

measure infant growth, and would not discourage clinical studies for this time period, FDA believes it is not necessary to conduct a clinical study, for the purpose of evaluating physical growth as a quality factor, for the infants' entire first 6 months of age.

FDA proposed that a clinical study be no less than 4 months in duration, enrolling infants no more than 1 month old at the time of entry into the study. FDA received several comments on this issue, both in response to the 1996 proposed rule and in response to the 2003 proposed rule. None of the comments were in favor of a study duration requirement of 6 months. The comments FDA received favored a duration requirement ranging between 112 and 120 days, and recommended an enrollment requirement of between the age of 8 days and 1 month.

To better capture the maximum amount of time during the most rapid growth period for infants, FDA is considering whether to require a time period for clinical studies of a period of no less than 15 weeks that would commence at no more than 2 weeks of age. FDA believes 15 weeks provides a sufficient amount of time for assessing the physical growth of infants. Given this relatively short time period and the importance of a sufficient length of time for determining growth outcomes, FDA believes it is important to require that the study commence no later than 2 weeks of age. These changes would result in a clinical study extending through approximately the infant's first 4 months of age. A required study duration of no less than 15 weeks corresponds to the Iowa reference data recommendations regarding the duration of a clinical study. FDA requests comments on whether, in light of the IOM report's 180-day recommendation, FDA should consider requiring a study period of no less than the infant's first 180 days (6 months). Comments should include any available supporting data and information.

III. What Comments Will Be Considered?

Comments submitted in response to this proposed rule should focus solely on one or more of the following issues: (1) Whether FDA should require a microbiological standard for *E. sakazakii* for powdered infant formula of negative in 30 x 10 g samples; (2) whether FDA should not require microbiological standards for aerobic plate count, coliforms, fecal coliforms, *Listeria monocytogenes*, *Staphylococcus aureus*, and *Bacillus cereus*; (3) whether FDA should require measurements of healthy growth beyond the two

proposed quality factors of normal physical growth (as measured by body weight, recumbent length, head circumference, and average daily weight increment) and protein quality; (4) whether FDA should require a measure for body composition as an indicator of normal physical growth, and if so, what measure, and (5) whether FDA should require the duration for a clinical study, if required, be no less than 15 weeks, and commence when infants are no older than 2 weeks of age. FDA requests comments on how, if we make the changes to the proposed rule outlined in this document, the costs and benefits would either be greater or less than estimated in the 1996 proposed rule (61 FR 36154 at 36202). We also request comment on the extent to which the description of industry practices in the Rome meeting report (Ref. 2) accurately describes the activities of all firms supplying infant formula in the United States. Data supplied in response to these questions will be used to inform any rulemaking. FDA will not consider comments outside the scope of these issues.

Comments previously submitted to the Division of Dockets Management do not need to be resubmitted, because all comments submitted to the docket number, found in brackets in the heading of this document, will be considered in development of the final rule.

IV. How to Submit 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 Docket Management between 9 a.m. and 4 p.m., Monday through Friday.

V. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. The Food and Agriculture Organization of the United Nations and the World Health Organization, "*Enterobacter sakazakii* and Other Microorganisms in Powdered Infant

Formula: Joint FAO/WHO Meeting 2–4 February 2004," available at http://www.fao.org/documents/show_cdr.asp?url_file=/docrep/007/y5502e/y5502e00.htm (last visited May 10, 2006).

2. The Food and Agriculture Organization of the United Nations and the World Health Organization, "*Enterobacter sakazakii* and *Salmonella* in Powdered Infant Formula: Meeting Report, FAO Headquarters, Rome, Italy, 16–20 January 2006," available at ftp://ftp.fao.org/ag/agn/jemra/e_sakazakii_salmonella.pdf (last visited May 10, 2006).

3. Committee on the Evaluation of Ingredients New to Infant Formula, "Infant Formula: Evaluating the Safety of New Ingredients," National Institute of Medicine, March 1, 2004.

