

the appropriate Food and Drug Administration district office specified in part 5, subpart M of this chapter.

PART 107—INFANT FORMULA

■ 3. The authority citation for 21 CFR part 107 continues to read as follows:

Authority: 21 U.S.C. 321, 343, 350a, 371.

■ 4. Section 107.50 is amended by revising paragraph (e)(2) to read as follows:

§ 107.50 Terms and conditions.

* * * * *

(e) * * *

(2) The manufacturer shall promptly notify FDA when the manufacturer has knowledge (as defined in section 412(c)(2) of the act) that reasonably supports the conclusion that an exempt infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer may not provide the nutrients required by paragraph (b) or (c) of this section, or when there is an exempt infant formula that may be otherwise adulterated or misbranded and if so adulterated or misbranded presents a risk of human health. This notification shall be made, by telephone, to the Director of the appropriate FDA district office specified in part 5, subpart M of this chapter. After normal business hours (8 a.m. to 4:30 p.m.), contact the FDA Emergency Call Center at 866-300-4374. The manufacturer shall send a followup written confirmation to the Center for Food Safety and Applied Nutrition (HFS-605), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and to the appropriate FDA district office specified in part 5, subpart M of this chapter.

■ 5. Section 107.240 is amended by revising paragraph (b) to read as follows:

§ 107.240 Notification requirements.

* * * * *

(b) *Method of notification.* The notification made pursuant to § 107.240(a) shall be made, by telephone, to the Director of the appropriate Food and Drug Administration district office listed in part 5, subpart M of this chapter. After normal business hours (8 a.m. to 4:30 p.m.), contact the FDA Emergency Call Center at 866-300-4374. The manufacturer shall send written confirmation of the notification to the Center for Food Safety and Applied Nutrition (HFS-605), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and to the appropriate Food and Drug

Administration district office listed in part 5, subpart M of this chapter.

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PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

■ 6. The authority citation for 21 CFR part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360bbb, 371; 42 U.S.C. 262.

■ 7. Section 312.310 is amended by revising paragraph (d)(1) to read as follows:

§ 312.310 Individual patients, including for emergency use.

* * * * *

(d) * * *

(1) Emergency expanded access use may be requested by telephone, facsimile, or other means of electronic communications. For investigational biological drug products regulated by the Center for Biologics Evaluation and Research, the request should be directed to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 301-827-1800 or 1-800-835-4709, e-mail: ocod@fda.hhs.gov. For all other investigational drugs, the request for authorization should be directed to the Division of Drug Information, Center for Drug Evaluation and Research, 301-796-3400, e-mail: druginfo@fda.hhs.gov. After normal working hours (8 a.m. to 4:30 p.m.), the request should be directed to the FDA Emergency Call Center, 866-300-4374, e-mail: emergency.operations@fda.hhs.gov.

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PART 803—MEDICAL DEVICE REPORTING

■ 8. The authority citation for 21 CFR part 803 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

■ 9. Section 803.12 is amended by revising paragraph (c) to read as follows:

§ 803.12 Where and how do I submit reports and additional information?

* * * * *

(c) If an entity is confronted with a public health emergency, this can be brought to FDA's attention by contacting the FDA Office of Emergency Operations, Office of Crisis Management, Office of the Commissioner, at 866-300-4374, followed by the submission of an e-mail to emergency.operations@fda.hhs.gov or a fax report to 301-847-8544.

* * * * *

Dated: June 4, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-13820 Filed 6-8-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9485]

RIN 1545-BF28

Contributed Property

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations under section 704(c) of the Internal Revenue Code (Code) providing that the section 704(c) anti-abuse rule takes into account the tax liabilities of both the partners in a partnership and certain direct and indirect owners of such partners. These final regulations further provide that a section 704(c) allocation method cannot be used to achieve tax results inconsistent with the intent of subchapter K of the Code. The final regulations affect partnerships and their partners.

DATES: *Effective Date:* These final regulations are effective June 9, 2010.

Applicability Date: These final regulations are applicable for taxable years beginning after June 9, 2010.

FOR FURTHER INFORMATION CONTACT: Bryan A. Rimmke at (202) 622-3050 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to 26 CFR part 1 under section 704 of the Internal Revenue Code (Code). On May 19, 2008, a notice of proposed rulemaking (REG-100798-06, 2008-23 IRB 1135) was published in the **Federal Register** (73 FR 28765) in response to the Joint Committee on Taxation's recommendation that the partnership rules be strengthened to ensure that the allocation rules in the regulations under section 704(c) are not used to generate unwarranted benefits. *See The Report of Investigation of Enron Corporation and Related Entities Regarding Federal Tax and Compensation Issues, and Policy Recommendations*, (JCS-3-03) February 2003 at pg. 220. Because no requests to speak were submitted by August 18, 2008, no public hearing was held. Written comments, however, were

received in response to the notice of proposed rulemaking. After consideration of these comments, the proposed regulations are adopted without change by this Treasury decision.

