such suspension, revocation, modification or addition of further limitations will not have the effect of modifying the allocation of sugar made pursuant to the provisions of subdivision (b) of additional U.S. Note 5.

* * * * *

9. Section 2011.201 is revised to read as follows:

§ 2011.201 General.

This subpart sets forth the terms and conditions under which certificates will be issued to U.S. importers for importing specialty sugars from specialty sugar source countries. Specialty sugars imported from specialty sugar source countries may not be entered unless accompanied by a specialty sugar certificate. This subpart applies only to the ability to enter specialty sugar at the in-quota tariff rates of the quota (subheadings 1701.11.10, 1701.12.10, 1701.91.10, 1701.99.10, 1702.90.10, and 2106.90.44 of the HTS). Nothing in this subpart shall affect the ability to enter articles at the over-quota tariff rate (subheadings 1701.11.50, 1701.12.50, 1701.91.30, 1701.99.50, 1702.90.20, 2106.90.46).

10. Section 2011.202 is amended by removing paragraph (g), redesignating paragraphs (h) through (j) as paragraphs (g) through (i), respectively, revising paragraphs (b), (c), (f), (g), and (i), as redesignated, and adding a new paragraph (j) as follows:

§ 2011.202 Definitions.

* * * * *

(b) ''Certificate'' means a specialty sugar certificate issued by the Certifying Authority permitting the entry of specialty sugar.

(c) ''Certifying Authority'' means the Team Leader, Import Quota Programs, Foreign Agricultural Service, U.S. Department of Agriculture, or his or her designee.

* * * * *

(f) ''Person'' means any individual, partnership, corporation, association, estate, trust, or other legal entity, and, wherever applicable, any unit, instrumentality, or agency, of a government, domestic or foreign.

(g) ''Quota'' means the tariff-rate quota on imports of sugar provided in additional U.S. Note 5 to chapter 17 of the Harmonized Tariff Schedule of the United States.

* * * * *

(i) ''Specialty sugar'' means brown slab sugar (also known as slab sugar candy), pearl sugar (also known as perl sugar, perle sugar, and nibs sugar), vanilla sugar, rock candy, demerara sugar, dragees for cooking and baking, fondant (a creamy blend of sugar and glucose), ti light sugar (99.2% sugar with the residual comprised of the artificial sweeteners aspartame and acesulfame K), caster sugar, golden syrup, ferdiana granella grossa, golden granulated sugar, muscovado, molasses sugar, sugar decorations, sugar cubes, and other sugars, as determined by the United States Trade Representative, that would be considered specialty sugar products within the normal commerce of the United States, all of which in addition:

(1) are sugars, syrups, or molasses described in subheading 1701.11.10, 1701.12.10, 1701.91.10, 1701.99.10, 1702.90.10, or 2106.90.44 of the Harmonized Tariff Schedule of the United States,

(2) are the product of a specialty sugar source country, and

* * * * *

(j) ''Specialty sugar source country'' means any country or area to which the United States Trade Representative has allocated an amount of the quantity reserved for the importation of specialty sugars under additional U.S. Note 5 to chapter 17 of the Harmonized Tariff Schedule of the United States.

11. Section 2011.203 is amended by revising paragraphs (a) and (c) to read as follows:

§ 2011.203 Issuance of specialty sugar certificates.

(a) Specialty sugars imported into the United States from specialty sugar source countries may be entered only if such specialty sugars are accompanied by a certificate issued by the Certifying Authority.

* * * * *

(c) Subject to quota availability, an unlimited number of complying shipments may enter under a given certificate and a given certificate may cover more than one type of specialty sugar. Issuance of a certificate does not guarantee the entry of any specific shipment of specialty sugar, but only permits entry of such sugar if the amount allocated to the specialty sugar source country is not already filled.

12. Section 2011.204 is revised to read as follows:

§ 2011.204 Entry of specialty sugars.

