

Control Classification Numbers (ECCNs) are amended by revising the License Requirements section and License Exceptions section for ECCNs 6E001 and 6E002 to read as follows:

6E001 "Technology" according to the General Technology Note for the "development" of equipment, materials or "software" controlled by 6A (except 6A018, 6A991, 6A992, 6A994, 6A995, 6A996, 6A997, or 6A998), 6B (except 6B995), 6C (except 6C992 or 6C994), or 6D (except 6D991, 6D992, or 6D993).

#### License Requirements

*Reason for Control:* NS, MT, NP, RS, CC, AT, UN.

| Control(s)                                                                                                                                              | Country chart |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| NS applies to "technology" for items controlled by 6A001 to 6A008, 6B004 to 6B008, 6C002 to 6C005, or 6D001 to 6D003.                                   | NS Column 1.  |
| MT applies to "technology" for items controlled by 6A002, 6A007, 6A008, 6A102, 6A107, 6A108, 6B008, 6B108, 6D001, 6D002, 6D102 or 6D103 for MT reasons. | MT Column 1.  |
| NP applies to "technology" for equipment controlled by 6A003, 6A005, 6A202, 6A203, 6A205, 6A225, 6A226 or 6D001 for NP reasons.                         | NP Column 1.  |
| RS applies to "technology" for equipment controlled by 6A002.a.1, .a.2, .a.3, .c, or .e, 6A003.b.3 or .b.4, or 6A008.j.1.                               | RS Column 1.  |
| CC applies to "technology" for equipment controlled by 6A002 for CC reasons.                                                                            | CC Column 1.  |
| AT applies to entire entry ....                                                                                                                         | AT Column 1.  |
| UN applies to "technology" for equipment controlled by 6A002 or 6A003 for UN reasons.                                                                   | Rwanda.       |

**License Requirement Notes:** See § 743.1 of the EAR for reporting requirements for exports under License Exceptions.

#### License Exceptions

CIV: N/A.

TSR: Yes, except for the following:

(1) Items controlled for MT reasons;  
(2) "Technology" for commodities controlled by 6A002.e, 6A004.e, or 6A008.j.1;

(3) "Technology" for "software" specially designed for "space qualified" "laser" radar or Light Detection and Ranging (LIDAR) equipment defined in 6A008.j.1 and controlled by 6D001 or 6D002;

(4) Exports or reexports to destinations outside of Austria,

Belgium, Canada, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Luxembourg, the Netherlands, Portugal, Spain, Sweden, or the United Kingdom of "technology" for the "development" of the following: (a) Items controlled by 6A001.a.2.a.1, 6A001.a.2.a.2, 6A001.a.2.a.5, 6A001.a.2.b, 6A001.a.2.e., 6A002.a.1.c, 6A008.l.3, 6B008, 6D003.a; (b) Equipment controlled by 6A001.a.2.c or 6A001.a.2.f when specially designed for real time applications; or (c) "Software" controlled by 6D001 and specially designed for the "development" or "production" of equipment controlled by 6A008.l.3 or 6B008; or

(5) Exports or reexports to Rwanda.

\* \* \* \* \*

6E002 "Technology" according to the General Technology Note for the "production" of equipment or materials controlled by 6A (except 6A018, 6A991, 6A992, 6A994, 6A995, 6A996, 6A997 or 6A998), 6B (except 6B995) or 6C (except 6C992 or 6C994).

#### License Requirements

*Reason for Control:* NS, MT, NP, RS, CC, AT, UN.

| Control(s)                                                                                                                       | Country chart |
|----------------------------------------------------------------------------------------------------------------------------------|---------------|
| NS applies to "technology" for equipment controlled by 6A001 to 6A008, 6B004 to 6B008, or 6C002 to 6C005.                        | NS Column 1.  |
| MT applies to "technology" for equipment controlled by 6A002, 6A007, 6A008, 6A102, 6A107, 6A108, 6B008, or 6B108 for MT reasons. | MT Column 1.  |
| NP applies to "technology" for equipment controlled by 6A003, 6A005, 6A202, 6A203, 6A205, 6A225 or 6A226 for NP reasons.         | NP Column 1.  |
| RS applies to "technology" for equipment controlled by 6A002.a.1, .a.2, .a.3, .c or .e, 6A003.b.3 or .b.4, or 6A008.j.1.         | RS Column 1.  |
| CC applies to "technology" for equipment controlled by 6A002 for CC reasons.                                                     | CC Column 1.  |
| AT applies to entire entry ....                                                                                                  | AT Column 1.  |
| UN applies to "technology" for equipment controlled by 6A002 or 6A003 for UN reasons.                                            | Rwanda.       |

**License Requirement Notes:** See § 743.1 of the EAR for reporting requirements for exports under License Exceptions.

#### License Exceptions

CIV: N/A.

