

would serve any useful purpose at this time.

The agency has carefully considered the potential environmental impact of this final rule and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement therefore will not be prepared. The agency's finding of no significant impact and the evidence supporting this finding contained in an environmental assessment (pursuant to 21 CFR 25.31, proposed December 11, 1979; 44 FR 71742) may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

The agency has examined the economic impact of this rule and has determined that it does not require either a regulatory impact analysis, as specified in Executive Order 12291, or a regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96-354). Specifically, the agency has determined that because the effect of this final rule is to revoke a stayed regulation, no economic impact will result. Therefore, the agency concludes that the final rule is not a major rule as defined in Executive Order 12291. Further, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Medical devices, Reporting and recordkeeping requirements.

PART 310—NEW DRUGS

§ 310.511 [Removed]

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 505, 701(a), 52 Stat. 1052-1053 as amended, 1055 (21 U.S.C. 355, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 310 is amended by removing § 310.511 *Inhalation anesthetic drugs*.

Effective date. November 29, 1982.

(Secs. 505, 701(a), 52 Stat. 1052-1053 as amended, 1055 (21 U.S.C. 355, 371(a)))

Dated: October 8, 1982.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 82-29728 Filed 10-28-82; 8:45 am]

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21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Monensin

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Products Co., providing for additional labeling statements for use of monensin in cattle feeds, feed supplements, and premixes.

DATES: Effective October 29, 1982; revised labeling must be submitted by December 28, 1982.

FOR FURTHER INFORMATION CONTACT: David N. Scarr, Bureau of Veterinary Medicine (HFV-214), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3183.

SUPPLEMENTARY INFORMATION: Elanco Products Co., a Division of Eli Lilly & Co., 740 South Alabama St., Indianapolis, IN 46206, submitted a supplemental NADA (95-735) revising the labeling for monensin cattle feeds, feed supplements, and premixes to add warning statements or clarify existing warning statements as follows: (1) Monensin cattle feeds are safe for use in cattle only; (2) premixes must not be fed undiluted; (3) feeds must be thoroughly mixed before use; (4) high concentrations of monensin could be fatal to cattle; (5) excess levels of monensin may result in reduced weight gains; (6) do not allow horses or other equines access to feeds containing monensin. Ingestion of monensin by horses has been fatal. These revisions are consistent with the changes provided for the Federal Register of May 4, 1982 (47 FR 19119) relating to use of monensin liquid feed supplements in the production of finished cattle feed.

On or before December 28, 1982, current holders who wish to maintain their approved medicated feed applications (MFA's) providing for the use of monensin in dry feeds must submit revised labeling to their application conforming to the new revised labeling. MFA holders who no longer wish to manufacture monensin dry feeds or supplements should request withdrawal of approval of their application(s) and waive the opportunity for a hearing. The agency will proceed to withdraw approval of any medicated feed application if it is not appropriately amended on or before December 28, 1982. Labeling bearing the statements required by this revised regulation and otherwise consistent with labeling

provided for by Elanco's supplemental NADA may be placed into effect in advance of approval of the supplemental MFA because the changes provide for safer use of monensin medicated feed. Revised labeling submitted, consistent with the provisions of 21 CFR 558.355 as amended, will be filed with the original application.

Approval of this supplement does not change the previously approved use of the drug, but provides added warnings for safer use. It results in no increased human risk from exposure to residues of the animal drug because the number of food-producing animals receiving the drug will not significantly increase. The drug will not be used at a higher dosage, for longer duration, or for different indications.

Accordingly, under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367; December 23, 1977), this is a Category I supplemental approval, which does not require reevaluation of the effectiveness or human safety data supporting the parent NADA.

The supplement is approved, and the regulations are amended accordingly.

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 558 is amended in § 558.355 by adding new paragraph (d) (6), (7), (8), and (9), by removing the last five sentences in paragraph (f)(3)(i)(b)(1), by removing the last sentences in paragraph (f)(3)(ii)(b), and by removing the last two sentences in paragraph (f)(3)(iii)(b), as follows:

§ 558.355 Monensin.

(d)

(6) The labeling of all formulations containing monensin shall bear the following caution statement: Do not allow horses or other equines access to formulations containing monensin. Ingestion of monensin by equines has been fatal.

(7) The labeling of all premixes and feed supplements (liquid and dry) containing monensin intended for use in cattle shall bear, in addition to the caution statement in paragraph (d)(6) of this section, the following caution statements:

(i) Monensin medicated cattle feed is safe for use in cattle only. Consumption by unapproved species may result in toxic reactions;

(ii) Feeding undiluted or mixing errors resulting in high concentrations of monensin could be fatal to cattle;

(iii) Must be thoroughly mixed in feeds before use;

(iv) Do not feed undiluted;

(v) Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result.

(8) The labeling of complete feeds containing monensin intended for use in cattle shall bear the caution statements specified in paragraph (d)(6) and (7) (i) and (v) of this section.

