Until 1951, the act did not contain criteria for determining when to limit a drug's approval to prescription use. Consequently, different manufacturers made different decisions about whether to market a drug as prescription or OTC. This resulted in confusion and uncertainty for pharmacists and consumers, and made it difficult for FDA to ensure that the only drugs available OTC were those that were safe for use without the supervision of a licensed medical practitioner.

To eliminate this confusion and uncertainty, and to protect the public health, Congress enacted the Durham-Humphrey Amendments in 1951 (Public Law 82–215, 65 Stat. 648). Congress had two primary objectives in enacting the Amendments: (1) To protect the public from abuses in the sale of potent Rx drugs; and (2) to relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs that are safe for use without the supervision of a physician. See S. Rep. No. 946, at 1 (1951), reprinted in 1951 U.S.C.C.A.N. 2454. To this end, the new legislation codified a statutory definition of prescription drug in section 503(b) of the act.

Section 503(b) of the act sets forth the Federal standard used to classify drugs as prescription or OTC, and it describes when and how to switch a drug from prescription to OTC status. Section 503(b)(1) of the act defines a prescription drug as:

(1) A drug intended for use by man which—

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug.

The act does not define ''OTC drug,'' but the term has been adopted to refer to any drug that does not meet the definition of prescription drug in section 503(b) of the act.

Given this dichotomy between prescription and OTC drugs, questions have arisen over the years about whether there are any conditions under which an active ingredient may be simultaneously marketed in both a prescription drug product and an OTC drug product. FDA has interpreted the language in 503(b)(1) of the act to allow marketing of the same active ingredient in products that are both prescription and OTC, assuming some meaningful difference exists between the two that makes the prescription product safe only under the supervision of a licensed practitioner. Examples of such drugs include: Meclizine (prescription for vertigo/OTC for nausea with motion sickness); Clotrimazol (prescription for candidiasis/OTC for athlete's foot, ring worm, jock itch); Loperamide (prescription for chronic diarrhea/OTC for acute diarrhea); Nicotine products (prescription for administration through inhalers and nasal sprays/OTC in gums, lozenges and patches); ibuprofren (prescription at 400mg+ for arthritis/OTC at 400mg and below for aches and pains); and H2 blockers (prescription at 300mg+ for ulcers/OTC at 200mg for heartburn). The key distinction in these examples is that there is some meaningful difference between the two products (e.g., indication, strength, route of administration, dosage form) that makes the prescription product safe only under the supervision of a licensed practitioner. To date, FDA has not allowed marketing of the same active ingredient in a prescription product for one population and in an OTC product for a subpopulation.

## II. Agency Request for Information

Despite the preceding examples, we recognize that FDA's interpretation of section 503(b) of the act has not been explicitly set forth in any of the regulations that discuss the process by which FDA classifies (or re-classifies) drugs as OTC or prescription. See, e.g., 21 CFR 310.200 and 310.201.

To address this concern, we therefore ask for comments on the following questions:

1.

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

C. If so, would a rulemaking on this issue help dispel that confusion?

2.

A. If FDA limited sale of an OTC product to a particular subpopulation, e.g., by making the product available to the subpopulation by prescription only, would FDA be able to enforce such a limitation as a matter of law?

B. If it could, would it be able to do so as practical matter and, if so, how?

3.

A. Assuming it is legal to market the same active ingredient in both a prescription and OTC product, may the different products be legally sold in the same package?

B. If the two products may be lawfully sold in a single package, under what circumstances would it be inappropriate to do so?

## III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Dated: August 26, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05–17390 Filed 8–26–05; 4:59 pm]

**BILLING CODE 4160–01–S**

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Part 1

**[REG–102144–04]**

**RIN 1545–BD10**

## Dual Consolidated Loss Regulations; Hearing Cancellation

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Cancellation of notice of public hearing on proposed rulemaking.

**SUMMARY:** This document cancels a public hearing on proposed regulations under section 1503(d) of the Internal Revenue Code (Code) regarding dual consolidated losses.