TSR: Yes, except for the following:

(1) Items controlled for MT reasons;  
(2) "Technology" for commodities controlled by 6A002.e, 6A004.e, 6A008.j.1;

(3) Exports or reexports to destinations outside of Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Luxembourg, the Netherlands, Portugal, Spain, Sweden, or the United Kingdom of "technology" for the "development" of the following: (a) Items controlled by 6A001.a.2.a.1, 6A001.a.2.a.2, 6A001.a.2.a.5, 6A001.a.2.b, and 6A001.a.2.c; and (b) Equipment controlled by 6A001.a.2.e and 6A001.a.2.f when specially designed for real time applications; or (c) "Software" controlled by 6D001 and specially designed for the "development" or "production" of equipment controlled by 6A002.a.1.c, 6A008.l.3 or 6B008; or

(4) Exports or reexports to Rwanda.

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Dated: June 24, 2003.

**Eileen M. Albanese,**

*Director, Office of Exporter Services, Export Administration.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 520

#### Oral Dosage Form New Animal Drugs; Ivermectin and Praziquantel Paste

**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 Merial, Ltd. The NADA provides for use of an ivermectin and praziquantel oral paste for the control of various species of internal parasites in horses.

**DATES:** This rule is effective June 30, 2003.

#### FOR FURTHER INFORMATION CONTACT:

Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7543, e-mail: [mberson@cvm.fda.gov](mailto:mberson@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640, filed NADA 141-214 for ZIMECTERIN GOLD

(ivermectin 1.55 percent/praziquantel 7.75 percent) Paste. The application provides for use of an ivermectin and praziquantel oral paste for the control of various species of internal parasites in horses. The NADA is approved as of April 17, 2003, and 21 CFR part 520 is amended by adding new § 520.1198 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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 Dockets Management Branch (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)(ii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning April 17, 2003.

The agency has determined under 21 CFR 25.33(d)(1) 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. Section 520.1198 is added to read as follows:

#### § 520.1198 Ivermectin and praziquantel paste.

(a) *Specifications.* Each milligram (mg) of paste contains 0.0155 mg (1.55 percent) ivermectin and 0.0775 mg (7.75 percent) praziquantel.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use in horses*—(1) Amount. 200 micrograms (µg) per kilogram (/kg) ivermectin (91 µg per pound (/lb)) and 1 mg/kg praziquantel (454 µg/lb) body weight.

(2) *Indications for use*—For treatment and control of tapeworms *Anoplocephala perfoliata*; large strongyles (adults)—*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*; *Triodontophorus* spp., including *T. brevicauda* and *T. serratus*; and *Craterostomum acuticaudatum*; small strongyles including those resistant to some benzimidazole class compounds (adults and fourth-stage larvae)—*Coronocylus* spp., including *C. coronatus*, *C. labiatus*, and *C. labratus*; *Cyathostomum* spp., including *C. catinatum* and *C. pateratum*; *Cylicocylus* spp., including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*; *Cylicodontophorus* spp.; *Cylicostephanus* spp., including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*; *Petrovinema poculatum*; pinworms (adults and fourth-stage larvae)—*Oxyuris equi*; ascarids (adults and third- and fourth-stage larvae)—*Parascaris equorum*; hairworms (adults)—*Trichostrongylus axei*; large-mouth stomach worms (adults)—*Habronema muscae*; bots (oral and gastric stages)—*Gasterophilus* spp., including *G. intestinalis* and *G. nasalis*; lungworms (adults and fourth-stage larvae)—*Dictyocaulus arnfieldi*; intestinal threadworms (adults)—*Strongyloides westeri*; summer sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

Dated: June 20, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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## DEPARTMENT OF LABOR

### Occupational Safety and Health Administration

#### 29 CFR Part 1904

[Docket Nos. R-02, R-02A, R-02B]

RIN 1218-AC06

### Occupational Injury and Illness Recording and Reporting Requirements

**AGENCY:** Occupational Safety and Health Administration (OSHA), U.S. Department of Labor.

**ACTION:** Final rule.

**SUMMARY:** The Occupational Safety and Health Administration (OSHA) is deleting two provisions of the Occupational Injury and Illness Recording and Reporting Requirements rule published January 19, 2001. These provisions required employers to check the MSD column on the OSHA 300 Log if an employee experienced a work-related musculoskeletal disorder (MSD), and stated that MSDs are not considered privacy concern cases. The effective date of these provisions has been delayed since publication of the Recordkeeping rule in January 2001; consequently, the requirements deleted by this final rule have never been in effect.

**DATES:** The amendments in this rule will become effective on January 1, 2004.

**FOR FURTHER INFORMATION CONTACT:** Steven F. Witt, OSHA Directorate of Standards and Guidance, Room N-3718, Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, telephone (202) 693-1950.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On January 19, 2001, OSHA published revisions to its rule on recording and reporting occupational injuries and illnesses (66 FR 5916-6135) to take effect on January 1, 2002. Section 1904.12(a) of that rule, which has never become effective, required an employer to check the MSD column on the OSHA 300 Log if an employee experienced a work-related musculoskeletal disorder (MSD) meeting the MSD definition contained in the regulation. The term MSD was defined in § 1904.12(b) to include disorders of the muscles, nerves, tendons, ligaments, joints, cartilage and spinal discs, except those caused by slips, trips, falls, motor vehicle accidents or other similar accidents.