upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9L dated September 2, 2003, and effective September 16, 2003, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to 14 CFR part 71 modifies Class E airspace at Albert Lea, MN, to accommodate aircraft executing instrument flight procedures into and out of Albert Lea Municipal Airport. The area will be depicted on appropriate aeronautical charts.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS E, AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 95665, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9L, Airspace Designations and Reporting Points, dated September 2, 2003, and effective September 16, 2003, is amended as follows:

* * * * *

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL MN E5 Albert Lea, MN [Revised]

Albert Lea Municipal Airport, MN
(Lat. 43°40′54″ N., long.93°22′02″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Albert Lea Municipal Airport.

* * * * *

Issued in Des Plaines, Illinois, on September 9, 2004.

Keith A. Thompson,

Area Staff Manager, Central Terminal Operations.

[FR Doc. 04–21395 Filed 9–22–04; 8:45 am]

BILLING CODE 4910–13–M

FEDERAL TRADE COMMISSION

16 CFR Part 228

Tire Advertising and Labeling Guides

AGENCY: Federal Trade Commission (''FTC'' or ''Commission'').

ACTION: Final decision.

SUMMARY: The Commission previously announced its intention to review and seek public comment on its Tire Advertising and Labeling Guides (''Tire Guides'' or ''Guides''). That review has been completed, and this document announces the Commission's decision to rescind the Guides.

DATES: *Effective Date:* September 23, 2004.

ADDRESSES: Requests for copies of this document should be sent to the Consumer Response Center, Room 130, Federal Trade Commission, 600 Pennsylvania Ave., NW., Washington, DC 20580. The document is available on the Internet at the Commission's Web site *http://www.ftc.gov.*

FOR FURTHER INFORMATION CONTACT: Jonathan L. Kessler, Federal Trade Commission, 1111 Superior Avenue, Suite 200, Cleveland, Ohio, 44114, telephone number (216) 263–3436, E-mail <jkessler@ftc.gov>.

SUPPLEMENTARY INFORMATION:

I. Overview of FTC Tire Advertising Regulation and the Consumer Tire Industry

The Commission's Tire Guides address aspects of the marketing, use, and servicing of tires ''for use on passenger automobiles, station wagons, and similar vehicles.'' [1] 16 CFR 228.0. The Commission first promulgated Trade Practice Rules For The Tire Industry in 1936. The Tire Guides in their current form were published in 1968.[2] Commission hearings in the mid-1960s revealed problems with deceptive advertising by sellers, and the Commission concluded that consumers lacked the information needed to make informed purchasing decisions. The problems appear to have revolved around the lack of standard definitions for the terms ''ply'' and ''ply rated,'' the lack of recognized standards for safety and quality, and pricing practices.

The tire industry, however, has changed considerably in the last 35 years. First, in 1968, bias ply tires were standard on passenger cars. Today, radial tires dominate the consumer market, with bias tires relegated to large trucks and historical vehicles. As a result, factors such as the number of plies in a tire or its cord material are no longer relevant to consumer decision making. Second, in 1968, consumers bought tires at full-service gas stations or locally-owned stores that carried only one brand of tire. Today, sales also occur through national retailers, regional tire stores, new car dealerships, and the Internet.[3] These new retail establishments offer multiple brands, tread patterns, and mileage warranties. Moreover, prices for these tires are widely advertised, often in full-page newspaper ads or inserts. As a result, consumers have more choices of tires and more information about prices and options. Third, in 1968, no government or industry association established standards for measuring tire quality or insuring safety. Today, the National Highway Traffic Safety Administration (''NHTSA'') oversees the industry and has promulgated comprehensive regulations requiring disclosure of important safety and quality features.[4]

[1] This definition does not include minivans and sport utility vehicles.

[2] The only change since 1968 was the addition of a provision regarding retreaded tires in 1994.