An importer or the importer's agent must present a certificate to the appropriate customs official at the date of entry of specialty sugars. Entry of specialty sugars shall be allowed only in conformity with the description of sugars and other conditions, if any, stated in the certificate.

13. Section 2011.206 is amended by revising paragraph (c) to read as follows:

§ 2011.206 Suspension or revocation of individual certificates.

* * * * *

(c) The determination of the Certifying Authority under paragraph (a) that the importer has failed to comply with the requirements of this subpart may be appealed to the Director, Import Policy and Trade Analysis Division, Foreign Agricultural Service (FAS), U.S. Department of Agriculture, Washington, D.C. 20250, within 30 days from the date of suspension or revocation. The request for reconsideration shall be presented in writing and shall specifically state the reason or reasons why such determination should not stand. The Director shall provide such person with an opportunity for an informal hearing on such matter. A further appeal may be made to the Administrator, FAS, U.S. Department of Agriculture, Washington, D.C. 20250, within five working days of receipt of the notification of the Director's decision. The Certifying Authority may take action under paragraph (b) during the pendency of any appeal.

14. Section 2011.207(a) is revised to read as follows:

§ 2011.207 Suspension of the certificate system.

(a) Suspension. The U.S. Trade Representative may suspend the provisions of this subpart whenever he or she determines that the quota is no longer in force or that this subpart is no longer necessary to implement the quota. Notice of such suspension and the effective date thereof shall be published in the Federal Register.

* * * * *

15. Subpart B of part 2011 is amended by adding § 2011.208 to read as follows:

§ 2011.208 Paperwork Reduction Act assigned number.

The Office of Management and Budget (OMB) has approved the information collection requirements contained in the regulations in this subpart in accordance with 44 U.S.C. Chapter 25 and OMB control number 0551–0014 has been assigned with corresponding clearance effective through April 30, 1997.

Subpart C—[Removed]

16. Subpart C of part 2011 is removed.

Signed at Washington, D.C. on May 15, 1996.

Charlene Barshefsky

Acting United States Trade Representative

[FR Doc. 96–12807 Filed 5–28–96; 8:45 am]

BILLING CODE 3190–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 94F–0189]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Dimethyl Dicarbonate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of dimethyl dicarbonate (DMDC) as a yeast inhibitor in sports drinks and fruit or juice sparklers. This action is in response to a petition filed by Miles, Inc. (now Bayer Corp.).

DATES: Effective May 29, 1996; written objections and requests for a hearing by June 28, 1996.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Martha D. Peiperl, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3077.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the Federal Register of June 28, 1994 (59 FR 33299), FDA announced that a food additive petition (FAP 4A4420) had been filed by Miles, Inc., Mobay Rd., Pittsburgh, PA 15205–9741 (now Bayer Corp., 100 Bayer Rd., Pittsburgh, PA 15205–9741), proposing that the food additive regulations in § 172.133 *Dimethyl dicarbonate* (21 CFR 172.133) be amended to provide for the safe use of DMDC as a yeast inhibitor in sports drinks and fruit or juice sparklers. The petition defines sports drinks as carbonated or noncarbonated, nonjuice-containing (less than or equal to 1 percent juice), flavored or unflavored beverages containing added electrolytes (5–20 milliequivalents (meq)/liter sodium ion (Na+) and 3–7 meq/liter potassium ion (K+)). Fruit or juice sparklers are defined as carbonated, dilute beverages containing juice, fruit flavor, or both, with juice content not to exceed 50 percent.

DMDC is currently approved in § 172.133 for use as a yeast inhibitor in wine, dealcoholized wine, and low alcohol wine (53 FR 41325, October 21, 1988; and 58 FR 6088, January 26, 1993) and in ready-to-drink tea beverages (59 FR 5317, February 4, 1994) (hereinafter referred to as the October 1988 final rule, the January 1993 final rule, and the February 1994 final rule, respectively).