Summary of Comments and Explanation of Provisions

The comments on the proposed regulations requested that examples be given to specifically describe the types of transactions to which these regulations apply. Additionally, the comments requested examples to describe the types of transactions which would not be abusive under this regulation but would be abusive under the general subchapter K anti-abuse rule found in § 1.701-2. In light of the fact that these regulations are anti-abuse provisions and the factually intensive analysis needed to determine whether this regulation is applicable, the Treasury Department and the IRS decline to adopt these comments.

Additional comments requested that the Treasury Department and the IRS consider both a de minimis partner rule for direct partners similar to § 1.704-1(b)(2)(iii) and a rule for indirect partners where the owners would need to be related to the look-through entity within the meaning of sections 267 or 707 in order to be considered indirect partners for the purposes of the regulation. For purposes of § 1.704-1(b)(2)(iii), a de minimis partner is any partner, including a look-through entity, that owns less than 10 percent of the capital and profits of a partnership, and who is allocated less than 10 percent of each partnership item. The Treasury Department and the IRS have determined that neither a de minimis partner provision nor a related partner provision for indirect partners would conform to the intent of this anti-abuse provision and therefore decline to adopt such rules.

This Treasury decision adopts the proposed regulations without substantive change. Accordingly, the regulations amend § 1.704-3(a)(10) to provide that, for purposes of applying the anti-abuse rule, both direct and indirect partners are considered. The final regulations provide that an indirect partner is any direct or indirect owner of a partnership, S corporation, or controlled foreign corporation (as defined in section 957(a) or 953(c)), or direct or indirect beneficiary of a trust or estate, that is a partner in the partnership, and any consolidated group of which the partner in the partnership is a member (within the meaning of § 1.1502-1(h)). However, an owner of a controlled foreign corporation is treated

as an indirect partner only with respect to the allocation of items that enter into the computation of a United States shareholder's inclusion under section 951(a) with respect to the controlled foreign corporation, enter into any person's income attributable to a United States shareholder's inclusion under section 951(a) with respect to the controlled foreign corporation, or would enter into the computations described in this paragraph if such items were allocated to the controlled foreign corporation.

These final regulations further provide that the principles of section 704(c), together with the allocation methods described in § 1.704-3, paragraphs (b), (c) and (d), apply only with respect to the contributions of property to the partnership. In that regard, the anti-abuse rule of § 1.701-2(b) provides that, if a partnership is formed or availed of in connection with a transaction a principal purpose of which is to reduce substantially the present value of the partners' Federal tax liability in a manner inconsistent with the intent of subchapter K, the IRS may recast the transaction for Federal tax purposes as appropriate to achieve tax results that are consistent with the intent of subchapter K. Thus, even though a transaction may satisfy the literal words of the statute or regulations, the IRS may recast a transaction as appropriate to avoid tax results that are inconsistent with the intent of subchapter K, including but not limited to: (i) Disregarding purported partnerships, in whole or part, so that partnership assets are treated as owned by the partner; (ii) disregarding one or more contributions or (iii) disregarding one or more purported partners. The final regulations also provide that, in determining if a purported contribution of property to a partnership should be recast to avoid results that are inconsistent with subchapter K, one factor that may be relevant is the use of the remedial method in which allocations of remedial items of income, gain, loss or deduction are made to one partner and allocations of offsetting remedial items are made to a related partner.

Effective/Applicability Date

These regulations apply to taxable years beginning after June 9, 2010. No inference should be drawn from this effective date with respect to prior law.

Special Analyses

It has been determined that this Treasury decision 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 section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these final regulations is Bryan A. Rimmke, Office of the Associate Chief Counsel (Passthroughs and Special Industries), IRS. However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

■ Accordingly, 26 CFR part 1 is 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 * * *

■ **Par. 2.** Section 1.704-3 is amended by:

■ 1. Adding four sentences to paragraph (a)(1) at the end of the last sentence and revising paragraph (a)(10).

■ 2. Revising the first sentence of paragraph (f) and adding one sentence to the end of the paragraph.

The revisions and additions read as follows:

§ 1.704-3 Contributed property.

