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) * * *

(iv) Zilpaterol alone or in combination as in § 558.665.

■ 3. In § 558.625, add paragraph (f)(2)(ix) to read as follows:

§ 558.625 Tylosin.

* * * * *

(f) * * *

(2) * * *

(ix) Zilpaterol alone or in combination as in § 558.665.

■ 4. In § 558.665, revise paragraph (e) to read as follows:

§ 558.665 Zilpaterol.

* * * * *

(e) *Conditions of use in cattle.* It is administered in feed as follows:

Zilpaterol in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(1) 6.8 to provide 60 to 90 mg/head/day		Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed.	Feed continuously as the sole ration during the last 20 to 40 days on feed. Withdrawal period: 3 days.	057926
(2) [Reserved]				
(3) [Reserved]				
(4) 6.8 to provide 60 to 90 mg/head/day	Monensin 10 to 40, plus tylosin 8 to 10	Cattle fed in confinement for slaughter: As in paragraph (e)(1) of this section; 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*.	As in paragraph (e)(1) of this section; see §§ 558.355(d) and 558.625(c) of this chapter. Monensin and tylosin as provided by No. 000986 in § 510.600(c) of this chapter.	057926

Dated: January 24, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–1903 Filed 1–31–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Parts 502, 522, 559 and 573

RIN 3141–AA23

Facility License Standards

AGENCY: National Indian Gaming Commission (''NIGC'' or ''Commission'').

ACTION: Final rule.

SUMMARY: The rule adds new sections and a new part to the Commission's regulations that require tribes to adopt and enforce standards for facility licenses. These standards will help the Commission ensure that each place, facility or location where class II or class III gaming will occur is located on Indian lands eligible for gaming as required by the Indian Gaming Regulatory Act. The rules will ensure that gaming facilities are constructed, maintained and operated in a manner that adequately protects the environment and the public health and safety.

DATES: Effective March 3, 2008.

FOR FURTHER INFORMATION CONTACT: Penny J. Coleman, Acting General Counsel, at 202–632–7003; fax 202–632–7066 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

I. Background

On October 17, 1988, Congress enacted the Indian Gaming Regulatory Act (''IGRA'' or ''Act''), 25 U.S.C. 2701–21, creating the National Indian Gaming Commission (''NIGC'' or ''Commission'') and developing a comprehensive framework for the regulation of gaming on Indian lands. 25 U.S.C. 2702. The NIGC was granted, among other things, the authority to promulgate such regulations and guidelines as it deems appropriate to implement the provisions of IGRA, 25 U.S.C. 2706(b)(10), as well as oversight and enforcement authority, including the authority to monitor tribal compliance with the Act, Commission regulations, and tribal gaming ordinances.

First, the IGRA allows gaming on Indian lands pursuant to 25 U.S.C. 2703(4), and it contains a general prohibition against gaming on lands acquired into trust by the United States for the benefit of the tribe after the Act's effective date of October 17, 1988, unless one of several exceptions are met. 25 U.S.C. 2719. The Commission has jurisdiction only over gaming operations on Indian lands and therefore must establish that it has jurisdiction as a prerequisite to its monitoring, enforcement, and oversight duties. 25 U.S.C. 2702(3).

Second, the NIGC needs to obtain information on a tribe's environmental and public health and safety laws to oversee the implementation of approved tribal gaming ordinances. Before opening a gaming operation, a tribe must adopt an ordinance governing gaming activities on its Indian lands. 25 U.S.C. 2710. The Act specifies a number of mandatory provisions to be contained in each tribal gaming ordinance and subjects such ordinances to the NIGC Chairman's approval. *Id.* Approval by the Chairman is predicated on the inclusion of each of the Act's specified mandatory provisions in the tribal gaming ordinance. *Id.* Among these is a requirement that the ordinance must contain a provision ensuring that ''the construction and maintenance of the gaming operation, and the operation of that gaming is conducted in a manner that adequately protects the environment and the public health and safety.'' 25 U.S.C. 2710(b)(2)(E). Since 1993, when the Commission became operational, the Chairman has required each tribal gaming ordinance submitted for approval to include the express environmental and public health and safety statement set out in 25 U.S.C. 2710(b)(2)(E).

The Commission believes that tribes must have some form of basic laws in the following environmental and public health and safety areas: (1) Emergency preparedness, including but not limited