

consequent presence in byproduct distiller grains used as an animal feed or feed ingredient.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the Agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see **DATES** and **ADDRESSES**) for public review and comment.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the Agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the Agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.51(b).

Dated: April 15, 2011.

**Bernadette Dunham**,  
Director, Center for Veterinary Medicine.  
[FR Doc. 2011-9913 Filed 4-22-11; 8:45 am]  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-D-0431]

#### Guidance for Food and Drug Administration Staff and Tobacco Retailers on Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Civil

Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers." This guidance document describes FDA's current policies with respect to civil money penalties and no-tobacco-sale orders for retailers who violate requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) relating to tobacco products, including the FD&C Act requirement that tobacco products may not be sold or distributed in violation of FDA's "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." With the release of this final guidance document, several provisions in the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) that relate to civil money penalties and no-tobacco-sale orders become effective.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance entitled "Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers" to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Gerie A. Voss, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1-877-287-1373, [gerie.voss@fda.hhs.gov](mailto:gerie.voss@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for FDA staff and tobacco retailers entitled "Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers." On June 22, 2009, President Obama signed the Tobacco Control Act (Pub. L. 111-31) into law. The Tobacco Control Act grants FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Among its many provisions, the Tobacco Control Act authorizes FDA to impose civil money penalties for violations of the FD&C Act requirements that relate to tobacco products (section 303(f)(9) of the FD&C Act (21 U.S.C. 333(f)(9)). Of special interest to retailers, one of the FD&C Act's requirements is that tobacco products may not be sold or distributed in a manner that violates regulations issued under section 906(d) of the FD&C Act (21 U.S.C. 387f(d)), such as the "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" that were published by FDA on March 19, 2010 (75 FR 13225) (21 CFR part 1140). The Tobacco Control Act also authorizes FDA to impose a no-tobacco-sale order on a retail outlet for repeated violations of regulations issued under section 906(d) of the FD&C Act, and discusses a number of technical and procedural issues relating to civil money penalties and no-tobacco-sale orders.

This guidance document describes the penalty structure and FDA policies with respect to civil money penalties and no-tobacco-sale orders. With the release of this final guidance document, several Tobacco Control Act provisions that relate to civil money penalties and no-tobacco-sale orders become effective (section 103(q)(3) of the Tobacco Control Act).

In the **Federal Register** of August 31, 2010 (75 FR 53316), FDA announced the availability of the draft guidance of the same title dated August 2010. FDA received a few comments on the draft guidance, and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity.

##### II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on "Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

##### III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments.

Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm> or <http://www.regulations.gov>.

Dated: April 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2006-D-0094]

#### Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled, "Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities." This guidance document was developed as a special control to support the reclassification of the topical oxygen chamber for extremities (TOCE) from class III (premarket approval) into class II (special controls). This guidance document describes a means by which manufacturers of TOCE may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule reclassifying these devices from class III into class II (special controls).

**DATES:** Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled, "Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities," to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and

Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240-276-3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Charles N. Durfor, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3555.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of April 6, 2006 (71 FR 17390), FDA's Center for Devices and Radiological Health (CDRH) published a proposed rule to reclassify the TOCE device type from class III (premarket approval) into class II (special controls) after reviewing current technological and scientific developments. To support the reclassification, CDRH issued a draft class II special controls guidance document entitled "Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities" (71 FR 17476). Interested persons were invited to comment on the proposed rule and guidance by July 5, 2006. FDA received 11 comments on the proposed rule. The comments received discussed academic literature, clinical experiences, and patient outcomes that support the proposed reclassification's determinations of the safety and effectiveness of the TOCE device. The comments did not recommend any changes to the proposed regulation.

FDA is now identifying the guidance document entitled "Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities" as the special control for these devices. This guidance document provides a means by which manufacturers of TOCE devices may comply with the requirement of special controls for class II devices. Following the effective date of the final reclassification rule, any manufacturer submitting a premarket notification submission under section 510(k) of the Federal Food, Drug, and

Cosmetic Act (the FD&C act) (21 U.S.C. 360(k)) for a TOCE device will need to address the issues covered in the special controls guidance document. However, the manufacturer need only show that its device meets the recommendations in the guidance document or in some other way provides equivalent assurances of safety and effectiveness.

##### II. Significance of Special Controls Guidance

FDA believes that adherence to the recommendations described in this guidance document, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of TOCE classified under § 878.5650 (21 CFR 878.5650). The final rule establishing this guidance document as a special control will be effective May 25, 2011. Following the effective date of the final rule, TOCE classified under § 878.5650 must comply with the requirement of special controls; manufacturers must address the issues requiring special controls as identified in the guidance, either by following the recommendations in the guidance or by some other means that provides equivalent assurances of safety and effectiveness.

##### III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/RegulatoryInformation/Guidances/default.htm> or <http://www.regulation.gov>. Always access an FDA guidance document by using FDA's Web site listed previously to find the most current version of the guidance.

##### IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information were subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520).

The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; and the collections of information in 21 CFR parts 50 and