

associated with the musculoskeletal system.

DATES: This rule is effective July 10, 2003.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: West-Ward Pharmaceutical Corp., 465 Industrial Way West, Eatontown, NJ 07724, filed ANADA 200-323 for the oral use of Phenylbutazone Tablets in horses for relief of inflammatory conditions associated with the musculoskeletal system. West-Ward Pharmaceutical's Phenylbutazone Tablets are approved as a generic copy of Boehringer Ingelheim Vetmedica's BIZOLIN (phenylbutazone) Tablets, approved under NADA 99-618. The ANADA is approved as of March 28, 2003, and the regulations are amended in 21 CFR 520.1720a to reflect the approval and current format. The basis of approval is discussed in the freedom of information summary.

In addition, West-Ward Pharmaceutical Corp., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR part 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.

FDA has determined under 21 CFR 25.33(a)(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 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 520
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 parts 510 and 520 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for "West-Ward Pharmaceutical Corp." and in the table in paragraph (c)(2) by numerically adding a new entry for "000143" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *				
(c) * * *				
(1) * * *				
Firm name and address			Drug labeler code	
* * *			* *	
West-Ward Pharmaceutical Corp., 465 Industrial Way West, Eatontown, NJ 07724.			000143	
* * *			* *	
(2) * * *				
Drug labeler code		Firm name and address		
* *		* * *		
000143		West-Ward Pharmaceutical Corp., 465 Industrial Way West, Eatontown, NJ 07724		
* *		* * *		

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

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

4. Section 520.1720a is amended by adding paragraph (b)(5) to read as follows:

§ 520.1720a Phenylbutazone tablets and boluses.

* * * * *				
(b) * * *				
(5) No. 000143 for use of 1-gram tablets in horses.				
* * * * *				

Dated: June 26, 2003.

Andrew J. Beaulieu,
Acting Director, Center for Veterinary Medicine.

[FR Doc. 03-17439 Filed 7-9-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Salinomycin, Chlortetracycline, and Roxarsone

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 Pennfield Oil Co. The ANADA provides for the use of single-ingredient Type A medicated articles containing salinomycin, chlortetracycline, and roxarsone to make three-way combination drug Type C medicated feeds for broiler chickens.

DATES: This rule is effective July 10, 2003.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144, filed ANADA 200-355 for use of PENNCHLOR (chlortetracycline), salinomycin, and roxarsone Type A medicated articles to make three-way combination drug Type C medicated feeds for broiler chickens. Pennfield Oil Co.'s ANADA 200-355 is approved as a generic copy of Alpharma, Inc.'s NADA 140-867. The ANADA is approved as of March 31, 2003, and the regulations are amended in 21 CFR 558.550 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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, 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)(2) 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 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: 21 U.S.C. 360b, 371.

2. Section 558.550 is amended by adding paragraph (a)(3); and in paragraph (d)(1)(xv)(c) by removing "and 046573" and by adding in its place "and 053389" to read as follows:

§ 558.550 Salinomycin.

(a) * * *

(3) To 053389 for use as in paragraph (d)(1)(xv) of this section.

* * * * *

Dated: June 26, 2003.

Andrew J. Beaulieu,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 03-17409 Filed 7-9-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9074]

RIN 1545-AY83

Treatment of Community Income for Certain Individuals Not Filing Joint Returns

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the treatment of community income under Internal Revenue Code section 66 for certain married individuals in community property states who do not file joint Federal income tax returns. The final regulations also reflect changes in the law made by the Internal Revenue Service Restructuring and Reform Act of 1998.

EFFECTIVE DATE: These final regulations are effective July 10, 2003.

FOR FURTHER INFORMATION CONTACT: Robin M. Tuczak, 202-622-4940 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in the final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) under control number 1545-1770. Responses to this collection of information are required in order for certain individuals to receive relief from the operation of community property law.

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 assigned by the Office of Management and Budget.

Estimated total annual reporting burden for 2001 for Form 8857, "Request for Innocent Spouse Relief": 21,123 hours.

Estimated average annual burden hours per response: 59 minutes.

Estimated number of responses for 2001 for Form 8857: 21,336.

Requests for relief under section 66(c) constitute less than 1% of the total requests filed using Form 8857.

Comments on the collection of information should be sent 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, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, W:CAR:MP:T:T:SP, Washington, DC 20224.

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 return information are confidential, as required by section 6103 of the Internal Revenue Code (Code).

Background

This document contains amendments to 26 CFR part 1 under section 66 of the Code, relating to the treatment of community income for certain individuals not filing joint returns. For rules regarding relief from joint and several liability when a joint return is filed, see section 6015 and the regulations thereunder.

A notice of proposed rulemaking (REG-115054-01) was published in the **Federal Register** (67 FR 2841) on January 22, 2002. No public hearing was requested or held. Written comments responding to the notice of proposed rulemaking were received. After consideration of all the comments, the proposed regulations are adopted as amended by this Treasury Decision. The comments and revisions are discussed below.

Explanation and Summary of Comments

1. General

One commentator suggested that the proposed regulations under section 66 (particularly § 1.66-2) were not helpful, given the community property laws of the commentator's state. This commentator also suggested that the proposed regulations appear to assume that the community property laws of all community property states are the same. The intent of these regulations is not to provide guidance based on the community property laws of any particular state. Instead, the regulations provide guidance on the effect of section 66 on taxpayers' community income as determined under state law. After a determination that an item of income is community income under state law, these regulations provide guidance on the treatment of this income under section 66 for certain individuals not filing joint returns.

One commentator noted that there are fundamental differences between married taxpayers who filed joint returns and request relief from joint and several liability under section 6015 and married taxpayers who filed separate returns and request relief from the Federal income tax liability resulting from the operation of community property law under section 66(c).

The final regulations do not address differences between or make generalizations concerning married taxpayers who file joint returns and those who do not. The final regulations focus on providing guidance on the treatment of community income for certain taxpayers under section 66.

The preamble to the proposed regulations under section 66 references