

filed by Pharmacia & Upjohn Co. The NADA provides for veterinary prescription use of Adspec™ (spectinomycin) sterile solution for cattle. The document incorrectly listed the tolerance for spectinomycin residues in cattle muscle. This document corrects that error.

EFFECTIVE DATE: July 16, 1998.

FOR FURTHER INFORMATION CONTACT:

George K. Haibel, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1644.

SUPPLEMENTARY INFORMATION: In FR Doc. 98-11686 appearing on page 24106 in the **Federal Register** of Friday, May 1, 1998, the following correction is made:

§ 556.600 [Corrected]

1. On page 24107, in the second column, in § 556.600 *Spectinomycin*, in paragraph (c), in the fourth line, "0.4" is corrected to read "0.25".

Dated: July 9, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98-18956 Filed 7-15-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Formalin Solution

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 a supplemental new animal drug application (NADA) filed by Western Chemical, Inc. The supplement provides for use of formalin solution in the water of all finfish as a parasiticide and all finfish eggs as a fungicide.

EFFECTIVE DATE: July 16, 1998.

FOR FURTHER INFORMATION CONTACT:

Thomas A. Bell, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1649.

SUPPLEMENTARY INFORMATION: Western Chemical, Inc., 1269 Lattimore Rd., Ferndale, WA 98248, is sponsor of NADA 140-989 that provides for use of Parasite-S® (formalin, an aqueous solution of 37 percent formaldehyde) in the water (tanks, raceways, and ponds) of select fish and penaeid shrimp for the

control of specific external parasites, and as a fungicide for select fish eggs. Western Chemical, Inc., filed a supplemental NADA that provides for use of formalin in the water of all finfish for the control of specific external parasites and as a fungicide for all finfish eggs. The supplemental NADA is approved as of June 18, 1998, and the regulations are amended in 21 CFR 529.1030 to reflect the approval.

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 supplement 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 carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 529

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 529 is amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 529 continues to read as follows:

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

2. Section 529.1030 is amended by revising paragraphs (b)(1) and (b)(2), by redesignating paragraph (c) as paragraph (d) and reserving paragraph (c), by revising newly redesignated paragraphs (d) introductory text, (d)(1) and (d)(2)(i), and by adding paragraphs (d)(2)(iv) and (d)(2)(v) to read as follows:

§ 529.1030 Formalin solution.

* * * * *

(b) * * *

(1) No. 050378 for use as in paragraphs (d)(1)(iii), (d)(1)(iv), (d)(1)(v), (d)(2)(iii), (d)(2)(iv), (d)(2)(v), and (d)(3).

(2) Nos. 049968 and 051212 for use as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(2)(i), (d)(2)(ii), and (d)(3).

* * * * *

(c) [Reserved]

(d) *Conditions of use.* It is added to environmental water as follows:

(1) *Indications for use.* (i) Select finfish. For control of external protozoa *Ichthyophthirius* spp., *Chilodonella* spp., *Costia* spp., *Scyphidia* spp., *Epistylis* spp., and *Trichodina* spp., and monogenetic trematodes *Cleidodiscus* spp., *Gyrodactylus* spp., and *Dactylogyrus* spp., on salmon, trout, catfish, largemouth bass, and bluegill.

(ii) Select finfish eggs. For control of fungi of the family Saprolegniaceae on salmon, trout, and esocid eggs.

(iii) Penaeid shrimp. For control of external protozoan parasites *Bodo* spp., *Epistylis* spp., and *Zoothamnium* spp.

(iv) All finfish. For control of external protozoa *Ichthyophthirius* spp., *Chilodonella* spp., *Costia* spp., *Scyphidia* spp., *Epistylis* spp., and *Trichodina* spp., and monogenetic trematodes *Cleidodiscus* spp., *Gyrodactylus* spp., and *Dactylogyrus* spp.

(v) All finfish eggs: For control of fungi of the family Saprolegniaceae.

(2) * * *

(i) For control of external parasites on select finfish:

* * * * *

(iv) For control of external parasites on all finfish:

Aquatic species	Administer in tanks and raceways for up to 1 hour (microliter/liter or part per million (µL/L or ppm))	Administer in earthen ponds indefinitely (µL/L or ppm)
Salmon and trout:		
Above 50 °F	Up to 170	15 to 25 ^{1, 2}
Below 50 °F	Up to 250	15 to 25 ^{1, 2}
All other finfish	Up to 250	15 to 25 ^{1, 2}

¹ Use the lower concentration when ponds, tanks, or raceways are heavily loaded with phytoplankton or fish to avoid oxygen depletion due to the biological oxygen demand by decay of dead phytoplankton. Alternatively, a higher concentration may be used if dissolved oxygen is strictly monitored.

² Although the indicated concentrations are considered safe for cold and warm water finfish, a small number of each lot or pond to be treated should always be used to check for any unusual sensitivity to formalin before proceeding.

(v) For control of fungi of the family Saprolegniaceae on all finfish eggs: Eggs

of all finfish except Acipenseriformes, 1,000 to 2,000 µL/L (ppm) for 15 minutes; eggs of Acipenseriformes, up to 1,500 µL/L (ppm) for 15 minutes.

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Dated: July 9, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98-18955 Filed 7-15-98; 8:45 am]

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PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4011, 4022, 4041A, 4044, 4050 and 4281

RIN 1212-AA88

Valuation and Payment of Lump Sum Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation is amending its regulations to increase the maximum value of benefits that the PBGC may pay in lump sum form, and certain other lump sum thresholds, from \$3,500 to \$5,000. The amendments do not affect lump sum benefits paid by ongoing plans.