As discussed below, FDA has evaluated data in the petition and other relevant material and concludes that DMDC is efficacious in preventing the growth of yeasts and molds in sports drinks and fruit or juice sparklers and that the proposed use of DMDC is safe.

II. Determination of Safety

Under the so-called ''general safety clause'' in section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

The food additive anticancer or Delaney clause in section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A)) further provides that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to the impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety clause using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive, *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984).

III. Safety of DMDC in Sports Drinks and Fruit or Juice Sparklers

DMDC is currently permitted as a yeast inhibitor in wine and wine substitutes (dealcoholized wine and low-alcohol wine) and in ready-to-drink tea beverages under § 172.133. In the October 1988, January 1993, and February 1994 final rules, the agency concluded that, because DMDC decomposes almost immediately after addition to aqueous beverages, there will be virtually no exposure to the additive from the consumption of the above-listed beverages.

Data submitted in the petition to support the proposed use of the additive at levels up to 250 parts per million (ppm) in sports drinks and fruit or juice sparklers are consistent with these findings. Specifically, data from a study of sparkling juice drink formulated with 250 ppm DMDC showed no detectable amount of the additive (limit of detection (LOD) = 40 parts per billion (ppb)) after 4 hours (Ref. 1). A study of water with 250 ppm DMDC added yielded the same result (Ref. 1). Based on these data and data incorporated from the petition that resulted in the October 1988 final rule (FAP 2A3636), the agency concludes that there will be virtually no consumer exposure to DMDC, per se, from the use of the additive in sports drinks and fruit or juice sparklers. Therefore, FDA concludes that DMDC itself presents no hazard to the consumer.

IV. Safety of Substances That May be Present in Sports Drinks and Fruit or Juice Sparklers Due to the Use of the Additive

DMDC is unstable in aqueous solution and breaks down almost immediately after addition to beverages. In aqueous liquids, the principal breakdown products are methanol and carbon dioxide. Dimethyl carbonate (DMC) may be present as an impurity in DMDC. Section 172.133 sets a specification of 0.2 percent DMC in DMDC. DMDC also may react with traces of ammonium ions in beverages to produce methyl carbamate (MC), a known carcinogen.

In previous evaluations of DMDC, the agency, in accordance with § 171.1 (21 CFR 171.1), reviewed the safety not only of DMDC but also of its decomposition products in aqueous beverages. The results of the agency's analysis of the additive's use in wine and wine substitutes were discussed extensively in the October 1988 and January 1993 final rules, and its use in ready-to-drink tea beverages was discussed in the February 1994 final rule. The agency applied the same type of analysis as in past reviews to its review of the petitioned use of DMDC. Aspects of the safety evaluation that were not previously addressed in final rules for other uses of DMDC are discussed below.

A. Methanol

As stated in previous final rules on DMDC, the tolerable (safe) level of exposure to methanol is 7.1 to 8.4 milligrams per kilogram body weight per day (mg/kg body weight/day), or approximately 426 to 504 mg/person/day for a 60 kg adult. FDA estimates that the cumulative methanol exposure for a consumer at the 90th percentile from its presence naturally in untreated fruit juice and wine and from all uses of

DMDC, including its currently regulated uses and the proposed use in sports drinks and fruit or juice sparklers, is 59 mg/person/day (Ref. 2). This estimate is based on a maximum level of methanol that can be derived from DMDC of 48.7 ppm methanol per 100 ppm DMDC used. This level is less than one-seventh of the tolerable safe level. The agency, therefore, concludes that there is an adequate margin of safety between total methanol consumption from all sources, including the petitioned use of DMDC, and the amount of methanol that can be safely ingested.

