

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 106 and 107

[Docket No. 1995N-0309]

RIN 0910-AA04

Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports for the Production of Infant Formula; Extension of Reopened Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of reopened comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to August 26, 2003, the comment period, reopened on April 28, 2003, for the proposed rule published in the **Federal Register** of July 9, 1996 (61 FR 36154). The proposed rule would establish requirements for current good manufacturing practice (CGMP) and audits, establish requirements for quality factors, and amend quality control procedures, notification, and records and reports requirements for infant formula. This action is being taken in response to a request for more time to submit comments to FDA.

DATES: Submit written or electronic comments on the proposed rule by August 26, 2003.

ADDRESSES: Submit written comments 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.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Shellee Anderson, Center for Food Safety and Applied Nutrition (HFS-800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park,

MD 20740, 301-436-1491, or e-mail: Shellee.Anderson@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 9, 1996 (61 FR 36154), FDA proposed regulations to revise its infant formula regulations to establish requirements for quality factors and CGMP; to amend quality control procedure, notification, and records and report requirements for infant formulas; to require that infant formulas contain, and be tested for, required nutrients and for any nutrient added by the manufacturer throughout their shelf life, and that they be produced under strict microbiological controls; and to require that manufacturers implement the CGMP and quality control procedure requirements by establishing a production and in-process control system of their own design.

In the **Federal Register** of April 28, 2003 (68 FR 22341), FDA announced that the time period for public comment would be reopened to June 27, 2003. On May 6, 2003, FDA received a request to extend the reopened comment period to allow interested persons additional time to comment. The requester asserts that the time period of 60 days is insufficient to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address the original proposal in light of new issues that have arisen since 1996.

FDA believes that an extension of the reopened comment period is appropriate, given the variety of issues raised by the proposed rule and the April 28, 2003, document. However, because the agency wants to move forward on finalizing the rule as quickly as possible, FDA is extending the comment period only for an additional 60 days, until August 26, 2003. This extension will provide the public with a total of 120 days to submit comments during the reopened comment period.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the proposal. 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 numbers 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: June 23, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-16357 Filed 6-26-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG-108676-03]

RIN 1545-BC00

Distributions of Interests in a Loss Corporation from Qualified Trusts

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations and notice of public hearing.

SUMMARY: This document contains proposed regulations under section 382 of the Internal Revenue Code of 1986. The proposed regulations affect loss corporations and provide guidance on whether a loss corporation has an ownership change where a qualified trust described in section 401(a) distributes an ownership interest in an entity. The text of the temporary regulations published in this issue of the **Federal Register** serves as the text of these proposed regulations.

DATES: Written or electronic comments and requests for a public hearing must be received by September 25, 2003.

ADDRESSES: Send submissions to: CC:PA:RU (REG-108676-03), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:RU (REG-108676-03), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC. Alternatively, taxpayers may submit electronic comments directly to the IRS Internet site at <http://www.irs.gov/regs>.

FOR FURTHER INFORMATION CONTACT:

Concerning the proposed regulations, Martin Huck, (202) 622-7750; concerning submissions of comments and/or requests for a public hearing, Treena Garrett, (202) 622-7180 (not toll-free numbers).

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 section 382. The temporary regulations provide rules for determining whether a loss corporation has an ownership change where a qualified trust described in section 401(a) distributes an ownership interest in an entity. The text of those regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the amendments and these proposed regulations.

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 proposed regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the regulations provide relief to qualifying loss corporations that might be affected by an unintended consequence of the operation of the statute. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Nevertheless, the IRS and Treasury request comments from small entities that believe they might be adversely affected by these regulations. 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 their impact.

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. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested in writing by any person that timely submits written comments. If a public

hearing is scheduled, notice of the date, time, and place for the hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these regulations is Martin Huck, Office of Associate Chief Counsel (Corporate). 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 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 * * *

Section 1.382-10 is also issued under 26 U.S.C. 382(m). * * *

Par. 2. Section 1.382-1 is amended by revising the entry for § 1.382-10 to read as follows:

§ 1.382-10 Special rules for determining time and manner of acquisition of an interest in a loss corporation (temporary).

Par. 3. Section 1.382-10 is added to read as follows:

§ 1.382-10 Special rules for determining time and manner of acquisition of an interest in a loss corporation (temporary).

[The text of proposed § 1.382-10 is the same as the text of § 1.382-10T published elsewhere in this issue of the **Federal Register**].

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

[FR Doc. 03-16230 Filed 6-26-03; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY**Alcohol and Tobacco Tax and Trade Bureau****27 CFR Part 9**

[Notice No. 12]

RIN 1512-AC78

Proposed McMinnville Viticultural Area (2002R-217P)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau (TTB), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau proposes to establish the "McMinnville" viticultural area in Yamhill County, Oregon, within the existing Willamette Valley viticultural area. The proposed viticultural area would include only the land at and between the elevations of 200 feet and 800 feet within the described boundaries. We propose to amend the regulations to include this area, and we invite comments on this proposal, especially from those whose brand names may be affected by this proposal.

DATE: We must receive written comments by August 26, 2003.

ADDRESSES: You may send comments to any of the following addresses—

- Chief, Regulations and Procedures Division, Alcohol and Tobacco Tax and Trade Bureau, P.O. Box 50221, Washington, DC 20091-0221 (Attn: Notice No. 12);

- 202-927-8525 (facsimile);
- NPRM@ttb.gov (e-mail); or
- <http://www.ttb.gov> (An online comment form is posted with this Notice on our Web site).

You may view copies of this notice and any comments received at <http://www.ttb.gov/alcohol/rules/index.htm> or by appointment at the ATF Reference Library, 650 Massachusetts Avenue, NW., Washington, DC 20226; phone 202-927-7890.

See the **Public Participation** section of this Notice for specific instructions and requirements, as well as information on how to request a public hearing.

FOR FURTHER INFORMATION CONTACT: Jennifer Berry, Alcohol and Tobacco Tax and Trade Bureau, Regulations and Procedures Division, P.O. Box 18152, Roanoke, VA 24014; telephone 540-344-9333.

SUPPLEMENTARY INFORMATION:**Background on Viticultural Areas**

What Is TTB's Authority To Establish a Viticultural Area?

The Federal Alcohol Administration Act (FAA Act) at 27 U.S.C. 205(e) requires that alcohol beverage labels provide the consumer with adequate information regarding a product's identity, while prohibiting the use of deceptive information on such labels. The FAA Act also authorizes the Secretary of the Treasury to issue regulations to carry out its provisions.

Regulations in 27 CFR Part 4, Labeling and Advertising of Wine, allow the establishment of definitive viticultural areas and the use of their names as appellations of origin on wine labels and in wine advertisements. Title 27 CFR Part 9, American Viticultural