DATES: The amendments to 29 CFR 4022.7, 4044.52(b), and 4044.54 are effective July 16, 1998. (However, except to the extent they affect determinations under § 4022.7, the amendments to 29 CFR 4044.52(b) and 4044.54 apply only to a plan with a termination date on or after August 17, 1998.) The final rule is otherwise effective August 17, 1998.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, or Marc L. Jordan, Attorney, Pension Benefit Guaranty Corporation, Office of the General Counsel, Suite 340, 1200 K Street, NW., Washington, DC 20005-4026, 202-326-4024. (For TTY/TTD users, call the Federal relay service toll-free at 1-800-877-8339 and ask to be connected to 202-326-4024.)

SUPPLEMENTARY INFORMATION: Section 203(e) of ERISA specifies the maximum value that a plan may provide it will pay in a lump sum (i.e., single installment) to a participant or surviving spouse without consent. The Taxpayer Relief Act of 1997 increased the section 203(e) maximum from \$3,500 to \$5,000 effective for plan years beginning after August 5, 1997.

On April 30, 1998, the PBGC proposed to amend its regulations to increase various \$3,500 thresholds to

\$5,000 and to make other changes relating to lump sum payments. The PBGC received no comments in response to the proposed rule and is issuing the final rule without change, as follows:

- Under the final rule, the PBGC may make a lump sum payment of a benefit that has a value of \$5,000 or less as of the plan's termination date. (See § 4022.7 and, to the extent they affect determinations under § 4022.7, §§ 4044.52(b), and 4044.54.) There are special rules for applying the lump sum threshold where the PBGC issues a determination on title IV benefits before it issues a determination on benefits payable under ERISA section 4022(c). Consistent with its current practice, the PBGC will give the participant the option to receive the benefit in the form of an annuity if the monthly benefit (at normal retirement age in the normal form for an unmarried participant) is equal to or greater than \$25.

Applicability: This amendment applies to any initial determination issued on or after July 16, 1998. For any initial determination issued before July 16, 1998, the PBGC may make a lump sum payment of a benefit with a value of \$5,000 or less, provided (1) the benefit is not yet in pay status, and (2) the participant (with spousal consent) or beneficiary elects the lump sum payment.

- Under the final rule, the lump sum threshold under §§ 4044.52(b) and 4044.54, which is used for determining whether lump sum or annuity assumptions are used to value benefits for purposes of allocating assets to benefits under ERISA section 4044, is \$5,000.

Applicability: This amendment applies to any plan with a termination date on or after August 17, 1998.

- The reference to the lump sum threshold in the PBGC's Model Participant Notice (Part 4011, Appendix A) is changed from \$3,500 to \$5,000.

Applicability: This amendment applies to any Participant Notice issued on or after August 17, 1998. However, for a reasonable time period, the PBGC will not treat a Participant Notice as failing to satisfy the Participant Notice requirements merely because it refers to the \$3,500 threshold.

- The dollar thresholds in the Missing Participants regulation are increased from \$3,500 to \$5,000. See §§ 4050.2 (definition of *missing participant annuity assumptions*) and 4050.5(a)(2) (*de minimis* lump sum).

Applicability: This amendment applies to missing participants for whom the deemed distribution date is on or after August 17, 1998.

- The dollar threshold up to which the plan sponsor of a terminated multiemployer plan that is closing out may make a lump sum payment of nonforfeitable benefits is increased from \$3,500 to \$5,000 (see § 4041A.43(b)(1)).

Applicability: This amendment applies to any distribution made on or after August 17, 1998.

- In the case of participant deaths after the termination date, the final rule allows the PBGC to make a lump sum payment of a qualified preretirement survivor annuity with a value of \$5,000 or less if the surviving spouse elects a lump sum (§ 4022.7(b)(1)(iii)).

Applicability: This amendment applies to any lump sum payment made on or after July 16, 1998.

- The final rule allows the PBGC to make a lump sum payment, without regard to amount, of any benefits due to an estate (e.g., under a certain and continuous benefit where the designated beneficiary predeceases the participant) if the estate elects a lump sum (see § 4022.7(b)(1)(iv)).

Applicability: This amendment applies to any payment made on or after July 16, 1998.

Finally, the final rule (1) eliminates, as unnecessary, two provisions in its multiemployer valuation regulation that refer to the \$3,500 limit, and (2) makes clear that the lump sum value of a benefit is calculated by valuing the monthly annuity benefit (which excludes the value of certain preretirement death benefits, such as a qualified preretirement survivor annuity).

Rulemaking Requirements

The PBGC has determined that good cause exists to make certain amendments (the amendments to 29 CFR 4022.7 and, to the extent they affect determinations under 29 CFR 4022.7, the amendments to §§ 4044.52(b) and 4044.54) effective and applicable immediately. These amendments impose requirements only on the PBGC. A delayed effective date is unnecessary because no person other than the PBGC needs time to prepare. See 5 U.S.C. 553(d)(3).

E.O. 12866 and the Regulatory Flexibility Act

The PBGC has determined that this final rule is not a "significant regulatory action" under the criteria set forth in Executive Order 12866. The PBGC certifies that the amendments will not have a significant economic impact on a substantial number of small entities. The amendments will affect only *de minimis* benefits and will have an immaterial effect on liabilities