

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

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 new animal drug application (NADA) filed by Abbott Laboratories. The NADA provides for veterinary prescription use of propofol emulsion for intravenous injection in dogs as an anesthetic.

EFFECTIVE DATE: May 4, 1998.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center For Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1612.

SUPPLEMENTARY INFORMATION: Abbott Laboratories, 1401 Sheridan Rd., North Chicago, IL 60064-4000, filed NADA 141-098 that provides for veterinary prescription use of PropoFlo® (propofol) emulsion for intravenous injection in dogs for induction of anesthesia, maintenance of anesthesia, or induction of anesthesia where maintenance is provided by inhalation anesthetic. The NADA is approved as of March 13, 1998, and the regulations are amended in 21 CFR 522.2005(b) 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 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, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval for nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning March 13, 1998, because the application contains substantial evidence of the effectiveness of the drug involved and studies of animal safety required for approval and conducted or sponsored by the applicant.

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.

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: 21 U.S.C. 360b.

§ 522.2005 [Amended]

2. Section 522.2005 *Propofol injection* is amended in paragraph (b) by removing "No. 000061" and adding in its place "Nos. 000061 and 000074".

Dated: April 22, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98-11740 Filed 5-1-98; 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; Monensin

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) filed by Elanco Animal Health, Division of Eli Lilly and Co. The supplemental NADA's provide a revised specification for monensin bulk drug substance used to make monensin Type A medicated articles.

EFFECTIVE DATE: May 4, 1998.

FOR FURTHER INFORMATION CONTACT:

Mary G. Leadbetter, Center for Veterinary Medicine (HFV-142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1662.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, is the sponsor of NADA 38-878 that provides for use of monensin Type A medicated articles to make monensin Type C medicated feeds for chickens, turkeys, and quail, and NADA 95-735 that provides for use of monensin Type A medicated articles to make monensin Type B and C medicated feeds for cattle and goats. Elanco filed supplemental NADA's that provide revised assay information used in checking the specifications of the monensin bulk drug substance used in Type A medicated articles. The supplemental NADA's were approved as of March 17, 1997, and the regulations are amended in 21 CFR 558.355(a) to reflect the approval.

Approval of these supplements did not require a freedom of information summary because the approvals concern a change in specifications of the monensin bulk drug substance. This change does not affect the product's safety or effectiveness.

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 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.

§ 558.355 [Amended]

2. Section 558.355 *Monensin* is amended in paragraph (a) after the parenthetical phrase by removing the period at the end of the second sentence, and by adding the phrase " or, using High Performance Liquid Chromatography, the factor distribution of monensin Factor A or B is calculated as the percentage of total biopotency of all peaks."

Dated: April 21, 1998.

Andrew J. Beaulieu,

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

[FR Doc. 98-11741 Filed 5-1-98; 8:45 am]

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PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4231

RIN 1212-AA69

Mergers and Transfers Between Multiemployer Plans

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation is amending its regulation on Mergers and Transfers Between Multiemployer Plans to clarify how the rules are to be applied to plans terminated by mass withdrawal and to make other minor changes and clarifications in the regulation.

EFFECTIVE DATE: June 3, 1998.

FOR FURTHER INFORMATION CONTACT:

Deborah C. Murphy, Attorney, Office of the General Counsel, suite 340, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005-4026; 202-326-4024 (202-326-4179 for TTY and TDD).

SUPPLEMENTARY INFORMATION:

Background

Under section 4231 (a) and (b) of ERISA, a merger, or a transfer of assets and liabilities, between multiemployer plans must satisfy four requirements unless otherwise provided in regulations prescribed by the PBGC:

(1) The PBGC must receive 120 days' advance notice of the transaction;

(2) Accrued benefits must not be reduced;

(3) There must be no reasonable likelihood that benefits will be suspended as a result of plan insolvency; and

(4) An actuarial valuation of each affected plan must have been performed as prescribed in section 4231(b)(4).