**DATES:** The public hearing originally scheduled for September 7, 2005, at 10 a.m., is cancelled.

**FOR FURTHER INFORMATION CONTACT:** Robin R. Jones of the Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration) at (202) 622–7180 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:** A notice of proposed rulemaking and notice of public hearing that appeared in the **Federal Register** on Tuesday, May 24, 2005 (70 FR 29868) announced that a public hearing was scheduled for September 7, 2005, at 10 a.m., in the IRS Auditorium, Internal Revenue Service

Building, 1111 Constitution Avenue, NW., Washington, DC. The subject of the public hearing is under section 1503(d) of the Internal Revenue Code. The public comment period for these regulations expired on August 17, 2005.

The notice of proposed rulemaking and notice of public hearing, instructed those interested in testifying at the public hearing to submit a request to speak and an outline of the topics to be addressed. As of Wednesday, August 24, 2005, no one has requested to speak. Therefore, the public hearing scheduled for September 7, 2005, is cancelled.

**Cynthia E. Grigsby,**

*Acting Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).*

[FR Doc. 05–17377 Filed 8–31–05; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 100

**[CGD05–05–107]**

**RIN 1625–AA08**

## Special Local Regulations for Marine Events; John H. Kerr Reservoir, Clarksville, VA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to establish special local regulations for the ''Clarksville Hydroplane Challenge'', a power boat race to be held on the waters of the John H. Kerr Reservoir adjacent to Clarksville, Virginia. These special local regulations are necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in portions of the John H. Kerr Reservoir adjacent to Clarksville, Virginia during the power boat race.

**DATES:** Comments and related material must reach the Coast Guard on or before September 16, 2005.

**ADDRESSES:** You may mail comments and related material to Commander (oax), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704–5004, hand-deliver them to Room 119 at the same address between 9 a.m. and 2 p.m., Monday through Friday, except Federal holidays, fax them to (757) 398–6203, or e-mail them to *DSens@lantd5@uscg.mil.* The Auxiliary and Recreational Boating Safety Branch, Fifth Coast Guard District, maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at the above address between 9 a.m. and 2 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Dennis Sens, Project Manager, Auxiliary and Recreational Boating Safety Branch, at (757) 398–6204.

**SUPPLEMENTARY INFORMATION:**

### Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking (CGD05–05–107), indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

In order to provide notice and an opportunity to comment before issuing an effective rule, we are providing a shorter than normal comment period. Because the event organizer provided the Coast Guard late notice of the event, there is not sufficient time for a full 45-day comment period. We believe that by providing the possibility of facsimile and e-mail submission options, this shorter period will provide the public with sufficient time to comment on this regulation that will only affect a small portion of the waterway for a short period of time.

We further anticipate that if a Final Rule is issued time constraints will require us to provide less than a 30-day period before the rule becomes effective. Immediate action is needed to protect the safety of life at sea from the danger posed by high-speed power boats. For the safety concerns noted, it is in the public interest to have the regulations in effect during the event.

### Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to the address listed under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

### Background and Purpose

On October 1 and 2, 2005, the Virginia Boat Racing Association will sponsor the ''Clarksville Hydroplane Challenge'', on the waters of the John H. Kerr Reservoir. The event will consist of approximately 60 inboard hydroplanes racing in heats counter-clockwise around an oval racecourse. A fleet of spectator vessels is anticipated to gather nearby to view the competition. Due to the need for vessel control during the event, vessel traffic will be temporarily restricted to provide for the safety of participants, spectators and transiting vessels.

### Discussion of Proposed Rule

The Coast Guard proposes to establish temporary special local regulations on specified waters of the John H. Kerr Reservoir adjacent to Occoneechee State Park, Clarksville, Virginia and State Route 15 Highway Bridge. The regulated area includes a section of the John H. Kerr Reservoir approximately one half mile long, and bounded in width by each shoreline. This rule will be enforced from 7:30 a.m. to 6:30 p.m. on October 1 and 2, 2005, and will restrict general navigation in the regulated area during the power boat race. The Coast Guard, at its discretion, when practical will allow the passage of vessels when races are not taking place. Except for participants and vessels authorized by the Coast Guard Patrol Commander, no person or vessel will be allowed to enter or remain in the regulated area during the enforcement period. These regulations are needed to control vessel traffic during the event to enhance the safety of participants, spectators and transiting vessels.

### Regulatory Evaluation

This proposed rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, 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 not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under the