(9) The labeling of premixes containing monensin intended for use in chickens shall bear the caution statements specified in paragraph (d)(6) and (7) (iii) and (iv) of this section.

Effective date, October 29, 1982.

(Sec. 5f2(i); 82 Stat. 347 (21 U.S.C. 360(i)))

Dated: October 21, 1982.

Gerald B. Guest,

Acting Director, Bureau of Veterinary Medicine.

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21 CFR Parts 600, 610, and 640

[Docket No. 79N-0405]

Platelet Concentrate (Human);
Additional Standards

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations by: (1) eliminating the volume limits required for the shipping, processing, and storage of Platelet Concentrate (Human); (2) requiring that the Rh and ABO blood

group be designated on the label of Platelet Concentrate (Human); and (3) reducing the dating period for Platelet Concentrate (Human) and Single Donor Plasma (Human), Platelet Rich stored at 1° to 6° C from 72 hours to 48 hours from the time of collection of the source blood. These updated regulations, based on recently published scientific studies and experience, reflect an improvement in the safety, purity, potency, and efficacy of Platelet Concentrate (Human).

DATES: Effective November 29, 1982; labeling requirements shall become effective April 29, 1983.

FOR FURTHER INFORMATION CONTACT: T. Rada Proehl, National Center for Drugs and Biologics (HFB-620), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306.

SUPPLEMENTARY INFORMATION: FDA issued additional standards for Platelet Concentrate (Human) on January 29, 1975 (40 FR 4300) under §§ 640.20 through 640.26 (21 CFR 640.20 through 640.26). As a result of significant changes in platelet production since the publication of the additional standards for Platelet Concentrate (Human), FDA published a notice of proposed rulemaking in the *Federal Register* on January 15, 1980 (45 FR 2852) to amend the biologics regulations specifically by (1) eliminating the volume limits for Platelet Concentrate (Human), (2) requiring that Rh and ABO blood groups be designated on the label for Platelet Concentrate (Human), and (3) reducing the dating period for Platelet Concentrate (Human) and Single Donor Plasma (Human). These changes are discussed below.

A. Elimination of Volume Limits for
Platelet Concentrate (Human)

Section 640.24(d) (21 CFR 640.24(d)) previously required that a specified volume of original plasma be used for the resuspension of platelets and that the plasma be stored at a specified temperature in order to maintain a pH of not less than 6.0 during the storage period. The required storage temperature and corresponding volume of resuspension plasma to be used continuously was: 20° to 24° C resuspended in 30 to 50 milliliters of plasma or 1° to 6° C resuspended in 20 to 30 milliliters of plasma. The pH was required to be measured on a sample of platelet concentrate at the selected storage temperature. As stated in the proposal, current manufacturing techniques produce a higher concentration of platelets in each unit of Platelet Concentrate (Human). This change in platelet concentration is

significant because the current upper limit of 50 milliliters for the volume of resuspension plasma for Platelet Concentrate (Human) no longer ensures the maintenance of the required pH of not less than 6.0 during the storage period. Platelet viability is known to be compromised at a pH of less than 6.0. Consequently, the present limits for the volume of resuspension plasma for Platelet Concentrate (Human) do not ensure the quality of the product or encourage the development of techniques that improve the yield of platelets from a unit of source blood. FDA therefore proposed to eliminate the volume limits and to require that the volume of resuspension plasma be determined solely by the maintenance of a pH of not less than 6.0 during the storage period. The proposal did not recommend change of the storage temperatures which continue to be 20° to 24° C or 1° to 6° C with pH measured on a sample of platelet concentrates stored for the maximum dating period at the selected storage temperature. Consistent with the elimination of the volume limits of resuspension plasma in § 640.24(d), FDA also proposed to amend § 640.20(a) (21 CFR 640.20(a)) to revise the wording concerning the volume of resuspension plasma in the definition of Platelet Concentrate (Human). Correspondingly, FDA proposed to eliminate references to the volume limits of the resuspension plasma for Platelet Concentrate (Human) in § 600.15(a) (21 CFR 600.15(a)) and § 640.25(a) (21 CFR 640.25(a)).

B. Requiring Label Designation of ABO
and Rh Blood Group

Section 640.26(e) (21 CFR 640.26(e)) previously required the container label for Platelet Concentrate (Human) to bear the blood group designations. Although tests used to identify both the ABO and Rh blood groups are required for the blood from which plasma is separated for the preparation of Platelet Concentrate (Human), the existing labeling requirements were interpreted by many people to apply only to the ABO blood group designation because of its clinical use. The proposal explained that designation of the Rh blood group is important because platelet products are contaminated with significant number of red blood cells which can cause immunization to the Rh antigen. Therefore, FDA proposed to amend § 640.26(e) to specify that the container label for Platelet Concentrate (Human) bear the ABO and Rh blood group designation of the source blood.