B. Methyl Carbamate

The reaction of ammonium ions in beverages with DMDC produces MC, a known carcinogen. The petitioner provided data showing that MC was detected at a level of 3.7 ppb in a fruit sparkler formulated with 250 ppm DMDC. MC was not detected in DMDC-treated sports drinks, using an analytical method with an LOD of 0.5 ppb. Using the residual level of 3.7 ppb and the LOD of 0.5 ppb for MC in fruit sparklers and sports drinks, respectively, the agency estimates the exposure to MC for all ages from the petitioned use of DMDC to be 1.5 microgram/person/day at the 90th percentile (Ref. 1). Using established procedures for quantitative risk assessment, the agency estimates that the 90th percentile upper-bound lifetime risk from potential exposure to MC from the petitioned use of DMDC is 1.5×10^{-8}, or less than 1 in 67 million, and the 90th percentile upper-bound lifetime risk from exposure to MC from all approved and petitioned uses of DMDC is 1.8×10^{-8}, or less than 1 in 56 million (Refs. 1 and 3).

Therefore, the agency concludes that there is a reasonable certainty of no harm from the exposure to MC that may result from the use of up to 250 ppm of DMDC in sports drinks and fruit or juice sparklers.

V. Conclusion on Safety

FDA has evaluated all of the data in the petition pertaining to the use of DMDC in sports drinks and fruit or juice sparklers, as well as other data in its files, and concludes that the additive is safe for its proposed use.

To ensure the safe use of the additive in sports drinks and fruit or juice sparklers, FDA, under 21 U.S.C. 348(c)(1)(A), finds that it is necessary to require directions on the food additive label limiting the level of use of the additive in these beverages to 250 ppm.

In accordance with § 171.1(h), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VI. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

The agency received one comment on the environmental assessment in response to the filing notice published in the Federal Register of June 28, 1994 (59 FR 33299). The comment states that approval of the subject additive could have two environmental benefits due to switching from hot-fill bottling of sports drinks and sparklers to cold-fill. The comment claims that this switch could greatly reduce water usage in the bottling process and could reduce cooling water flow into municipal wastewater treatment plants. However, the comment did not provide quantitative data on the magnitude of the claimed environmental benefits of the approval of this petition. FDA has concluded that the comment does not affect the agency's determination that the approval of this petition will have no significant impact on the environment. This comment can be seen at the Dockets Management Branch, along with the petitioner's environmental assessment and the agency's finding of no significant impact.

VII. Objections

Any person who will be adversely affected by this regulation may at any time on or before June 28, 1996, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from the Chemistry Review Branch to the Direct Additives Branch, ''FAP 4A4420–Dimethyl Dicarbonate as a Yeast Inhibitor in Sports Drinks and in Fruit or Juice Sparkling Beverages,'' dated July 8, 1994.

2. Memorandum from the Chemistry Review Branch to the Direct Additives Branch, ''FAP 4A4420–DMDC as a Yeast Inhibitor in Sports Drinks and Sparkling Fruit or Juice Beverages. Background Methanol Exposure,'' dated May 8, 1996.

3. Memorandum from the Direct Additives Branch to the Quantitative Risk Assessment Committee, ''Estimation of the Upper-Bound Lifetime Risk from Methyl Carbamate (MC) Formed by the Reaction of Ammonium Ions with Dimethyl Dicarbonate (DMDC) During the Use of DMDC as Requested in FAP 4A4420 (Miles Inc.),'' dated May 23, 1995.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: Secs. 201, 401, 402, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 348, 371, 379e).

2. Section 172.133 is amended by adding new paragraphs (b)(3) and (b)(4)

and by revising paragraph (c)(2) to read as follows:

§ 172.133 Dimethyl dicarbonate.

* * * * *

(b) * * *

(3) Inhibitor of yeast in carbonated or noncarbonated, nonjuice-containing (less than or equal to 1 percent juice), flavored or unflavored beverages containing added electrolytes (5–20 milliequivalents (meq)/liter sodium ion (Na+) and 3–7 meq/liter potassium ion (K+)). The additive may be added to the beverage in an amount not to exceed 250 ppm.