The PBGC's regulation on Mergers and Transfers Between Multiemployer Plans (29 CFR part 4231) prescribes procedures for requesting a determination that a merger or transfer satisfies applicable requirements, allows the PBGC to waive the 120-day notice requirement, and sets higher-level and lower-level requirements for "safe harbor" plan solvency tests and for valuation standards. Whether the

higher-level or lower-level requirements apply depends on whether a "significant transfer" is involved.

On May 1, 1997, the PBGC published for public comment (at 62 FR 23700) a proposed rule to amend part 4231. One commenter submitted comments. The final rule reflects changes made in response to the comments.

Terminated Plan Transactions

The proposed amendment provided that transactions involving plans terminated by mass withdrawal under ERISA section 4041A(a)(2) would (except for "*de minimis*" transactions) be governed by the higher-level valuation standard and "safe harbor" solvency test. The proposed amendment also extended to "*de minimis*" terminated plan transactions the requirement that actuarial valuation reports be submitted to the PBGC.

The commenter expressed concern that the proposed amendment would "have the adverse effect of making it more expensive for a large, well-funded plan to rescue a small terminated plan by absorbing it into a large, stable asset pool." The final regulation adopts the commenter's suggestion that a plan not be subjected to the higher-level valuation provisions simply because it was involved in a terminated plan transaction if it were not otherwise "significantly affected" (see §§ 4231.5 and 4231.9(b)(1)(iii)).

Other Changes

The commenter pointed out that for consistency with other provisions, redesignated § 4231.6(a)(2) should refer to "the first five years beginning on or after the proposed effective date" (rather than just "after" that date). The PBGC agrees and has made the suggested change.

Paperwork Reduction Act

The collection of information requirements in Part 4231 as amended have been approved by the Office of Management and Budget under control number 1212-0022 (expires June 30, 2000). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Compliance With Rulemaking Guidelines

The PBGC has determined that this action is not a "significant regulatory action" under the criteria set forth in Executive Order 12866.

The PBGC certifies that the amendment in this rule will not have a significant economic impact on a

substantial number of small entities. This certification is based on the fact that the primary substantive effect of the amendment is to liberalize certain existing requirements and to clarify the application of existing requirements to a very rare category of transactions, viz., multiemployer mergers and transfers involving plans that have terminated by mass withdrawal. (The PBGC is aware of only two such transactions since section 4231 of ERISA was enacted.) Accordingly, as provided in section 605(b) of the Regulatory Flexibility Act, compliance with sections 603 and 604 of the Regulatory Flexibility Act is not required.

List of Subjects in 29 CFR Part 4231

Pensions, Reporting and recordkeeping requirements.

For the reasons given above, 29 CFR part 4231 is revised to read as follows.

PART 4231—MERGERS AND TRANSFERS BETWEEN MULTIEMPLOYER PLANS

Sec.

4231.1 Purpose and scope.

4231.2 Definitions.

4231.3 Requirements for mergers and transfers.

4231.4 Preservation of accrued benefits.

4231.5 Valuation requirement.

4231.6 Plan solvency tests.

4231.7 *De minimis* mergers and transfers.

4231.8 Notice of merger or transfer.

4231.9 Request for compliance determination.

4231.10 Actuarial calculations and assumptions.

Authority: 29 U.S.C. 1302(b)(3), 1411.

§ 4231.1 Purpose and scope.

(a) *Purpose.* The purpose of this part is to prescribe notice requirements under section 4231 of ERISA for mergers and transfers of assets or liabilities among multiemployer pension plans. This part also interprets the other requirements of section 4231 and prescribes special rules for *de minimis* mergers and transfers. The collections of information in this part have been approved by the Office of Management and Budget under OMB control number 1212-0022.

(b) *Scope.* This part applies to mergers and transfers among multiemployer plans where all of the plans immediately before and immediately after the transaction are multiemployer plans covered by title IV of ERISA.

§ 4231.2 Definitions.

The following terms are defined in § 4001.2 of this chapter: Code, EIN, ERISA, fair market value, IRS, multiemployer plan, PBGC, plan, plan year, and PN.