(a) * * * (1) * * * The principles of this paragraph (a)(1), together with the methods described in paragraphs (b), (c) and (d) of this section, apply only to contributions of property that are otherwise respected. See for example § 1.701-2. Accordingly, even though a partnership's allocation method may be described in the literal language of paragraphs (b), (c) or (d) of this section, based on the particular facts and circumstances, the Commissioner can recast the contribution as appropriate to avoid tax results inconsistent with the intent of subchapter K. One factor that

may be considered by the Commissioner is the use of the remedial allocation method by related partners in which allocations of remedial items of income, gain, loss or deduction are made to one partner and the allocations of offsetting remedial items are made to a related partner.

* * * * *

(10) *Anti-abuse rule*—(i) *In general.* An allocation method (or combination of methods) is not reasonable if the contribution of property (or event that results in reverse section 704(c) allocations) and the corresponding allocation of tax items with respect to the property are made with a view to shifting the tax consequences of built-in gain or loss among the partners in a manner that substantially reduces the present value of the partners' aggregate tax liability. For purposes of this paragraph (a)(10), all references to the partners shall include both direct and indirect partners.

(ii) *Definition of indirect partner.* An *indirect partner* is any direct or indirect owner of a partnership, S corporation, or controlled foreign corporation (as defined in section 957(a) or 953(c)), or direct or indirect beneficiary of a trust or estate, that is a partner in the partnership, and any consolidated group of which the partner in the partnership is a member (within the meaning of § 1.1502-1(h)). An owner (whether directly or through tiers of entities) of a controlled foreign corporation is treated as an indirect partner only with respect to allocations of items of income, gain, loss, or deduction that enter into the computation of a United States shareholder's inclusion under section 951(a) with respect to the controlled foreign corporation, enter into any person's income attributable to a United States shareholder's inclusion under section 951(a) with respect to the controlled foreign corporation, or would enter into the computations described in this sentence if such items were allocated to the controlled foreign corporation.

* * * * *

(f) *Effective/Applicability Dates.* With the exception of paragraphs (a)(1), (a)(8)(ii), (a)(8)(iii), (a)(10), and (a)(11) of this section, this section applies to properties contributed to a partnership and to restatements pursuant to § 1.704-1(b)(2)(iv)(f) on or after December 21, 1993. * * * Paragraphs (a)(1) and (a)(10) of this section are applicable for taxable years beginning after June 9, 2010.

Approved: May 28, 2010.

Linda E. Stiff,

Deputy Commissioner for Services and Enforcement.

Michael Mundaca,

Assistant Secretary of the Treasury (Tax Policy).

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2010-0435]

RIN 1625-AA08

Special Local Regulation; Hydroplane Exhibition, Detroit River, Detroit, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard will enforce a temporary special local regulation on the Detroit River, Detroit, Michigan from June 18, 2010 to June 20, 2010. This special local regulation is intended to restrict vessels from portions of the Detroit River during the Hydroplane Exhibition. This special local regulation is necessary to protect spectators and vessels from the hazards associated with powerboat races.

DATES: This regulation is effective from 3 p.m. on June 18, 2010, to 5 p.m. on June 20, 2010.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2010-0435 and are available online by going to <http://www.regulations.gov>, inserting USCG-2010-0435 in the "Keyword" box, and then clicking "Search." They are also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail CDR Joseph Snowden, Prevention Department, Sector Detroit, Coast Guard; telephone (313) 568-9508, e-mail Joseph.H.Snowden@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the permit application for the Hydroplane Exhibition event was not received by the Coast Guard in time to publish an NPRM followed by a final rule before the effective date. Delaying this rule would be contrary to the public interest of ensuring the safety of vessels during the race, and immediate action is necessary to prevent possible loss of life and property. The Coast Guard has not received any complaints or negative comments previously with regard to events of this type and duration.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying this rule would be contrary to the public interest of ensuring the safety of vessels during the construction, and immediate action is necessary to prevent possible loss of life and property. The Coast Guard has not received any complaints or negative comments previously with regard to events of this type and duration.

Background and Purpose

This temporary special local regulation is necessary to ensure the safety of vessels and spectators from hazards associated with a powerboat race. The Captain of the Port Detroit has determined that powerboat races in close proximity to watercraft and waterfront structures pose a significant risk to public safety and property. The likely combination of large numbers of recreational vessels, powerboats traveling at high speeds, and large numbers of spectators in close proximity to powerboats on the water pose a significant risk of serious injuries or fatalities. Establishing a special local regulation around the location of the race course will help ensure the safety of persons and property at these events and help minimize the associated risks.