

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b-360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b-263n.

2. Section 310.545 is amended by adding new paragraphs (a)(12)(iv)(C) and (d)(30), and by revising paragraph (d) introductory text to read as follows:

§ 310.545 Drug products containing active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(12) * * *

(iv)(C) *Stimulant laxatives*—

Approved as of (date of publication in the **Federal Register**).

Aloe

Bisacodyl

Cascara sagrada in any form (e.g., casanthranol, cascara fluidextract aromatic, cascara sagrada bark, cascara sagrada extract, cascara sagrada fluidextract)

Senna in any form (e.g., senna fluidextract, senna fruit extract, senna leaf powder, senna pod concentrate, senna syrup, or sennosides A and B)

* * * * *

(d) Any OTC drug product that is not in compliance with this section is subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the dates specified in paragraphs (d)(1) through (d)(30) of this section.

* * * * *

(30) (Date 6 months after date of publication in the **Federal Register**), for products subject to paragraph (a)(12)(iv)(C) of this section.

PART 334—LAXATIVE DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

3. The authority citation for 21 CFR part 334 is revised to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

§ 334.18 [Amended]

4. Section 334.18 *Stimulant laxative active ingredients* is amended by removing paragraphs (a), (b), (c)(1) through (c)(5), and (f) and redesignating paragraphs (d) and (e) as paragraphs (a) and (b), respectively.

§ 334.30 [Amended]

5. Section 334.30 *Permitted combinations of active laxative ingredients* is amended by removing and reserving paragraphs (c), (e), (g), (h), and (i).

§ 334.32 [Amended]

6. Section 334.32 *Bowel cleansing systems* is amended by removing and reserving paragraph (a).

§ 334.60 [Amended]

7. Section 334.60 *Labeling of stimulant laxative drug products* is amended by removing paragraphs (b)(3), (d)(1) through (d)(7), (d)(10), and (d)(11), by removing and reserving paragraph (c), and by redesignating paragraphs (d)(8) and (d)(9) as paragraphs (d)(1) and (d)(2), respectively.

§ 334.66 [Amended]

8. Section 334.66 *Labeling of bowel cleansing systems identified in § 334.32* is amended in paragraph (a) by removing “§ 334.32(a)” and adding in its place “§ 334.32” and by removing and reserving paragraphs (c)(1) and (d)(3)(iii)(A).

§ 334.80 [Amended]

9. Section 334.80 *Professional labeling* is amended in paragraph (a)(2) by removing the words “or bisacodyl identified in § 334.18(b)”, by removing paragraphs (a)(4) and (c)(5) through (c)(10), and by adding the word “or” after “§ 334.16(a)” in paragraph (a)(2), and by redesignating paragraphs (c)(11), (c)(12), and (c)(13) as paragraphs (c)(5), (c)(6), (c)(7), respectively.

Dated: June 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-16290 Filed 6-18-98; 8:45 am]

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DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 1**

[REG-209035-86]

RIN 1545-AI32

Foreign Liquidations and Reorganizations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Amendment to notice of proposed rulemaking.

SUMMARY: This document removes from an existing (1991) notice of proposed rulemaking the special (August 26, 1991) effective date rule for the definition of the all earnings and profits amount. The IRS and the Treasury Department believe that issues regarding the all earnings and profits amount should be studied; thus, when final

regulations under section 367(b) are issued with respect to the all earnings and profits amount, such regulations will have a prospective effective date. This modification may affect domestic corporations in connection with an acquisition of a foreign corporation in a liquidation described in section 332 or in an asset acquisition described in section 368(a)(1).

DATES: Written comments must be received by September 17, 1998.

ADDRESSES: Send submissions to: CC:DOM:CORP:R (REG-209035-86), Room 5228, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. In the alternative, submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:R (REG-209035-86), Courier's Desk, Internal Revenue Service, 1111 Constitution Ave. NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Philip L. Tretiak at (202) 622-3860 (not a toll-free call).

SUPPLEMENTARY INFORMATION:**Background**

Section 367(b) was enacted in its current form by the Tax Reform Act of 1976. On December 27, 1977, proposed and temporary regulations §§ 7.367(b)-1 through 7.367(b)-12 were adopted (TD 7530, 1978-1 C.B. 92). Prior to the issuance of a notice of proposed rulemaking in 1991 (the 1991 proposed regulations), discussed below, the regulations under section 367(b) were amended on several occasions. The 1991 proposed regulations, which were published in the **Federal Register** on August 26, 1991 (56 FR 41993), propose to completely revise the regulations under section 367(b), as well as the rules under section 367(a) with respect to certain transfers of stock or securities by U.S. persons to foreign corporations.

Section 1.367(b)-6(a) of the proposed regulations provides that the rules contained in the section 367(b) proposed regulations will be effective for exchanges that occur on or after the date that is 30 days after final regulations are published. However, an exception to the general effective date provides that § 1.367(b)-2(d) (relating to the definition and computation of the “all earnings and profits amount”) is effective for exchanges that occur on or after August 26, 1991.

A package of final regulations, published elsewhere in this issue of the **Federal Register**, contains final rules with respect to the section 367(a) portion of the 1991 proposed regulations (to the extent that such rules were not previously finalized) and final

rules with respect to the section 367(b) portion of the 1991 proposed regulations, but generally only to the extent that a particular transaction is subject to both sections 367(a) and (b). The final regulations do not address the all earnings and profits amount.

The IRS and the Treasury Department believe that issues regarding the all earnings and profits amount should be studied before final regulations are promulgated. Moreover, the IRS and the Treasury Department believe that the final regulations concerning the all earnings and profits amount should not be subject to a special effective date. Thus, this notice of proposed rulemaking removes from the 1991 proposed regulations the special (August 26, 1991) effective date rule for the definition of the all earnings and profits amount. When final regulations under section 367(b) are issued with respect to the all earnings and profits amount, such regulations will have a prospective effective date.

Special Analysis

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that this regulation does not have a significant impact on small entities because this regulation, which only contains a limited effective date rule, impacts only U.S. corporations with investments in foreign corporations. Thus, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply to these regulations, and therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) that are submitted timely to the Internal Revenue Service. All comments will be available for public inspection and copying.

Drafting Information

The principal author of these proposed regulations is Philip L. Tretiak of the Office of Associate Chief Counsel (International), IRS. However, other personnel from the IRS and the Treasury

Department participated in their development.

List of Subjects in 26 CFR Part 1

Income tax, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805. * * *

§ 1.367(b)–6 [Amended]

Par. 2. Section 1.367(b)–6, as proposed to be added on Monday, August 26, 1991 (56 FR 42015), is amended by removing the last sentence of paragraph (a).

Michael P. Dolan,

Deputy Commissioner of Internal Revenue.

[FR Doc. 98–15453 Filed 6–18–98; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD07–98–033]

RIN 2115–AE46

Special Local Regulations; St. Johns River, Jacksonville, Florida

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to amend the permanent special local regulations for the Annual Greater Jacksonville Kingfish Tournament, by increasing the size of the No Wake Zone on the waters of the St. Johns River and establishing the annual date of the event during the second full week of July. The increased size of the zone is needed to safeguard the increasingly larger number of participants and other vessels transiting the St. Johns River and Sisters Creek during the Annual Greater Jacksonville Kingfish Tournament. Vessel operators should use minimum speed in this area to avoid creating wakes, unless otherwise authorized by the Captain of the Port.

DATES: Comments must be received on or before July 9, 1998.

ADDRESSES: Comments may be mailed to Commander, U.S. Coast Guard Group Mayport, 4200 Ocean Street, Mayport,

FL 32233, or may be delivered to the operations office at the same address between 7:30 a.m. and 3:30 p.m., Monday through Friday, except federal holidays. Comments will become a part of the public docket and will be available for copying and inspection at the same address.

FOR FURTHER INFORMATION CONTACT:

Ensign Gary Watson, Group Mayport, Tel: (904) 247–7318.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written views, data, or arguments. Persons submitting comments should include their names, addresses, identify this rulemaking (CGD07–98–033), and the specific section of this proposal to which their comments apply, and give reasons for each comment.

The Coast Guard will consider all comments received during the comment period. The regulations may be changed in view of the comments received. The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the address under **ADDRESSES** and stating why a hearing would be beneficial. The comment period of twenty days is justified because the persons affected by this rulemaking are within the greater Jacksonville area and additional efforts are being made to notify that community of the rulemaking so they may be able to comment within the shortened period.

Background and Purpose

The event requiring this regulation is the Annual Greater Jacksonville Kingfish Tournament, which will be held annually during the second full week in July. It will begin in 1998 on July 14 in the Sisters Creek Marina, Sisters Creek, Jacksonville, Florida, at 6 a.m. and terminate at 4 p.m. each day until July 19. Due to the large number of participants and spectator craft, a larger No Wake Zone has been proposed on the waters of the St. Johns River lying between the eastern boundary formed by St. Johns River Lighted Buoy 7 position 30–23.56N, 081–23.04W, and Lighted Buoy 8 position 30–24.03N, 081–23.01W, and the western boundary formed by Lighted Buoy 25 position 30–23.40N, 081–28.26W, and Short Cut Light 26 position 30–23.46N, 081–28.16W with the northern and southern boundaries formed by the banks of the St. Johns River and extended north from the boundary formed by the St. Johns River and the Intracoastal Waterway, Sisters Creek, to Lighted Buoy 83 on the