[3] In the United States, six tire manufacturers sell nearly 200 million passenger car replacement tires every year. Almost three-fourths (72%) of these tires are sold through independent tire dealers, including chain stores like Tire Kingdom and NTB. Mass merchandisers like Wal-Mart, Sears, and K-Mart account for 18% of replacement tire sales. Company-owned stores (*e.g.*, Goodyear and Firestone), service stations, new car dealers, and, more recently, the Internet, account for the remainder.

[4] NHTSA's Uniform Tire Quality Grading System regulations (''NHTSA regulations'') set standards for treadwear, traction, and temperature ratings, giving consumers the ability to compare the quality of one tire with that of another. See 49 CFR 575.104. NHTSA's New Pneumatic Tires for Light Vehicles regulations, 49 CFR 571.139 (TREAD Act regulations), require disclosure on the tire of, among other things, the tire's size, maximum inflation pressure, maximum load, generic name of cord material, number of plies, whether it has radial plies, and whether it is tube or tubeless.

II. Regulatory Review of the Guides and Public Comment

The Commission reviewed the Tire Guides as part of its continuing review of all current rules and guides.[5] On August 25, 2003, the Commission published a **Federal Register** notice seeking comments about the costs and benefits of the Guides. Three written comments were received, all in favor of significantly revising the Guides.[6] For example, one comment stated: ''[A]s currently written, the Guides have limited utility to tire manufacturers, tire dealers and tire consumers, appear to be redundant with other consumer protection laws, and have been superseded in part by regulations issued by another government agency.'' [7] All three comments substantially agreed on four points:

(1) If retained, the Guides should be expanded from passenger car and station wagon tires to include tires for minivans, sport utility vehicles, and other light trucks.

(2) Section 228.2 is obsolete and in need of substantial revision or deletion. This provision requires that ads making comparative quality claims across tire brands also disclose that no generally accepted standards of tire quality exist. In 1978, however, NHTSA promulgated its Uniform Tire Quality Grading System, which establishes tests and criteria for grading tire quality.

(3) The ply count and cord material provisions of Sections 228.6 and 228.7 are obsolete because of the market change from bias ply to radial tires (nearly 100% of tires sold for consumer vehicles are radials).[8]

(4) Ads for used and retreaded tires should continue to disclose that those tires are not new, as required by Section 228.9.

Not all comments addressed each section of the Guides, but the overall suggestion of each comment was to revise and retain the Guides rather than to rescind them.

III. Determination To Rescind the Guides

After reviewing the Tire Guides, the consumer tire industry, the NHTSA regulations, the above-referenced comments, and other industry guides, the Commission has decided to rescind the Guides. This decision is based on the fact that many provisions in the Guides duplicate other laws and regulations or are obsolete. In addition, some provisions describe conduct that is addressed by section 5 of the FTC Act, which generally prohibits unfair or deceptive acts or practices.[9] A description and analysis of each of the Guides' nineteen substantive provisions follows.[10]

Section 228.1 requires point-of-sale disclosure of the load carrying capacity of the tire, the composition of the cord material and the actual number of plies. It also provides for permanent disclosures on the tire itself of the tire's size, whether it is tube or tubeless, and its number of plies. This section also requires disclosure via a label or tag on the tire of its cord material, load-carrying capacity, and inflation pressure. Today, however, NHTSA regulations require this information on the tire. Moreover, with radial tires dominating the market, the ply count and cord material disclosures provide no meaningful information to consumers buying tires for personal, family, or household use; NHTSA requires this information because it is important to tire retreaders.[11]

Section 228.2 prohibits the use of terms like ''line,'' ''level,'' and ''premium'' without also disclosing the lack of any ''industry-wide or other accepted system of quality standards or grading of industry products' and that any representations of grade or level only apply to the marketer's brand. Marketers are prohibited from describing tires as ''first line'' ''unless the products so described are the best products, exclusive of premium quality products embodying special features, of the manufacturer or brand name distributor.'' § 228.2 (d). Today, however, NHTSA regulations enable consumers to compare tires on several measures of quality: treadwear, traction, load capability, and temperature. Consumers also have the benefit of tire warranties, which typically warrant a tire for a particular number of miles.[12]

