

Dated: June 22, 1998.

Margaret Ann Miller,

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

[FR Doc. 98-17542 Filed 7-1-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Penicillin

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 two supplemental new animal drug applications (NADA's), one filed by Alpharma Inc., the other by Pfizer, Inc. The supplemental NADA's provide for using approved penicillin G procaine Type A medicated articles to make Type C medicated chicken, turkey, pheasant, quail, and swine feeds used for increased rate of weight gain and improved feed efficiency.

EFFECTIVE DATE: July 2, 1998.

FOR FURTHER INFORMATION CONTACT:

Dianne T. McRae, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1623.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is sponsor of NADA 46-666. Pfizer, Inc., 235 East 42d St., New York, NY 10017, is sponsor of NADA 46-668. The sponsors filed supplemental NADA's that provide for amending the regulations concerning use of penicillin Type A medicated articles to make Type B and C medicated feeds for chickens, turkeys, pheasants, quail, and swine for increased rate of weight gain and improved feed efficiency. The supplemental NADA's reflect the results

of the National Academy of Sciences/ National Research Council (NAS/NRC) Drug Efficacy Study Implementation (DESI) review of the products' effectiveness and FDA's conclusions based on that review (35 FR 11533, July 17, 1970).

NAS/NRC evaluated these products as probably effective for faster gain and/or feed efficiency. FDA concurred with these findings and concluded that the appropriate claim should be "for increased rate of weight gain and improved feed efficiency for (under appropriate conditions of use)." The evaluation concerned only the drug's effectiveness and safety to the animal to which administered, and it did not take into account the safety for food use of food derived from drug-treated animals. Nothing herein will constitute a bar to further proceedings with respect to questions of safety of the drugs or their metabolites as residues in food products derived from treated animals.

In the **Federal Register** of August 30, 1977 (42 FR 43772), the then Bureau of Veterinary Medicine issued a notice of opportunity for hearing (NOOH) on a proposal to withdraw approval of NADA's for all penicillin-containing premixes (Type A medicated articles) intended for subtherapeutic use in animal feeds. The NOOH was issued in response to scientific research suggesting that subtherapeutic use of such drugs has contributed to the pool of antibiotic-resistant pathogenic microorganisms in food animals. Furthermore, research indicated that the drug resistance could be transferred to pathogenic organisms in humans. The NOOH is still pending and approval of these supplements to finalize the DESI review process for penicillin-containing Type A medicated articles does not constitute a bar to subsequent action to withdraw approval on the grounds cited in the outstanding NOOH.

The supplemental NADA's are approved as of April 10, 1998. The regulations are amended in 21 CFR 558.460 by redesignating paragraphs (b) and (c) as paragraphs (c) and (d), by adding new paragraph (b), and by

revising the table in paragraph (d) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

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(a)(3) 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 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the 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: 21 U.S.C. 360b, 371.

2. Section 558.460 is amended by redesignating paragraphs (b) and (c) as paragraphs (c) and (d), by adding paragraph (b), and by revising the table in paragraph (d)(1) to read as follows:

§ 558.460 Penicillin.

* * * * *

(b) *Sponsors.* Type A medicated articles: To 000069, 100 grams per pound. To 046573, 100 and 227 grams per pound.

* * * * *

(d) * * *

(1) * * *

Penicillin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 2.4 to 50		Chickens, turkeys, and pheasants; for increased rate of weight gain and improved feed efficiency.	Do not feed to poultry producing eggs for human consumption.	000069, 046573.
(ii) 5 to 20		Quail; for increased rate of weight gain and improved feed efficiency.	Quail; not over 5 weeks of age.	Do.

Penicillin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(iii) 10 to 50		Swine; for increased rate of weight gain and improved feed efficiency.		Do.

* * * * *

Dated: June 22, 1998.

Margaret Ann Miller,

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

[FR Doc. 98-17546 Filed 7-1-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 8775]

RIN 1545-AV79

Election Not to Apply Look-Back Method in De Minimis Cases

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains regulations explaining how a taxpayer elects under section 460(b)(6) not to apply the look-back method to long-term contracts in de minimis cases. The regulations reflect changes to the law made by the Taxpayer Relief Act of 1997 and affect manufacturers and construction contractors whose long-term contracts otherwise are subject to the look-back method.

DATES: *Effective date:* These regulations are effective July 2, 1998.

Applicability date: These regulations apply to long-term contracts completed in taxable years ending after August 5, 1997.

FOR FURTHER INFORMATION CONTACT: Leo F. Nolan II or John M. Aramburu at (202) 622-4960 (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 1545-1572. Responses to this collection of information are required for a taxpayer to elect not to apply the look-back method to long-

term contracts in de minimis cases. 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 OMB control number. The estimated average burden per respondent is 0.2 hours.

Comments concerning the accuracy of this burden estimate should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, OP:FS: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 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

This document contains amendments to the Income Tax Regulations (26 CFR part 1). Section 460(b)(6) of the Internal Revenue Code was added by section 1211 of the Taxpayer Relief Act of 1997, Public Law 105-34, 111 Stat. 788, 998, to provide an election not to apply the look-back method of section 460(b)(2) to long-term contracts in de minimis cases. These regulations provide guidance concerning this new election.

A notice of proposed rulemaking was published in the **Federal Register** for January 13, 1998 (63 FR 1932). No written comments were received, and no public hearing was requested or held. The proposed regulations under section 460 are adopted by this Treasury decision with one revision. The final regulations provide that for long-term contracts completed in taxable years ending after August 5, 1997, an election not to apply the look-back method under section 460(b)(6) automatically revokes an election under § 1.460-6(e) to use the delayed reapplication method.

Special Analyses

It has been determined that this final regulation 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.

Moreover, it is hereby certified that the collection of information in these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the time required to prepare and file an election statement is minimal and will not have a significant impact on those small entities that choose to make the election. In addition, the election need only be made once by a taxpayer. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required.

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 the impact of the proposed regulations on small business.

Drafting Information

The principal author of these regulations is Leo F. Nolan II, Office of 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 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 602 are amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by removing the entry for “§ 1.460-6T” to read in part as follows: