§ 522.1660 [Amended]

2. Section 522.1660 *Oxytetracycline injection* is amended in paragraph (d)(1)(iii) by adding in the eighth sentence the number ''011722,'' after the number ''000010,''.

Dated: June 29, 1999.

George A. Mitchell,

Acting Deputy Director, Center for Veterinary Medicine.

[FR Doc. 99–20257 Filed 8–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Nystatin, Neomycin, Thiostrepton, and Triamcinolone Acetonide Ointment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Med-Pharmex, Inc. The ANADA provides for use of nystatin, neomycin, thiostrepton, and triamcinolone acetonide vanishing cream base ointment for topical management of dermatologic disorders of dogs and cats.

EFFECTIVE DATE: August 6, 1999.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861, filed ANADA 200–245 that provides for veterinary prescription use of Derma-Vet Cream (nystatin, neomycin, thiostrepton, and triamcinolone acetonide) for topical management of dermatologic disorders in dogs and cats characterized by inflammation and dry or exudative dermatitis, particularly those caused, complicated, or threatened by bacterial or candidal (*Candida albicans*) infections.

Med-Pharmex's ANADA 200–245 is approved as a generic copy of Solvay's NADA 96–676 for Panalog® Cream. The ANADA is approved as of June 7, 1999. The basis for approval is discussed in the freedom of information summary.

The regulation in § 524.1600a (21 CFR 524.1600a) does not designate which approvals are for petrolatum base products (ointments) and which are for vanishing cream base products (creams). The regulation in § 524.1600a(b) is amended at this time to designate the base of each sponsor's product and to reflect this approval.

In addition, due to enactment of the Generic Animal Drug and Patent Term Restoration Act of 1988, the footnote concerning the National Academy of Sciences/National Research Council review is outdated. At this time, the footnote and the footnote references are removed.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(d)(1) 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 524.1600a is amended by revising paragraph (b) and by removing the footnote of paragraphs (c)(1)(i), (c)(1)(ii), (c)(1)(iii), (c)(2)(i), and (c)(2)(ii) to read as follows:

§ 524.1600a Nystatin, neomycin, thiostrepton, and triamcinolone acetonide ointment.

* * * * *

(b) *Sponsors.* For petrolatum base ointments see 000031, 000069, 000332, 025463, 051259, and 053501 in § 510.600(c) of this chapter. For vanishing cream base ointments see 051259 and 053501.

* * * * *

Dated: June 29, 1999

George A. Mitchell,

Acting Deputy Director, Center for Veterinary Medicine.

[FR Doc. 99–20254 Filed 8–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 31

[TD 8832]

RIN 1545–AT56

Exception From Supplemental Annuity Tax on Railroad Employers

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide guidance to employers covered by the Railroad Retirement Tax Act. The Railroad Retirement Tax Act imposes a supplemental tax on those employers, at a rate determined by the Railroad Retirement Board, to fund the Railroad Retirement Board's supplemental annuity benefit. These regulations provide rules for applying the exception from the supplemental annuity tax with respect to employees covered by a supplemental pension plan established pursuant to a collective bargaining agreement and for applying a related excise tax with respect to employees for whom the exception applies.

DATES: *Effective Date:* These regulations are effective August 6, 1999.

Applicability Date: These regulations generally apply beginning on October 1, 1998, except as provided in § 31.3221–4(e)(2).

FOR FURTHER INFORMATION CONTACT: Linda S. F. Marshall, (202) 622–6030 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Employment Tax Regulations (26 CFR part 31) under section 3221(d). On September 23, 1998, a notice of proposed rulemaking was published in the **Federal Register** (63 FR 50819) under section 3221(d). The proposed

regulations provide guidance regarding the section 3221(d) exception from the tax imposed under section 3221(c) with respect to employees covered by a supplemental pension plan of the employer established pursuant to an agreement reached through collective bargaining. Two written comments were received on the proposed regulations. A public hearing was held on the proposed regulations on January 20, 1999. After consideration of the comments, the proposed regulations under section 3221(d) are adopted as revised by this Treasury decision.

Under the Railroad Retirement Act of 1974, as amended, codified at 45 U.S.C. 231 *et seq.*, if an employee has performed at least 25 years of covered service with the railroad industry, including service with the railroad industry before October 1, 1981, the Railroad Retirement Board (RRB) will pay the employee a supplemental annuity at retirement. The monthly amount of the supplemental annuity ranges from $23 to $43, based on the employee's number of years of service. See 45 U.S.C. 231b(e). Under 45 U.S.C. 231a(h)(2), the employee's supplemental annuity is reduced by the amount of payments received by the employee from any plan determined by the RRB to be a supplemental pension plan of the employer, to the extent those payments are derived from employer contributions.

