Oxytetracycline amount	Indications for use	Limitations	Sponsor
(ii) 10 mg/lb of body weight daily	Sheep: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter.	066104, 048164
(iii) 200 mg/colony	Honey bees: For control of American foulbrood caused by *Paenibacillus larvae* and European foulbrood caused by *Streptococcus pluton* susceptible to oxytetracycline.	Remove at least 6 weeks prior to main honey flow.	066104, 048164
(iv) 250 mg/kilogram of fish/day (11.35 g/100 lb of fish/day)	Pacific salmon: For marking of skeletal tissue.	For salmon not over 30 g body weight; administer as sole ration for 4 consecutive days; fish not to be liberated for at least 7 d following the last administration of medicated feed.	066104
(v) 2.5 to 3.75 g/100 lb of fish/day	1. Salmonids: For control of ulcer disease caused by *Hemophilus piscium*, furunculosis caused by *Aeromonas salmonicida*, bacterial hemorrhagic septicemia caused by *A. liquefaciens*, and pseudomonas disease. 2. Catfish: For control of bacterial hemorrhagic septicemia caused by *A. liquefaciens* and pseudomonas disease.	Administer in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed; do not administer when water temperature is below 9 °C (48.2 °F). Administer in mixed ration for 10 d; do not liberate fish or slaughter fish for food for 21 d following the last administration of medicated feed; do not administer when water temperature is below 16.7 °C (62 °F).	066104 066104
(vi) 1 g/lb of medicated feed	Lobsters: For control of gaffkemia caused by *Aerococcus viridans*.	Administer as sole ration for 5 consecutive days; withdraw medicated feed 30 d before harvesting lobsters.	066104

(6) Oxytetracycline may be used in accordance with the provisions of this section in the combinations as follows:

(i) Carbadox as in § 558.115.

(ii) Lasalocid as in § 558.311.

(iii) Melengestrol acetate as in § 558.342.

(iv) Robenidine hydrochloride as in § 558.515.

(v) Salinomycin as in § 558.550.

Dated: December 5, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–24146 Filed 12–12–07; 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 Feeds; Ractopamine

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 Elanco Animal Health. The supplemental NADA provides for an increased level of monensin in three-way combination Type C medicated feeds containing ractopamine, melengestrol, and monensin for heifers fed in confinement for slaughter.

DATES: This rule is effective December 13, 2007.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223, e-mail: *daniel.benz@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 141–234 that provides for use of OPTAFLEXX (ractopamine hydrochloride), MGA (melengestrol acetate), and RUMENSIN (monensin USP) Type A medicated articles to make dry and liquid three-way combination 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 suppression of estrus (heat) in heifers fed in confinement for slaughter during the last 28 to 42 days on feed. The supplemental NADA provides for an increased level of monensin. The supplemental NADA is approved as of November 20, 2007, and the regulations in 21 CFR 558.500 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 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 § 558.500, in the table in paragraph (e)(2), revise paragraph (e)(2)(viii) and add paragraph (e)(2)(xii) to read as follows:

§ 558.500 Ractopamine.

* * * * *

(e) * * *

(2) * * *

Ractopamine grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
*	* *	* *	*	*
(viii) 9.8 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers fed in confinement for slaughter: As in paragraph (e)(2)(vi) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and for suppression of estrus (heat).	As in paragraph (e)(2)(vi) of this section; see §§ 558.342(d) and 558.355(d) of this chapter. Melengestrol acetate as provided by No. 000009 in § 510.600(c) of this chapter.	000986
*	* *	* *	*	*
(xii) 9.8 to 24.6	Monensin 10 to 30, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers fed in confinement for slaughter: As in paragraph (e)(2)(vi) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and for suppression of estrus (heat).	As in paragraph (e)(2)(vi) of this section; see §§ 558.342(d) and 558.355(d) of this chapter. Melengestrol acetate as provided by No. 021641 in § 510.600(c) of this chapter.	021641

Dated: December 5, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–24145 Filed 12–12–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF STATE

22 CFR Part 127

[Public Notice: 6024]

Voluntary Disclosures

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending the Voluntary Disclosure provisions of the International Traffic in Arms Regulations (ITAR) by imposing a 60-calendar day deadline after the initial notification to submit a full disclosure, in order to ensure timely submissions; and by clarifying what identifying information should be provided, as well as who should sign the voluntary disclosure in cases of a major violation, a systemic pattern of violations, or in the absence of an effective compliance program, in order to improve the government's ability to assess and respond to the national security and foreign policy consequences of any export violation. These amendments will provide integrity to the voluntary disclosure process, but involve only minor changes to the current voluntary disclosure process.

EFFECTIVE DATE: This rule is effective December 13, 2007.

ADDRESSES: Interested parties may submit comments at any time by any of the following methods:

- *E-mail: DDTCResponseTeam@state.gov* with an appropriate subject line.
- *Mail:* Department of State, Directorate of Defense Trade Controls, Office of Defense Trade Controls Compliance, ATTN: Regulatory Change, 12th Floor, SA–1, Washington, DC 20522–0112.
- *Fax:* 202–261–8695.
- *Hand Delivery or Courier (regular work hours only:)* Department of State, Directorate of Defense Trade Controls, Office of Defense Trade Controls Compliance, ATTENTION: Regulatory Change, SA–1, 12th Floor, 2401 E Street, NW., Washington, DC 20037.

Persons with access to the Internet may also view this notice by going to the *regulations.gov* Web site at: *http://www.regulations.gov/index.cfm.*

FOR FURTHER INFORMATION CONTACT: Glenn Smith, Office of Defense Trade Controls Compliance, Department of State, 12th Floor, SA–1, Washington DC 20522–0112; Telephone 202–736–9230 or FAX 202–261–8695; *e-mail: DDTCResponseTeam@state.gov.* ATTN: Regulatory Change.

SUPPLEMENTARY INFORMATION: Section 127.12(c)(1)(i) imposes a 60-calendar day deadline after the initial notification to submit a full disclosure. A party may request an extension to the 60-calendar day deadline, and, in certain cases, the Department may require the requester to provide a written certification that the full disclosure in accordance with § 127.12(c)(2) will be submitted within a specified time period. Failure to submit a full disclosure may result in a decision by the Directorate of Defense Trade Controls not to consider the initial notification as a mitigating factor in determining the appropriate disposition of the violation.

Section 127.12(c)(2)(iii) is amended to provide additional details and examples of identifying information to be included in a voluntary disclosure.

Section 127.12(c)(2)(vi) is amended to clarify that corrective actions and compliance initiatives implemented must be directly in response to the violation in the voluntary disclosure, and designed to deter that particular violation from occurring again.

Further, Section 127.12(e) is amended to provide that, in cases of a major violation, a systemic pattern of violations, or the absence of an effective compliance program, DDTC may require that the written certification be signed by a senior officer.

The Directorate of Defense Trade Controls' website at § 127.12(g) is updated.