imposing requirements related to the regulation of nonprescription drug products. Section 751(b) through (e) of the act outlines the scope of the express preemption provision, the exemption procedures, and the exceptions to the provision.

This final rule provides an additional statement of identity for skin protectants formulated and marketed as lip protectants and allows omission of a warning for certain lip protectant products. Any final rule has a preemptive effect in that it precludes States from issuing requirements related to the labeling of OTC skin protectant drug products that are different from or in addition to, or not otherwise identical with a requirement in the final rule. This preemptive effect is consistent with what Congress set forth in section 751 of the act. Section 751(a) of the act displaces both State legislative requirements and State common law duties. We also note that even where the express preemption provision is not applicable, implied preemption may arise (see *Geier* v. *American Honda Co.*, 529 US 861 (2000)).

We believe that the preemptive effect of the final rule is consistent with Executive Order 13132. Section 4(e) of the Executive order provides that ''when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.''

We provided the States with an opportunity for appropriate participation in this rulemaking when we sought input from all stakeholders on the reduced labeling requirements that this rulemaking addresses, through publication of the request for comments in the **Federal Register** in the preamble to the final rule on June 4, 2003 (68 FR 33362). We received no comments from any States in response to the request.

In addition, on December 10, 2007, FDA's Division of Federal and State Relations provided notice via e-mail transmission to elected officials of State governments and their representatives of national organization. The notice provided the States with further opportunity to comment. It advised the States of the publication of the request for comments and encouraged State and local governments to review the request and to provide any comments to the dockets for this rulemaking (Docket Nos. 1978N–0021 and 1978N–0021P) by a date 30 days after the date of the notice (i.e., by January 10, 2008), or to contact certain named individuals. FDA received no comments in response to this notice. The notice has been filed in the previously mentioned dockets.

In conclusion, we believe that we have complied with all of the applicable requirements under the Executive order and have determined that the preemptive effects of this rule are consistent with Executive Order 13132.

VI. Environmental Impact

We have determined under 21 CFR 25.31(a) 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.

VII. References

The following references are on display in the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 under Docket No. 1978N–0021 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. C67.
2. Comment No. C68.
3. Comment No. C69.

List of Subjects in 21 CFR Part 347

Labeling, Over-the-counter drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 347 is amended as follows:

PART 347—SKIN PROTECTANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

■ 1. The authority citation for 21 CFR part 347 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

■ 2. Section 347.50 is amended by revising paragraphs (a) and (e)(1)(iii) to read as follows:

§ 347.50 Labeling of skin protectant drug products.

* * * * *

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product with one or more of the following:

(1) *For any product.* ''Skin protectant'' (optional, may add dosage form, e.g., ''cream,'' ''gel,'' ''lotion,'' or ''ointment'').

(2) *For any product formulated as a lip protectant.* ''Skin protectant,'' ''lip protectant,'' or ''lip balm'' (optional, may add dosage form, e.g., ''cream,'' ''gel,'' ''lotion,'' or ''ointment'').

(3) *For products containing any ingredient in § 347.10(b), (c), (j), (s), (t), and (u).* ''Poison ivy, oak, sumac drying'' (optional, may add dosage form, e.g., ''cream,'' ''gel,'' ''lotion,'' or ''ointment'').

(4) *For products containing any ingredient in § 347.10(b), (c), (f), (j), (o), (s), (t), and (u).* ''Poison ivy, oak, sumac protectant.''

* * * * *

(e) *Products formulated and labeled as a lip protectant and that meet the criteria established in § 201.66(d)(10) of this chapter.* * * *

(1) * * *

(iii) The ''external use only'' warning in § 347.50(c)(1) and in § 201.66(c)(5)(i) of this chapter may be omitted. The warnings in § 347.50(c)(2), (c)(3), and (c)(4) are not required.

* * * * *

Dated: January 28, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–1818 Filed 1–31–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Tulathromycin

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 Pfizer, Inc. The supplemental NADA provides for veterinarian prescription use of tulathromycin injectable solution for the treatment of infectious bovine keratoconjunctivitis and the addition of a pathogen to the indication for use for treatment of swine respiratory disease.

DATES: This rule is effective February 1, 2008.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8342, e-mail: *joan.gotthardt@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 141–244 for DRAXXIN (tulathromycin)

Injectable Solution. The supplemental NADA provides for treatment of infectious bovine keratoconjunctivitis associated with *Moraxella bovis* and the addition of a pathogen, *Mycoplasma hyopneumoniae*, to the indication for use for treatment of swine respiratory disease. The application is approved as of December 28, 2007, and the regulations are amended in 21 CFR 522.2630 to reflect the approval.

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 Division of Dockets Management (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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

The agency has determined under 21 CFR 25.33(a)(1) and (d)(5) 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 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.

■ 2. In § 522.2630, revise paragraphs (d)(1)(ii) and (d)(2)(ii) to read as follows:

§ 522.2630 Tulathromycin.

* * * * *

(d) * * *

(1) * * *

(ii) *Indications for use*. For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* (*Haemophilus somnus*), and *Mycoplasma bovis*; for the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis*; and for the treatment of infectious bovine keratoconjunctivitis (IBK) associated with *Moraxella bovis*.

* * * * *

(2) * * *

(ii) *Indications for use*. For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida, Bordetella bronchiseptica, Haemophilus parasuis*, and *Mycoplasma hyopneumoniae*.

* * * * *

Dated: January 24, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–1906 Filed 1–31–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feed; Zilpaterol

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 Intervet, Inc. The NADA provides for use of zilpaterol, monensin, and tylosin in three-way combination Type B and Type C medicated feeds for cattle fed in confinement for slaughter.

DATES: This rule is effective February 1, 2008.

FOR FURTHER INFORMATION CONTACT: Gerald L. Rushin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8103, e-mail: *gerald.rushin@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Intervet, Inc., P.O. Box 318, 29160 Intervet Lane, Millsboro, DE 19966, filed NADA 141–276 that provides for use of ZILMAX (zilpaterol hydrochloride), and RUMENSIN (monensin), and TYLAN (tylosin phosphate) Type A medicated articles to make dry and liquid three-way combination Type B and Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes* in cattle fed in confinement for slaughter during the last 20 to 40 days on feed. The NADA is approved as of January 10, 2008, and the regulations in 21 CFR 558.355, 558.625, and 558.665 are amended to reflect the approval.

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 Division of Dockets Management (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 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. In § 558.355, add paragraph (f)(7)(iv) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(7) * * *