

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]
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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.

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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