Dated: July 24, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–12268 Filed 7–31–06; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–159929–02]

RIN 1545–BB84

REMIC Residual Interests—Accounting for REMIC Net Income (Including Any Excess Inclusions (Foreign Holders))

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the rules and regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations relating to the income that is associated with a residual interest in a Real Estate Mortgage Investment Conduit (REMIC) and that is allocated through certain entities to foreign persons who have invested in those entities. The regulations accelerate the time when income is recognized for withholding tax purposes to conform to the timing of income recognition for general tax purposes. The foreign persons covered by these regulations include partners in domestic partnerships, shareholders of real estate investment trusts, shareholders of regulated investment companies, participants in common trust funds, and patrons of subchapter T cooperatives. These regulations are necessary to prevent inappropriate avoidance of current income tax liability by foreign persons to whom income from REMIC

residual interests is allocated. The regulations clarify the timing of income under section 860G for purposes of determining a domestic partnership's responsibility under sections 1441 and 1442 for withholding tax with respect to a foreign partner's share of REMIC net income as a result of indirectly holding a residual interest. The regulations also provide that an excess inclusion is treated as income from sources within the United States. The text of those temporary regulations also serves as the text of these proposed regulations.

DATES: Written or electronic comments and requests for a public hearing must be received by October 30, 2006.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG-159929-02), room 5203, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Alternatively, taxpayers may submit electronic comments directly to the IRS Internet site at <http://www.irs.gov/regs> or the Federal eRulemaking Portal at <http://www.regulations.gov> (IRS-REG-159929-02).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Dale Collinson, (202) 622-3900 (not a toll-free number); concerning the submission of comments, or a request for a public hearing, Kelly Banks (Kelly.D.Banks@irs.counsel.treas.gov).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** amend the Income Tax Regulations (26 CFR part 1) relating to sections 860A, 860G, 863, 1441, and 1442 of the Internal Revenue Code (Code). The temporary regulations provide rules relating to the recognition and sourcing of income and related withholding issues associated with a Real Estate Mortgage Investment Conduit (REMIC) residual interest that is allocated to a foreign person, including a foreign partner in a domestic partnership. The text of the temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the amendments.

Special Analyses

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 is hereby certified that these regulations will not have a significant economic impact on a substantial number of small

entities. This certification is based upon the fact that the regulations do not impose any new or different requirements on small entities. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the 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 and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and Treasury Department request comments on the clarity of the proposed rules and how they can be made easier to understand. All comments will be available for public inspection and copying. A public hearing will be scheduled if requested in writing by any person who timely submits written comments. If a public hearing is scheduled, notice of the date, time and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these regulations is Dale Collinson, Office of the Associate Chief Counsel (Financial Institutions and Products). 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.

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 is amended by adding an entry in numerical order to read, in part, as follows:

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

§ 1.860A-1 also issued under 26 U.S.C. 860G(b) and 860G(e). * * *

Par. 2. In § 1.860A-1, paragraph (b)(5) is added to read as follows:

§ 1.860A-1 Effective dates and transition rules.

* * * * *

(b) * * *

(5) [The text of the proposed amendment to § 1.860A-1(b)(5) is the same as the text of § 1.860A-1T(b)(5) published elsewhere in this issue of the **Federal Register**].

Par. 3. In § 1.860G-3, paragraph (b) is added to read as follows:

§ 1.860G-3 Treatment of foreign persons.

* * * * *

(b) [The text of the proposed amendment to § 1.860G-3(b) is the same as the text of § 1.860G-3T(b) published elsewhere in this issue of the **Federal Register**].

Par. 4. Section 1.863-1 is amended as follows:

1. The paragraph heading for paragraph (e) is revised.

2. The text of paragraph (e) is redesignated as (e)(1).

3. A new paragraph heading for paragraph (e)(1) is added.

4. A new paragraph (e)(2) is added.

5. The last sentence of paragraph (f) is revised and a new sentence is added to the end.

The revisions and additions read as follows:

§ 1.863-1 Allocation of gross income under section 863(a).