Section 3221(c) imposes a tax on each railroad employer to fund the supplemental annuity benefits payable by the RRB. The tax imposed under section 3221(c) is based on work-hours for which compensation is paid. The RRB establishes the rate of tax under section 3221(c) quarterly, and calculates the rate to generate sufficient tax revenue to fund the RRB's current supplemental annuity obligations.

Under section 3221(d), the tax imposed by section 3221(c) does not apply to an employer with respect to employees who are covered by a supplemental pension plan established pursuant to an agreement reached through collective bargaining between the employer and employees. However, if an employee for whom the employer is relieved of any tax under the section 3221(d) exception becomes entitled to a supplemental annuity from the RRB, the employer is subject to an excise tax equal to the amount of the supplemental annuity paid to the employee (plus a percentage determined by the RRB to be sufficient to cover administrative costs attributable to those supplemental annuity payments).

Section 3221(d) was enacted by Public Law 91–215, 84 Stat. 70, which amended the Railroad Retirement Act of 1937 and the Railroad Retirement Tax Act. The legislative history to Public Law 91–215 indicates that the exception under section 3221(d) from the tax imposed under section 3221(c) was ''directed primarily at the situation existing on certain short-line railroads which are owned by the steel companies. The employees of these lines are, for the most part, covered by other supplemental pension plans established pursuant to collective bargaining agreements between the steel companies and the unions representing the majority of their employees. * * * [T]hese railroads will no longer be required to pay a tax to finance the supplemental annuity fund, but will be required to reimburse the Railroad Retirement Board for any supplemental annuities that their employees may be paid upon retirement.'' S. Rep. 91–650, 91st Cong., 2d Sess. 6 (February 3, 1970).

Explanation of Provisions

These regulations retain the rules set forth in the proposed regulations for determining whether a plan is a supplemental pension plan established pursuant to an agreement reached through collective bargaining. Under these regulations, a plan is a supplemental pension plan only if the plan is a pension plan within the meaning of § 1.401–1(b)(1)(i). Under this definition, a plan is a pension plan only if the plan is established and maintained primarily to provide systematically for the payment of definitely determinable benefits to employees over a period of years, usually for life, after retirement. Thus, for example, a plan generally is not a supplemental pension plan if distributions from the plan that are attributable to employer contributions may be made prior to a participant's death, disability, or termination of employment. See Rev. Rul. 74–254 (1974–1 C.B. 90); Rev. Rul. 56–693 (1956–2 C.B. 282). A pension plan that is tax-qualified under section 401(a) is subject to special rules with respect to joint and survivor benefits under sections 401(a)(11) and 417.

One commentator requested clarification that these regulations do not preclude a plan from being a supplemental pension plan merely because the plan provides for a single sum distribution form (in addition to providing for periodic payments as described above). A plan is not precluded from being a pension plan within the meaning of § 1.401–1(b)(1)(i) merely because it provides for a single sum distribution form in addition to providing for the required periodic payment forms. See section 417(e)(1) and (2). Thus, the availability of a single sum distribution form (offered in addition to the periodic payment form or forms described above) does not preclude a plan from being a supplemental pension plan under these regulations.

Another commentator requested clarification that a plan in which the employer contribution is discretionary or conditioned on contributions made at the election of employees pursuant to a qualified cash or deferred arrangement described in section 401(k)(2) could not qualify as a supplemental pension plan under section 3221(d) and the regulations. A plan that provides for discretionary employer contributions cannot be a pension plan under § 1.401(b)–1(b)(1)(i) because it does not provide for the payment of definitely determinable benefits. Under section 401(k)(1), a qualified cash or deferred arrangement under section 401(k) must be part of a profit-sharing or stock bonus plan, a pre-ERISA money purchase plan, or a rural cooperative plan. Thus, a plan that provides for a section 401(k) qualified cash or deferred arrangement with employer matching contributions cannot be a pension plan under § 1.401(b)–1(b)(1)(i) (unless the plan is a pre-ERISA money purchase plan or a rural cooperative plan). Thus, apart from these narrow exceptions for certain pre-ERISA and rural cooperative plans, neither of the types of plans noted by the commentator could qualify as supplemental pension plans under section 3221(d) and these regulations.

As provided in the proposed regulations, these regulations also require that the RRB determine that a plan is a private pension under its regulations in order for the plan to be a supplemental pension plan under section 3221(d) and these regulations. This requirement is included because the section 3221(d) exception to the section 3221(c) tax is based on the assumption that any participant for whom the exception applies will receive a reduced supplemental annuity because of the supplemental pension plan on account of which the section 3221(c) tax is eliminated.

These regulations also retain the rules set forth in the proposed regulations for determining whether a plan is established pursuant to a collective bargaining agreement with respect to an employee. These rules generally follow the rules applicable to qualified plans for this purpose. Under these regulations, a plan is established pursuant to a collective bargaining agreement with respect to an employee

only if the employee is included in the collective bargaining unit covered by the collective bargaining agreement.

