

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 522****Implantation or Injectable Dosage Form New Animal Drugs; Phenylbutazone Injection**

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 Phoenix Scientific, Inc. The ANADA provides for the use of a generic phenylbutazone injection in horses as an anti-inflammatory agent.

EFFECTIVE DATE: October 16, 1995.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1617.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Ter., P.O. Box 6457, St. Joseph, MO 64506-0457, is the sponsor of ANADA 200-126 which provides for the use of generic Phenylbutazone 20% Injection (200 milligrams (mg) of phenylbutazone per milliliter (mL) of solution) for the relief of inflammatory conditions associated with the musculoskeletal system in horses.

Approval of ANADA 200-126 for Phoenix Scientific's Phenylbutazone 20% Injection is as a generic copy of Coopers Animal Health's Butazolidin® (200 mg of phenylbutazone per mL) which is covered by NADA 011-575. The ANADA is approved as of September 1, 1995, and the regulations are amended in 21 CFR 522.1720 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, the regulation contains an outdated footnote and superscript references citing the National Academy of Science/National Research Council (NAS/NRC) status of these products. The Generic Animal Drug and Patent Term Restoration Act of 1988 changed that status. The NAS/NRC footnote references are removed at this time.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 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, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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 522**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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.1720 is amended by removing the footnote in paragraphs (c) and (d) and by revising paragraph (b)(2) to read as follows:

§ 522.1720 Phenylbutazone injection.

* * * * *

(b) * * *

(2) Approval for use of the 200 milligrams per milliliter drug in horses: See sponsor Nos. 000010, 000402, 000864, and 059130 in § 510.600(c) of this chapter.

* * * * *

Dated: October 2, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95-25503 Filed 10-13-95; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 558**New Animal Drugs; Change of Sponsor**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from Syntex Animal Health, Division of Syntex Agribusiness, Inc., to Hoffman-La Roche, Inc.

EFFECTIVE DATE: October 16, 1995.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1646.

SUPPLEMENTARY INFORMATION: Syntex Animal Health, Division of Syntex Agribusiness, Inc., 3401 Hillview Ave., Palo Alto, CA 94304, has informed FDA that it has transferred the ownership of, and all rights and interests in, approved NADA 141-025 (Laidlomycin) to Hoffman-La Roche, Inc., Nutley, NJ 07110-1199.

Accordingly, the agency is amending the regulations in 21 CFR 558.305 to reflect the change of sponsor.

List of Subject in 21 CFR Part 558**Animal drugs, Animal feeds.**

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.305 [Amended]

2. Section 558.305 *Laidlomycin propionate potassium* is amended in paragraph (a) by removing "000033" and adding in its place "000004".

Dated: October 4, 1995.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 95-25504 Filed 10-13-95; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Parts 31 and 602**

[TD 8624]

RIN 1545-AT87

Reporting of Nonpayroll Withheld Tax Liabilities

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations relating to

the reporting of nonpayroll withheld income taxes under section 6011 of the Internal Revenue Code. The temporary regulations remove the requirement that a person file Form 945, Annual Return of Withheld Federal Income Tax, for each calendar year, whether or not the person is required to withhold the taxes reported on Form 945 in a particular calendar year. The temporary regulations require that a person file Form 945 only for a calendar year in which the person is required to withhold taxes required to be reported on Form 945. The text of these temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the Federal Register.

EFFECTIVE DATE: These regulations are effective October 16, 1995.

FOR FURTHER INFORMATION CONTACT: Vincent G. Surabian, 202-622-6232 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

These regulations are being issued without prior notice and public procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). For this reason, the collection of information contained in these regulations has been reviewed and, pending receipt and evaluation of public comments, approved by the Office of Management and Budget under control number 1545-1413. Responses to this collection of information are required to monitor compliance with the federal tax laws related to the reporting and deposit of nonpayroll withheld taxes.

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.

For further information concerning this collection of information, and where to submit comments on the collection of information and the accuracy of the estimated burden, and suggestions for reducing this burden, please refer to the preamble to the cross-referencing notice of proposed rulemaking published in the Proposed Rules section of this issue of the Federal Register.

Books or records relating to a 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 December 23, 1993, the IRS published final regulations (TD 8504) in the Federal Register (58 FR 68033) relating to both the reporting and depositing of Federal employment taxes. Those regulations simplify reporting requirements by removing all "nonpayroll" withheld taxes from reporting on Form 941, Employer's Quarterly Federal Tax Return (or Form 941E, Quarterly Return of Withheld Federal Income Tax and Medicare Tax) and requiring those taxes to be reported on Form 945. Those final regulations were effective December 23, 1993.

Section 31.6011(a)-4(b) of those regulations provides that every person required to make a return of income tax withheld from nonpayroll payments for calendar year 1994 must make a return for calendar year 1994 and for each subsequent calendar year (whether or not any such tax is required to be withheld that year) until a final return is made in accordance with § 31.6011(a)-6. In addition, every person not required to make a return of income tax withheld from nonpayroll payments for calendar year 1994 must make a return for the first calendar year after 1994 in which the person is required to withhold the tax and for each subsequent calendar year until a final return is made in accordance with § 31.6011(a)-6.

In the preamble to TD 8504, the IRS stated that it welcomed and would consider comments from the public regarding the requirement to continue filing Form 945 annually, regardless of liability, until a final return is filed in accordance with § 31.6011(a)-6. Several commentators responded to that invitation, all opposing the requirement to file a return for a calendar year for which there is no liability. As a result, the IRS has reconsidered the specific requirement.