(4) Inhibitor of yeast in carbonated, dilute beverages containing juice, fruit flavor, or both, with juice content not to exceed 50 percent. The additive may be added to the beverage in an amount not to exceed 250 ppm.

(c) * * *

(2) Directions to provide that not more than 200 ppm of dimethyl dicarbonate will be added to the wine, dealcoholized wine, or low alcohol wine and not more than 250 ppm of dimethyl dicarbonate will be added to the ready-to-drink tea or to the beverages described in parts (b)(3) and (b)(4) of this section.

Dated: May 17, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–13303 Filed 5–28–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 301 and 602

[TD 8671]

RIN 1545–AS83

Taxpayer Identifying Numbers (TINs)

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to requirements for furnishing a taxpayer identifying number on returns, statements, or other documents. These regulations set forth procedures for requesting a taxpayer identifying number for certain alien individuals for whom a social security number is not available. These numbers are called ''IRS individual taxpayer identification numbers.'' These regulations also require foreign persons to furnish a taxpayer identifying number on their tax returns.

DATES: These regulations are effective May 29, 1996.

For dates of applicability of these regulations, see § 301.6109–1(h).

FOR FURTHER INFORMATION CONTACT: Lilo A. Hester, (202) 874–1490 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1545–1461.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

The estimated annual burden for the collection of information contained in § 301.6109–1(d) is reflected in the burden of Form W–7.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, PC:FP, Washington, DC 20224, and to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Books or records relating to this collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

On June 8, 1995, the IRS published in the Federal Register (60 FR 30211) the withdrawal of the notice of proposed rulemaking published in the Federal Register on September 27, 1990 at 55 FR 39427, a notice of proposed rulemaking, and a notice of public hearing relating to taxpayer identifying numbers as contained in the Income Tax Regulations (26 CFR part 301) under section 6109 of the Internal Revenue Code (Code).

Written comments responding to the notice of proposed rulemaking were received, and a public hearing was held on September 28, 1995. After consideration of all the comments, the proposed regulations under 6109 of the Code are adopted as revised by this Treasury decision. The comments and revisions are discussed below.

Explanation of Provisions and Revisions

A. Principal Changes

Section 6109 of the Code generally provides that, when required by regulations, a person must furnish a taxpayer identifying number (TIN) for securing proper identification of that person on any return, statement, or other document made under the Code. The notice of proposed rulemaking contains two principal changes to the existing regulations. The first change is the introduction of a new IRS-issued TIN, called an IRS individual taxpayer identification number (ITIN), for use by alien individuals, whether resident or nonresident, who currently do not have, and are not eligible to obtain, social security numbers. The Social Security Administration generally limits its assignment of social security numbers to individuals who are U.S. citizens and alien individuals legally admitted to the United States for permanent residence or under other immigration categories which authorize U.S. employment. Therefore, this change is designed to help taxpayers (who need a TIN but cannot qualify for a social security number) maintain compliance with TIN requirements under the Code and regulations.

The second change is to modify the existing rule set forth in § 301.6109–1(g) that currently excludes from the general requirement of providing a TIN, foreign persons that do not have either (1) income effectively connected with the conduct of a U.S. trade or business or (2) a U.S. office or place of business or a U.S. fiscal or paying agent. Under these regulations, the exclusion is modified to require that any foreign person who makes a return of tax (i.e., income, gift, and estate tax returns, amended returns, or refund claims, but excluding information returns) furnish its TIN on that return. This change is intended to address the IRS' and Treasury's concern that, without TINs, taxpayers cannot be identified efficiently and tax returns cannot be processed effectively.

B. Comments

Regarding the assignment of ITINs under § 301.6109–1(d)(3)(iii) of the proposed regulations, commentators suggested that the IRS develop a process whereby either (1) the Social Security Administration (SSA) issues the ITIN when the individual is not eligible for a social security number, or (2) the Immigration and Naturalization Service (INS) (within the Department of Justice) and the U.S. consulate offices (within the Department of State) issue the ITIN