* * * * *

(e) *Residual interest in a REMIC—*(1) *REMIC inducement fees.* * * *

(2) [The text of the proposed amendment to § 1.863-1(e)(2) is the same as the text of § 1.863-1T(e)(2) published elsewhere in this issue of the **Federal Register**].

(f) [The text of proposed amendment to § 1.863-1(f) is the same as the text of § 1.863-1T(f) published elsewhere in this issue of the **Federal Register**].

Par. 5. Section 1.1441-2 is amended by adding paragraphs (b)(5) and (d)(4) and a sentence to the end of paragraph (f) to read as follows:

§ 1.1441-2 Amounts subject to withholding.

* * * * *

(b) * * *

(5) [The text of the proposed amendment to § 1.1441-2(b)(5) is the same as the text of § 1.1441-2T(b)(5) published elsewhere in this issue of the **Federal Register**].

* * * * *

(d) * * *

(4) [The text of the proposed amendment to § 1.1441-2(d)(4) is the same as the text of § 1.1441-2T(d)(4) published elsewhere in this issue of the **Federal Register**.]

* * * * *

(f) [The text of the proposed amendment to § 1.1441-2T(f)(1) is the same as the text of § 1.1441-2T(f)(1)]

published elsewhere in this issue of the **Federal Register**.

Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

[FR Doc. E6-12364 Filed 7-31-06; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[CGD05-06-075]

RIN 1625-AA08

Special Local Regulations for Marine Events; Back River, Poquoson, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish special local regulations during the "Poquoson Seafood Festival Workboat Races", a marine event to be held October 15, 2006 on the waters of the Back River, Poquoson, 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 temporarily restrict vessel traffic in a portion of the Back River during the event.

DATES: Comments and related material must reach the Coast Guard on or before August 31, 2006.

ADDRESSES: You may mail comments and related material to Commander (dpi), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704-5004, hand-deliver them to Room 415 at the same address between 9 a.m. and 2 p.m., Monday through Friday, except Federal holidays, or fax them to (757) 398-6203. The Inspections and Investigations 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 of 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, Fifth Coast Guard District, Inspections and Investigation 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 (CGD05-06-075), 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.

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 15, 2006, the City of Poquoson will sponsor "Poquoson Seafood Festival Workboat Races" on the Back River, immediately adjacent and south of Messick Point. The event will consist of approximately 60 traditional Chesapeake Bay deadrise workboats racing along a marked strait line race course in heats of 2 to 4 boats for a distance of approximately 600 yards. Due to the need for vessel control during the event, the Coast Guard will temporarily restrict vessel traffic in the event area to provide for the safety of participants, spectators and other transiting vessels.

Discussion of Proposed Rule

The Coast Guard proposes to establish temporary special local regulations on specified waters of the Back River, Poquoson, Virginia. The regulations will be in effect from 12 p.m. to 5 p.m. on October 15, 2006. The effect will be to restrict general navigation in the regulated area during the event. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area. Vessel traffic will be allowed to transit the regulated area at slow speed between heats, when the Coast Guard Patrol Commander determines it is safe to do so. 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 regulatory policies and procedures of DHS is unnecessary. Although this regulation will prevent traffic from transiting a portion of the Back River during the event, the effect of this regulation will not be significant due to the limited duration that the regulated area will be in effect and the extensive advance notifications that will be made to the maritime community via the Local Notice to Mariners, marine information broadcasts, area newspapers and local radio stations, so mariners can adjust their plans accordingly. Additionally, the regulated area has been narrowly tailored to impose the least impact on general navigation yet provide the level of safety deemed necessary. Vessel traffic will be able to transit the regulated area at slow speed between heats, when the Coast Guard Patrol Commander deems it safe to do so.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed rule would affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit or anchor in the affected portions of the Back River during the event.

Although this regulation prevents traffic from transiting a portion of the