Section 228.3 complements Section 228.2 by prohibiting a manufacturer from using terms that imply that one of its tires is better than another unless the first is actually superior. Section 228.4 prohibits describing a tire as ''original equipment'' unless it is currently used on new cars or the manufacturer discloses when the tire was last used on new cars. Under the Guides, original equipment tires are considered to be ''the same brand and quality tires used generally as original equipment on new current models of vehicles of domestic manufacture.'' There is no evidence, however, whether consumers still understand the term ''original equipment'' in this way or have changed their understanding over the years, and none of the commenters mentioned this section. Section 228.5 prohibits any other quality or performance claim unless the claim maker has test results to substantiate the claim. Today, most of these claims would clearly be covered by the FTC's deception standard and substantiation doctrine.[13]

Sections 228.6 and 228.7 govern representations of ''ply count,'' ''plies,'' ''ply rating,'' and ''cord material.'' These factors were important indicators of tire quality with bias ply tires. Today, however, radial tires make these measures far less meaningful; NHTSA requires them only because they affect the retread process. In their place, NHTSA regulations require more direct information about tire quality.

Sections 228.8, 228.9, and 228.11 require disclosures in ads for tires that are used or imperfect. In 1968, consumers who did not want to pay for new, perfect tires could purchase used, retreaded, or blemished tires. Today, however, these tires are seldom found in the consumer market. (Large truck tires, such as those for semis, are often retreaded, and retreads account for as much as 60% of that market.) Moreover, if a business were to sell a used, blemished, or defective tire without proper disclosures, such conduct would likely constitute deception in violation of section 5 of the FTC Act.

Section 228.10 requires disclosure if an advertised tire is a discontinued or

[5] The Commission periodically reviews its rules and guides. These reviews seek and assess information about the costs and benefits of the rules and guides, as well as their regulatory and economic impact. The information obtained assists the Commission in identifying rules and guides that warrant modification or rescission. In this instance, the Commission sought comments on, among other things: the economic impact of and the continuing need for the Guides; possible conflicts between the Guides and other federal, state, or local laws and regulations; and the effect of any technological, economic, or other industry changes on the Guides.

[6] Comments came from the Rubber Manufacturers Association, the National Automobile Dealers Association, and the Tire Industry Association.

[7] Letter dated October 24, 2003, from Ann Wilson, Rubber Manufacturers Association, to Secretary, Federal Trade Commission, at 2.

[8] The comments differed on whether to revise these sections or delete them entirely, however.

[9] 15 U.S.C. 45.

[10] Section 228.0 contains definitions and Section 228.0–1 provides ''[u]se of guide principles.'' Sections 228.1 through 228.19 are the substantive sections.

[11] The Guides recognize the unique features of radials and allow the ply count disclosure to be satisfied with just the statement ''radial ply.'' 16 CFR 228.2(b)(1) and (2).

[12] Tire ads for name-brand tires almost always state a mileage warranty. Such warranties provide additional, albeit non-specific, information about a tire's quality.

[13] Section 5 of the FTC Act, 15 U.S.C. 45, prohibits, among other things, deceptive acts or practices. The substantiation doctrine requires advertisers to have reasonable substantiation for claims in advertisements at the time the advertisement is published.

obsolete model. Tire manufacturers today, however, often change models, so it is questionable whether such information is material to consumers. None of the commenters discussed this provision and there is no evidence whether consumers are concerned about or would be adversely affected by purchasing a tire that is being discontinued. If problems were to surface in this area, they likely could be addressed by section 5 of the FTC Act.

Sections 228.12 and 228.13 address advertisements that use pictures or racing themes. Pictures must be of the tire advertised and ads using racing themes must disclose that the tires on race cars ''are not generally available all purpose tires, unless such is the fact.'' As in 1968, pictures and video can be used today to misrepresent the qualities of tires, but any material misrepresentations would violate section 5 of the FTC Act.

