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

reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act (21 U.S.C. 360c(a) (1)). FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued a notice on March 18, 2004, classifying the beta-glucan serological assay in class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On March 22, 2004, Associates of Cape Cod submitted a petition requesting classification of the beta-glucan serological assay under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II.

In accordance with section 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the beta-glucan serological assay can be classified in class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of safety and effectiveness of the device.

The device is assigned the generic name ''Beta-glucan serological assays'' and it is identified as a device that consists of antigens or proteases used in serological tests. It is intended for use in the presumptive diagnosis of fungal infection. The assay is indicated for use in patients with symptoms of, or medical conditions predisposing the patient to, invasive fungal infection. The device can be used as an aid in the diagnosis of deep-seated mycoses and fungemias. The assay should be used in conjunction with other diagnostic procedures, such as microbiological culture, histological examination of biopsy samples and radiological examination.

FDA has not identified any direct risks to health when tests are used as an aid to detecting invasive fungal infection. However, failure of the test to perform as indicated, or an error in interpretation of results, could lead to misdiagnosis, improper treatment and improper patient management. Therefore, in addition to the general controls of the act, the device is subject to special controls, identified as the guidance document entitled ''Class II Special Controls Guidance Document: Serological Assays for the Detection of Beta-Glucan.''

The class II special controls guidance document provides information on how to meet premarket (510(k)) submission requirements for the device including recommendations on validation of performance characteristics. FDA believes that following the class II special controls guidance document addresses the risks to health identified in the previous paragraph. Therefore, on May 21, 2004, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this classification by adding 21 CFR 866.3050.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for beta-glucan serological assays will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness; therefore, the device is not exempt from premarket notification requirements. The device is used as an adjunct in detecting invasive fungal infection. FDA's review of the test's sensitivity, specificity, and reproducibility with regard to key performance characteristics, test methodology and other relevant performance data, will provide reasonable assurance that acceptable levels of performance for both safety and effectiveness will be addressed before marketing clearance. Thus, persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the beta-glucan serological assay they intend to market.

## II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so it is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Classification of these devices into class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small

potential competitors to enter the marketplace by lowering their costs. The agency, therefore, certifies that the final rule will not have a significant impact on a substantial number of small entities. In addition, this final rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate and, therefore, a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act is not required.

**IV. Federalism**

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

**V. Paperwork Reduction Act of 1995**

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

**VI. Reference**

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Associates of Cape Cod dated March 22, 2004.

**List of Subjects in 21 CFR Part 866**

Biologics, Laboratories, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

## PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 866.3050 is added to subpart D to read as follows:

**§ 866.3050 Beta-glucan serological assays.**

(a) *Identification*. Beta-glucan serological assays are devices that consist of antigens or proteases used in serological assays. The device is intended for use for the presumptive diagnosis of fungal infection. The assay is indicated for use in patients with symptoms of, or medical conditions predisposing the patient to invasive fungal infection. The device can be used as an aid in the diagnosis of deep seated mycoses and fungemias.

(b) *Classification*. Class II (special controls). The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Serological Assays for the Detection of Beta-Glucan.'' See § 866.1(e) for the availability of this guidance document.

Dated: September 10, 2004.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 04–21316 Filed 9–22–04; 8:45 am]

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## DEPARTMENT OF THE TREASURY

## Office of Foreign Assets Control

## 31 CFR Part 592

## Rough Diamonds Control Regulations

**AGENCY:** Office of Foreign Assets Control, Treasury.

**ACTION:** Final rule.

**SUMMARY:** The Treasury Department's Office of Foreign Assets Control is revising the Rough Diamonds Control Regulations previously issued as an interim final rule. The regulations carry out the purposes of Executive Order 13312 of July 29, 2003, which implemented the Clean Diamond Trade Act and the Kimberley Process Certification Scheme for rough diamonds. Based on its experience and that of other involved agencies, OFAC is revising certain reporting and recordkeeping requirements of the regulations.

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

**FOR FURTHER INFORMATION CONTACT:** OFAC's Chief of Policy Planning and Program Management, tel.: (202) 622–4855, or Chief Counsel, tel.: (202) 622–2410.

**SUPPLEMENTARY INFORMATION:**

**Background**

On July 29, 2003, the President issued Executive Order 13312, to implement the Clean Diamond Trade Act (Pub. L. 108–19) and the multilateral Kimberley Process Certification Scheme for rough diamonds (KPCS). The Clean Diamond Trade Act requires the President, subject to certain waiver authorities, to prohibit the importation into, and exportation from, the United States of any rough diamond not controlled through the KPCS. This means shipments of rough diamonds between the United States and non-Participants in the KPCS generally are prohibited, and shipments between the United States and Participants are permitted only if they are handled in accordance with the standards, practices, and procedures of the KPCS set out in these regulations.

The Treasury Department's Office of Foreign Assets Control (OFAC), acting pursuant to Executive Order 13312 and delegated authority, published the Rough Diamonds Control Regulations, 31 CFR part 592 (the Regulations), as an interim final rule on August 4, 2003 (68 FR 45777). The Regulations, which are described in detail in the preamble to the interim final rule, implement the Clean Diamond Trade Act and the KPCS.

OFAC requested public comments on the Regulations. No public comments were received. However, based on its experience and that of other agencies that also participate in the implementation and administration of the Clean Diamond Trade Act and the KPCS, OFAC is revising the Regulations in four respects: (1) To specify that the ultimate consignee is responsible for retaining the original Kimberley Process Certificate accompanying an importation into the United States; (2) to require the ultimate consignee to report the receipt of a shipment of rough diamonds to the relevant foreign exporting authority within 15 calendar days of the date that the shipment arrived at a U.S. port of entry; (3) to advise persons engaged in the diamond trade of a pending requirement of U.S. Customs and Border Protection (Customs) that customs brokers, importers, and filers making entry of a shipment of rough diamonds either submit through Custom's Automated Broker Interface (ABI) system the unique identifying number of the Kimberley Process Certificate accompanying the shipment or, for non-ABI entries, indicate the certificate number on the Customs Form 7501 Entry Summary at each entry line; and (4) to clarify the country-of-origin reporting requirements for shipments of