

that duplicate, overlap, or conflict with this rule.

Based on the agency's understanding that most manufacturers have already reformulated or otherwise are in the process of reformulating, the agency expects that this final rule will not be economically significant under Executive Order 12866, nor would it impose an Unfunded Mandate (as that term is described in the Unfunded Mandate Reform Act). The agency also believes that it has undertaken steps to reduce the burden to small entities. Nevertheless, some entities may incur significant impacts, especially manufacturers that still must reformulate their phenolphthalein products and, to a lesser extent, private label manufacturers that provide labeling for a number of the affected products. Danthron was removed from OTC laxative drug products in 1987 and has not been available for approximately 10 years. Therefore, it is unlikely that reclassification of danthron as a nonmonograph ingredient would have any economic impact. This economic analysis, together with other relevant sections of this document, serves as the agency's final regulatory flexibility analysis, as required under the Regulatory Flexibility Act.

VI. Reference

1. Comment No. C173, Docket No. 78N-036L, Dockets Management Branch.

VII. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Environmental Impact

The agency has determined under 21 CFR 25.31(c) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, 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 310 is amended as follows:

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, 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 redesignating paragraph (a)(12)(iv) as paragraph (a)(12)(iv)(A) and by revising the newly redesignated heading, by adding paragraphs (a)(12)(iv)(B) and (d)(29), and by revising paragraph (d) introductory text and paragraph (d)(1) to read as follows:

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

(a) * * *
(12) * * *
(iv)(A) Stimulant laxatives—
Approved as of May 7, 1991. * * *
(iv)(B) Stimulant laxatives—Approved as of January 29, 1999.
Danthron
Phenolphthalein
* * * * *

(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)(29) of this section.

(1) May 7, 1991, for products subject to paragraphs (a)(1) through (a)(2)(i), (a)(3) through (a)(4), (a)(6)(i)(A), (a)(6)(ii)(A), (a)(7) (except as covered by paragraph (d)(3) of this section), (a)(8)(i), (a)(10)(i) through (a)(10)(iii), (a)(12)(i) through (a)(12)(iv)(A), (a)(14) through (a)(15)(i), and (a)(16) through (a)(18) of this section.
* * * * *

(29) January 29, 1999, for products subject to paragraph (a)(12)(iv)(B) of this section.

Dated: January 20, 1999.
William K. Hubbard,
Associate Commissioner for Policy
Coordination.
[FR Doc. 99-1938 Filed 1-28-99; 8:45 am]
BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs

CFR Correction

In Title 21 of the Code of Federal Regulations, parts 500 to 599, revised as of April 1, 1998, on page 176, second column, § 520.2158b is corrected by adding paragraph (d) to read as follows:

§ 520.2158b Dihydrostreptomycin tablets.
* * * * *

(d) *Conditions of use. Calves*—(1) *Amount.* 150 milligrams of dihydrostreptomycin and 1.5 grams of chlorhexidine dihydrochloride per 100 pounds of body weight per day.

(2) *Indications for use.* Treatment of bacterial scours in calves.

(3) *Limitations.* Administer orally once a day for 5 days; withdraw 3 days before slaughter.

[FR Doc. 99-55506 filed 1-28-99; 8:45 am]
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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 31

[TD 8815]

RIN 1545-AT99

Federal Unemployment Tax Act (FUTA) Taxation of Amounts Under Employee Benefit Plans

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations under section 3306(r)(2) of the Internal Revenue Code (Code), that provide guidance as to when amounts deferred under or paid from a nonqualified deferred compensation plan are taken into account as wages for purposes of the employment taxes imposed by the Federal Unemployment Tax Act (FUTA). Section 3306(r)(2), relating to treatment of certain nonqualified deferred compensation, was added to the Code by section 324 of the Social Security Amendments of 1983. These regulations provide guidance to employers who maintain nonqualified deferred compensation plans.

DATES: Effective Date: These regulations are effective January 29, 1999.

Applicability Date: These regulations are applicable on and after January 1, 2000. In addition, these regulations provide certain transition rules for amounts deferred and benefits paid before January 1, 2000, including allowing employers to use a reasonable, good faith interpretation of section 3306(r)(2).

FOR FURTHER INFORMATION CONTACT: Janine Cook, Linda E. Alsalihi, or Margaret A. Owens, (202) 622-6040 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

These final regulations amend the Employment Tax Regulations (26 CFR

part 31) under section 3306(r)(2). Section 3306(r)(2) was added to the Internal Revenue Code (Code) by section 324 of the Social Security Amendments of 1983 (1983 Amendments). Section 2662(f)(2) of the Deficit Reduction Act of 1984 (DEFRA) amended section 324 of the 1983 Amendments.