One commentator maintained that employers should also be exempted from supplemental annuity tax with respect to nonbargaining unit employees covered by a plan that is the subject of collective bargaining. The IRS and Treasury Department have determined that it is inappropriate to extend the exception to nonbargaining unit employees. This determination is consistent with the RRB's administrative rulings. As noted below, the final regulations include a delayed effective date for this requirement.

Section 3221(d) imposes an excise tax equal to the amount of the supplemental annuity paid to any employee with respect to whom the employer has been excepted from the section 3221(c) excise tax under the section 3221(d) exception. These regulations retain the rules set forth in the proposed regulations for applying this excise tax under section 3221(d).

Effective Date

These regulations generally apply beginning on October 1, 1998, as provided in the proposed regulations. However, the IRS and Treasury have determined that it is appropriate to provide a delayed applicability date with respect to the portion of the final regulations clarifying what constitutes a plan established pursuant to a collective bargaining agreement with respect to an employee for purposes of section 3221(d). Accordingly, the final regulations provide that the definition in § 31.3221–4(c) applies beginning on January 1, 2000.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 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 regulation does not impose a collection of information on small entities, 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 Small Business Administration for comment on its impact on small businesses.

Drafting Information

The principal author of these regulations is Linda S. F. Marshall, 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, Fishing vessels, Gambling, 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 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 31.3221–4 is added under the undesignated center heading ''Tax on Employers'' to read as follows:

§ 31.3221–4 Exception from supplemental tax.

(a) *General rule.* Section 3221(d) provides an exception from the excise tax imposed by section 3221(c). Under this exception, the excise tax imposed by section 3221(c) does not apply to an employer with respect to employees who are covered by a supplemental pension plan, as defined in paragraph (b) of this section, that is established pursuant to an agreement reached through collective bargaining between the employer and employees, within the meaning of paragraph (c) of this section.

(b) *Definition of supplemental pension plan*—(1) *In general.* A plan is a supplemental pension plan covered by the section 3221(d) exception described in paragraph (a) of this section only if it meets the requirements of paragraphs (b)(2) through (b)(4) of this section.

(2) *Pension benefit requirement.* A plan is a supplemental pension plan within the meaning of this section only if the plan is a pension plan within the meaning of § 1.401–1(b)(1)(i) of this chapter. Thus, a plan is a supplemental pension plan only if the plan provides for the payment of definitely determinable benefits to employees over a period of years, usually for life, after retirement. A plan need not be funded through a qualified trust that meets the requirements of section 401(a) or an annuity contract that meets the requirements of section 403(a) in order to meet the requirements of this paragraph (b)(2). A plan that is a profit-sharing plan within the meaning of § 1.401–1(b)(1)(ii) of this chapter or a stock bonus plan within the meaning of § 1.401–1(b)(1)(iii) of this chapter is not a supplemental pension plan within the meaning of this paragraph (b).

(3) *Railroad Retirement Board determination with respect to the plan.* A plan is a supplemental pension plan within the meaning of this paragraph (b) with respect to an employee only during any period for which the Railroad Retirement Board has made a determination under 20 CFR 216.42(d) that the plan is a private pension, the payments from which will result in a reduction in the employee's supplemental annuity payable under 45 U.S.C. 231a(b). A plan is not a supplemental pension plan for any time period before the Railroad Retirement Board has made such a determination, or after that determination is no longer in force.

(4) *Other requirements.* [Reserved]

(c) *Collective bargaining agreement.* A plan is established pursuant to a collective bargaining agreement with respect to an employee only if, in accordance with the rules of § 1.410(b)–6(d)(2) of this chapter, the employee is included in a unit of employees covered by an agreement that the Secretary of Labor finds to be a collective bargaining agreement between employee representatives and one or more employers, provided that there is evidence that retirement benefits were the subject of good faith bargaining between employee representatives and the employer or employers.

(d) *Substitute section 3221(d) excise tax.* Section 3221(d) imposes an excise tax on any employer who has been excepted from the excise tax imposed under section 3221(c) by the application of section 3221(d) and paragraph (a) of this section with respect to an employee. The excise tax is equal to the amount of the supplemental annuity paid to that employee under 45 U.S.C. 231a(b), plus a percentage thereof determined by the Railroad Retirement Board to be sufficient to cover the administrative costs attributable to such payments under 45 U.S.C. 231a(b).

(e) *Effective date*—(1) *In general.* Except as provided in paragraph (e)(2) of this section, this section applies beginning on October 1, 1998.

(2) *Delayed effective date for collective bargaining agreement*

provisions. Paragraph (c) of this section applies beginning on January 1, 2000.