Sections 228.14 and 228.15 address price advertising. Section 228.14 prohibits bait advertising, and Section 228.15 addresses price comparisons. Although both sections address concerns that may be relevant to the current tire market, the Commission has published guides devoted to both issues. *See* 16 CFR 238 (bait advertising) and 16 CFR 233 (deceptive pricing). These guides should provide adequate information for tire industry members to understand how section 5 of the FTC Act applies to their products, making Sections 228.14 and 228.15 redundant.

Section 228.16 requires ads containing guarantees to disclose details of those guarantees, including how price adjustments will be calculated if a tire fails during the guarantee period. Today, however, warranties must be available at a store for inspection before purchase. 16 CFR 702 (rule on the Presale Availability of Written Warranty Terms). Requiring disclosure of guarantee details in ads themselves thus appears unnecessary. Advertising claims about warranties and guarantees are also addressed by the Guides for the Advertising of Warranties and Guarantees, 16 CFR 239.

Section 228.17 prohibits absolute performance or safety claims such as ''blowout proof'' or ''skid proof'' unless the claims are true under all driving conditions. Any problems attributable to these or similar claims can be addressed by section 5 of the FTC Act.

Section 228.18 prohibits claims that deceive purchasers or prospective purchasers in any material respect. Even if updated, this section would still only restate established law and not provide additional guidance to the tire industry.

Section 228.19 requires that ads for metal studded snow tires disclose that their use is illegal in some places. Non-metal studded mud and snow tires and all weather tires, however, have made metal studded tires far less common now than in 1968.

In sum, the Commission's review has produced no clear reason for retaining the Guides. Even if revised as the comments suggested, the Guides would not provide consumers with any information not already required to be available to them by other laws and regulations. Moreover, neither the comments nor the Commission staff's own review of tire advertising has identified benefits to consumers from the existing Guides or areas where businesses are in particular need of Commission guidance. Indeed, one comment, after noting several changes in the industry that would make significant revisions necessary if the Guides were to be retained, admitted that ''[t]hese changes will not make a huge difference to consumers. They will simply update the Guides to reflect today's market.''[14] Because the vast majority of Tire Guide provisions are adequately addressed by other laws and regulations (including NHTSA regulations and Section 5 of the Federal Trade Commission Act) or have been rendered obsolete because of changes in the market, the Commission has determined to rescind the Guides.

List of Subjects in 16 CFR Part 228

Advertising, Automobile tires, Trade practices.

PART 228—[REMOVED]

■ The Commission, under authority of sections 5(a)(1) and 6(g) of the Federal Trade Commission Act, 15 U.S.C. 45(a)(1) and 46(g), amends Chapter 1 of Title 16 of the Code of Federal Regulations by removing part 228.

By direction of the Commission, Commissioner Leibowitz not participating.

Donald S. Clark,

Secretary.

[FR Doc. 04–21404 Filed 9–22–04; 8:45 am]

BILLING CODE 6750–01–P

[14] Letter dated October 24, 2003 from Becky MacDicken, Tire Industry Association, to Secretary, Federal Trade Commission, at 3.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2004N–0370]

Medical Devices; Immunology and Microbiology Devices; Classification of the Beta-Glucan Serological Assay

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the beta-glucan serological reagent device into class II (special controls). The special control that will apply to the device is the guidance document entitled ''Class II Special Controls Guidance Document: Serological Assays for the Detection of Beta-Glucan.'' The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990, the Food and Drug Administration Modernization Act of 1997, and the Medical Device User Fee and Modernization Act of 2002. The agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a guidance document that is the special control for this device.

DATES: This rule becomes effective October 25, 2004. The classification was effective May 21, 2004.

FOR FURTHER INFORMATION CONTACT: Freddie M. Poole, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–2096, ext. 111.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the 1976 amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or