1996.

**FOR FURTHER INFORMATION CONTACT:** Aydin Örstan, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3076.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In accordance with the procedures described in § 170.35 (21 CFR 170.35),

<sup>13</sup> Comments of Smokeless Tobacco Council at 7 (March 18, 1993); United States Tobacco Co. at 23 (March 18, 1993).