Notice 94-96 (1994-2 C.B. 564) provides that until final regulations are issued, the IRS will not challenge an employer's determination of FUTA tax liability with respect to a nonqualified deferred compensation plan for periods before the effective date of any final regulations if the determination is based on a reasonable, good faith interpretation of section 3306(r)(2). On January 25, 1996, a notice of proposed rulemaking (EE-55-95), under section 3306(r)(2) was published in the **Federal Register** (61 FR 2214), providing guidance related to the FUTA tax treatment of amounts deferred under or paid from certain nonqualified deferred compensation plans. On December 24, 1997, a notice of proposed rulemaking (REG-209484-87 and REG-209807-95), under section 3306(r)(2), extending the proposed general effective date of the regulations to January 1, 1998, was published in the **Federal Register** (62 FR 67304).

Comments regarding the proposed regulations were received from the public, and on June 24, 1996, the IRS held a public hearing concerning the proposed amendments. After consideration of the public comments received and the statements made at the public hearing, the proposed regulations are adopted as revised by this Treasury decision.

Explanation of Provisions

These final regulations provide guidance under section 3306(r)(2), relating to when amounts deferred under or paid from nonqualified deferred compensation plans are taken into account as wages for FUTA purposes. These rules are substantially similar to the rules applicable to the FICA (Federal Insurance Contributions Act) tax treatment of such amounts deferred under section 3121(v)(2). Thus, these final regulations cross-reference the final regulations under section 3121(v)(2) (FICA tax treatment of nonqualified deferred compensation), published elsewhere in this issue of the **Federal Register**.

Special Analyses

It has been determined that this Treasury decision is not a significant

regulatory action as defined in EO 12866. Therefore, a regulatory assessment is not required. It also has 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 notice of proposed rulemaking was issued prior to March 29, 1996, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal authors of these regulations are Janine Cook, Linda E. Alsalihi, and Margaret A. Owens, Office of the Associate Chief Counsel (Employee Benefits and Exempt Organizations). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 31

Employment taxes, Income taxes, Penalties, Pensions, Railroad retirement, Reporting and recordkeeping requirements, Social security, Unemployment compensation.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 31 is amended as follows:

PART 31—EMPLOYMENT TAXES AND COLLECTION OF INCOME TAX AT SOURCE

Paragraph 1. The authority citation for part 31 continues to read in part as follows:

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

Par. 2. Section 31.3306(r)(2)-1 is added to read as follows:

§ 31.3306(r)(2)-1 Treatment of amounts deferred under certain nonqualified deferred compensation plans.

(a) *In general.* Section 3306(r)(2) provides a special timing rule for the tax imposed by section 3301 with respect to any amount deferred under a nonqualified deferred compensation plan. Section 31.3121(v)(2)-1 contains rules relating to when amounts deferred under certain nonqualified deferred compensation plans are wages for purposes of sections 3121(v)(2), 3101, and 3111. The rules in § 31.3121(v)(2)-

1 also apply to the special timing rule of section 3306(r)(2). For purposes of applying the rules in § 31.3121(v)(2)-1 to section 3306(r)(2) and this paragraph (a), references to the Federal Insurance Contributions Act are considered references to the Federal Unemployment Tax Act (26 U.S.C. 3301 et seq.), references to FICA are considered references to FUTA, references to section 3101 or 3111 are considered references to section 3301, references to section 3121(v)(2) are considered references to section 3306(r)(2), references to section 3121(a), (a)(5), and (a)(13) are considered references to section 3306(b), (b)(5), and (b)(10), respectively, and references to § 31.3121(a)-2(a) are considered references to § 31.3301-4.

(b) *Effective dates and transition rules.* Except as otherwise provided, section 3306(r)(2) applies to remuneration paid after December 31, 1984. Section 31.3121(v)(2)-2 contains effective date rules for certain remuneration paid after December 31, 1983, for purposes of section 3121(v)(2). The rules in § 31.3121(v)(2)-2 also apply to section 3306(r)(2). For purposes of applying the rules in § 31.3121(v)(2)-2 to section 3306(r)(2) and this paragraph (b), references to section 3121(v)(2) are considered references to section 3306(r)(2), and references to section 3121(a)(2), (a)(3), or (a)(13) are considered references to section 3306(b)(2), (b)(3), or (b)(10), respectively. In addition, references to § 31.3121(v)(2)-1 are considered references to paragraph (a) of this section. For purposes of applying the rules of § 31.3121(v)(2)-2 to this paragraph (b)—

(1) References to “December 31, 1983” are considered references to “December 31, 1984”;

(2) References to “before 1984” are considered references to “before 1985”;

(3) References to “Federal Insurance Contributions Act” are considered references to “Federal Unemployment Tax Act”; and

(4) References to “FICA” are considered references to “FUTA”.

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

Approved: December 23, 1998.

Donald C. Lubick,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 99-1664 Filed 1-28-99; 8:45 am]

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