Explanation of Provisions

These temporary regulations remove the requirement that, once a person files an annual Form 945, the person must file a Form 945 every subsequent year until the person files a final return. Under these temporary regulations, a person must file a Form 945 only for a calendar year in which the person is required to withhold Federal income tax from nonpayroll payments.

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 has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations and, therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, a copy of these temporary regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these regulations is Vincent G. Surabian, Office of the Assistant Chief Counsel (Income Tax and Accounting). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects

26 CFR Part 31

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

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR parts 31 and 602 are amended as follows:

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

Paragraph 1. The authority citation for part 31 is amended by adding an entry in numerical order to read as follows:

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

Section 31.6011(a)-4T also issued under 26 U.S.C. 6011. * * *

Par 2. Section 31.6011(a)-4 is amended by revising paragraph (b) to read as follows:

§ 31.6011(a)-4 Returns of income tax withheld.

* * * * *

(b) [Reserved] For further guidance see § 31.6011(a)-4T(b).

* * * * *

Par. 3. Section 31.6011(a)-4T is added to read as follows:

§ 31.6011(a)-4T Returns of income tax withheld (temporary).

(a) [Reserved] For further guidance see § 31.6011(a)-4(a).

(b) *Withheld from nonpayroll payments.* Every person required to withhold tax from nonpayroll payments for calendar year 1994 must make a return for calendar year 1994 and for any subsequent calendar year in which any such tax is required to be withheld until the person makes a final return in accordance with § 31.6011(a)-6. Every person not required to withhold tax from nonpayroll payments for calendar year 1994 must make a return for the first calendar year after 1994 in which the person is required to withhold such tax and for any subsequent calendar year in which the person is required to withhold such tax until the person makes a final return in accordance with § 31.6011(a)-6. Form 945, Annual Return of Withheld Federal Income Tax, is the form prescribed for making the return required under this paragraph (b). Nonpayroll payments are—

- (1) Certain gambling winnings subject to withholding under section 3402(q);
- (2) Retirement pay for services in the Armed Forces of the United States subject to withholding under section 3402;
- (3) Certain annuities as described in section 3402(o)(1)(B);
- (4) Pensions, annuities, IRAs, and certain other deferred income subject to withholding under section 3405; and
- (5) Reportable payments subject to backup withholding under section 3406.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

Par. 4. The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

§ 602.101 [Amended]

Par. 5. Section 602.101, paragraph (c) is amended in the table by adding the

entry “31.6011(a)-4T 1545-1413” in numerical order.

Margaret Milner Richardson,
Commissioner of Internal Revenue.

Approved: September 22, 1995.
Leslie Samuels,
Assistant Secretary of the Treasury.
[FR Doc. 95-25314 Filed 10-13-95; 8:45 am]
BILLING CODE 4830-01-U

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

[SPATS No. IN-126-FOR; State Program Amendment No. 95-9]

Indiana Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving a proposed amendment to the Indiana regulatory program (hereinafter referred to as the “Indiana program”) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Indiana proposed additions to the Indiana Administrative Code [IAC] rules at 310 IAC 12 pertaining to definition of terms used in the Indiana Program. The amendment is intended to revise the Indiana program to be consistent with the corresponding Federal regulations and to provide additional safeguards.

EFFECTIVE DATE: October 16, 1995.

FOR FURTHER INFORMATION CONTACT: Mr. Roger W. Calhoun, Director, Indianapolis Field Office, Office of Surface Mining Reclamation and Enforcement, Minton-Capehart Federal Building, 575 North Pennsylvania Street, Room 301, Indianapolis, Indiana 46204, Telephone (317) 226-6700.

SUPPLEMENTARY INFORMATION:

- I. Background on the Indiana Program
- II. Submission of the Proposed Amendment
- III. Director’s Findings

- IV. Summary and Disposition of Comments
- V. Director’s Decision
- VI. Procedural Determinations

I. Background on the Indiana Program

On July 29, 1982, the Secretary of the Interior conditionally approved the Indiana program. Background information on the Indiana program, including the Secretary’s findings, the disposition of comments, and the conditions of approval can be found in the July 26, 1982, Federal Register (47 FR 32107). Subsequent actions concerning the conditions of approval and program amendments can be found at 30 CFR 914.10, 914.15, and 914.16.

II. Submission of the Proposed Amendment

By letter dated May 11, 1995 (Administrative Record No. IND-1469), Indiana submitted a proposed amendment to its program pursuant to SMCRA. Indiana submitted the proposed amendment at its own initiative. Indiana proposed to add definitions at 310 IAC 12-0.5-2, 12-0.5-14, 12-0.5-57, 12-0.5-95, 12-0.5-99, and 12-0.5-123. These definitions pertain to acid drainage; augmented seeding, fertilization, or irrigation; high level management; public building; randomly located; and support facility, respectively.

OSM announced receipt of the proposed amendment in the May 30, 1995, Federal Register (59 FR 28073), and in the same document opened the public comment period and provided an opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period closed on June 29, 1995.

III. Director’s Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director’s findings concerning the proposed amendment.

A. Revisions to Indiana Regulations That Are Substantively Identical to the Corresponding Provisions of the Federal Regulations

State regulation	Subject	Federal counterpart
310 IAC 12-0.5-2	Definition of Acid Drainage	30 CFR 701.5
310 IAC 12-0.5-95	Definition of Public Building	30 CFR 761.5