

statutory duties, and contrary to the public's national security interests.

In addition, BIS finds good cause to waive the requirement of 5 U.S.C. 553(d)(3) to delay the effectiveness of this regulation, because such a delay is contrary to the public's interest. When the U.S. Government has been notified of or has identified a material change in circumstances that warrants revocation or modification of VEU status for an end-user or a facility of an end-user, there is a need to quickly alert the public that the facility is no longer authorized as a recipient of items under Authorization VEU. Delaying this action's effectiveness could result in items that otherwise require licenses being exported, reexported or transferred (in-country), license-free, to an ineligible facility. Accordingly, it would be contrary to the public interest to delay this rule's effectiveness.

No other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under the Administrative Procedure Act or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable and no regulatory flexibility analysis has been prepared.

#### List of Subjects in 15 CFR Part 748

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

- Accordingly, part 748 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

#### PART 748—[AMENDED]

- 1. The authority citation for part 748 continues to read as follows:

**Authority:** 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2010 (75 FR 50681) (August 16, 2010).

- 2. Supplement No. 7 to part 748 is amended by removing “Cension Semiconductor Manufacturing Corporation” and its address “(3/F, 8–1 Kexin Road, Export Processing Zone (West Area), Chengdu, China 611731)” from the list of “Eligible Destinations” for “Validated End-User” “Semiconductor Manufacturing International Corporation” in “China (People's Republic of)”.

Dated: October 26, 2010.

**Kevin J. Wolf,**

*Assistant Secretary for Export Administration.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 520

[Docket No. FDA–2010–N–0002]

#### Oral Dosage Form New Animal Drugs; Domperidone

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the original approval of a new animal drug application (NADA) filed by Dechra, Ltd. The NADA provides for the veterinary prescription use of domperidone oral gel for prevention of fescue toxicosis in periparturient mares.

**DATES:** This rule is effective November 1, 2010.

#### FOR FURTHER INFORMATION CONTACT:

Amy L. Omer, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8336, e-mail: amy.omer@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** Dechra, Ltd., Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW, United Kingdom, filed NADA 141–314 that provides for veterinary prescription use of EQUIDONE (domperidone) Gel for prevention of fescue toxicosis in periparturient mares. The NADA is approved as of September 9, 2010, and the regulations in 21 CFR part 520 are amended by adding § 520.766 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)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this

approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

The agency has determined under 21 CFR 25.33 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 520

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 520 is amended as follows:

#### PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

- 1. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

- 2. Add § 520.766 to read as follows:

#### § 520.766 Domperidone.

(a) *Specifications.* Each milliliter of gel contains 110 milligrams (mg) domperidone.

(b) *Sponsor.* See No. 043264 in § 510.600 of this chapter.

(c) *Conditions of use in horses—(1) Amount.* Administer 0.5 mg per pound (mg/lb) (1.1 mg/kilogram (kg)) by mouth once daily starting 10 to 15 days prior to the expected foaling date. Treatment may be continued for up to 5 days after foaling if mares are not producing adequate milk.

(2) *Indications for use.* For prevention of fescue toxicosis in periparturient mares.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: October 27, 2010.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

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