John M. Dalrymple,

Acting Deputy Commissioner of Internal Revenue.

Approved: July 9, 1999.

Donald C. Lubick,

Assistant Secretary of the Treasury.

[FR Doc. 99–19936 Filed 8–5–99; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 801

[TD 8830]

RIN 1545–AW80

Establishment of a Balanced Measurement System

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the adoption by the IRS of a balanced system to measure organizational performance within the IRS. These regulations further prescribe rules relating to the measurement of employee performance and implement requirements that all employees be evaluated on whether they provided fair and equitable treatment to taxpayers and bar use of records of tax enforcement results to evaluate or to impose or suggest goals for any employee of the IRS. These regulations implement sections 1201 and 1204 of the Internal Revenue Restructuring and Reform Act of 1998. These regulations affect internal operations of the IRS and the systems that agency employs to evaluate the performance of organizations within IRS and individuals employed by IRS.

DATES: These regulations are effective September 7, 1999.

FOR FURTHER INFORMATION CONTACT: Michael G. Gallagher, 202–283–7900 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background

On January 5, 1999, the IRS published in the **Federal Register** (64 FR 457) a notice of proposed rulemaking regarding the establishment of a balanced system of measures for the IRS. Comments were received and a public hearing on the proposed regulations was held on May 13, 1999.

This document adopts, with modifications, the proposed regulations as final regulations.

Explanation of Revisions and Summary of Comments

A commentator suggested that certain organizational changes might add clarity to the regulation. We have adopted this suggestion and have reorganized the regulation to contain separate sections that describe the system for measuring organizational performance and the system for measuring employee performance. Consistent with the suggestion of the commentator, we have revised the heading on the latter performance measurement system to make it clear that it relates to measuring ''employee'' performance. The organizational changes required incidental reordering within the regulation, as well as the renumbering of additional sections.

A commentator suggested that the discussion of the performance criteria applicable to Senior Executive Service (SES) employees make explicit reference to 5 U.S.C. 4313, which contains certain performance criteria. We have adopted this suggestion and included references to 5 U.S.C. 4313 in section 801.3. The same commentator also suggested that the regulation be modified to provide that SES and managerial employees of the IRS will be evaluated on the basis of organizational performance, as measured under the balanced measurement system for organizational performance. While the IRS will modify the performance criteria for all employees to ensure that they support the organizational measures adopted in this regulation, it will evaluate employees on the basis of the performance criteria made applicable to the positions those employees occupy. Accordingly, this suggestion was not adopted.

A commentator suggested that, while it would be appropriate to gather data regarding customer and employee satisfaction via ''questionnaires, surveys and other types of information gathering mechanisms'' and a ''questionnaire,'' respectively, as the proposed regulation provides, the IRS might in the future find other appropriate means to gather such data and should not be confined by the regulation from adopting such other information gathering techniques. Although the IRS intends in the near term to gather such customer and employee satisfaction data via questionnaires and surveys, it may in the future determine that other methods of information gathering can provide accurate data. Accordingly, we have adopted the commentator's suggestion and made it clear that questionnaires and surveys are only examples of the information gathering techniques the IRS may employ to measure customer and employee satisfaction. Sections 801.4 and 801.5 of the regulations reflect the changes. A commentator suggested that since certain organizations within the IRS provide service to customers other than taxpayers, the final regulation should make clear that information gathered from persons other than taxpayers could be used in measuring customer satisfaction. We have adopted this suggestion and modified § 801.5.

A commentator suggested that the quantity element of the business results measure be eliminated because, in an attempt to improve organizational performance with respect to that quantity element, managers might exert pressure upon employees to dispose of taxpayer cases too quickly or without regard to merits of the issues presented. The fundamental premise of the balanced system of organizational measures is that the presence of measures that evaluate the quality of the work done by the unit, the satisfaction of customers served by the unit (including taxpayers), and the satisfaction of employees working in the unit will obviate the risk that managers place undue emphasis upon the quantity of work completed. The absolute prohibitions (1) on the use of tax enforcement results and (2) on the use of quantity data to evaluate non-supervisory employees who exercise judgment with respect to tax enforcement results operate as effective checks against the overzealous use of enforcement authority. Accordingly, we have not adopted this suggestion. We have slightly modified the description of the quantity measure to include customer education, assistance and outreach efforts.

A commentator suggested that taxpayers against whom collection actions have been taken would be unable to provide objective information regarding their interactions with IRS personnel and therefore should not be included among the taxpayers requested to provide information regarding customer satisfaction. IRS experience with customer satisfaction surveys, including those taken at Problem Solving Day events, indicates that this commentator's comments are not well founded. Accordingly, the suggestion was not adopted.

Finally, a commentator suggested that IRS should limit the authority delegated to lower-level employees. This suggestion was beyond the scope of the current regulation and was not adopted.