DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 524 and 556

Ophthalmic and Topical Dosage Form New Animal Drugs; Eprinomectin

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 Merial Ltd. The supplemental NADA provides for topical use of eprinomectin on cattle for treatment and control of two additional gastrointestinal roundworms and to establish of an acceptable daily intake (ADI) and tolerance for eprinomecrin residues in cattle muscle.

EFFECTIVE DATE: November 5, 1998.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830–3077, is sponsor of NADA 141–079 that provides for use of Ivomec® Eprinex™ Pour-On (5 milligrams per milliliter eprinomectin) on beef and dairy cattle for treatment and control of gastrointestinal roundworm, lungworm, cattle grub, lice, mange mite, and horn fly infections. The sponsor filed a supplemental NADA that provides for use of the product for treatment and control of *Strongyloides papillosus* (adults) and *Trichostrongylus longispicularis* (adults). The supplemental NADA is approved as of August 9, 1998, and 21 CFR 524.814(d)(2) is revised to reflect the approval. The basis of approval is discussed in the freedom of information summary.

A tolerance for residues of eprinomectin in the muscle of cattle has not previously been established. At this time, 21 CFR 556.227 is amended to establish a tolerance for eprinomectin residues in cattle muscle. Also, the regulation is amended to establish an ADI for safe daily human intake of residues of eprinomectin. The ADI is the amount of total drug residue that can be safely consumed by humans every day.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this supplemental 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 21 U.S.C. 360b(c)(2)(F)(iii), this supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning August 9, 1998, because the supplement contains substantial evidence of the effectiveness of the drug involved, studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to use of the drug as approved in this supplemental NADA.

The agency has determined under 21 CFR 25.33(a)(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.

List of Subjects

21 CFR Part 524

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 parts 524 and 556 are amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

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

2. Section 524.814 is amended by revising paragraph (d)(2) to read as follows:

§ 524.814 Eprinomectin.

* * * * *

(d) * * *

(2) *Indications for use*. The drug is used in beef and dairy cattle for treatment and control of gastrointestinal roundworms (*Haemonchus placei* (adult and L4), *Ostertagia ostertagi* (adult and L4, including inhibited L4), *Trichostrongylus axei* (adult and L4), *T. colubriformis* (adult and L4), *T. longispicularis* (adult), *Cooperia oncophora* (adult and L4), *C. punctata* (adult and L4), *C. surnabada* (adult and L4), *Nematodirus helvetianus* (adult and L4), *Bunostomum phlebotomum* (adult and L4), *Oesophagostomum radiatum* (adult and L4), *Strongyloides papillosus* (adults), *Trichuris* spp. (adults)); lungworms (*Dictyocaulus viviparus*, adult and L4); cattle grubs (all parasitic stages *Hypoderma lineatum*, *H. bovis*); lice (*Damalinia bovis*, *Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mange mites (*Chorioptes bovis*, *Sarcoptes scabiei*); and horn flies (*Haematobia irritans*). Controls and protects from reinfection of *D. vivaparus* for 21 days after treatment and *H. irritans* for 7 days after treatment.

* * * * *

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

4. Section 556.227 is revised to read as follows:

§ 556.227 Eprinomectin.

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of eprinomectin is 10 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*. Tolerances are established for residues of eprinomectin B1a (marker residue) in milk of 12 parts per billion, in liver (target tissue) of 4.8 parts per million, and in muscle of 100 parts per billion.

(2) [Reserved]

Dated: September 20, 1998.

Margaret Ann Miller,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 98–29614 Filed 11–4–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 98P–0731]

Dental Devices; Classification of Sulfide Detection Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the sulfide detection device into class II (special controls). The special controls that will apply to the sulfide detection device are restriction to prescription use, conformance with recognized standards relating to biocompatibility, electrical safety and sterility, submission of performance data from analytical and clinical studies demonstrating device effectiveness and adherence to specific labeling requirements. The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Food and Drug Modernization Act of 1997. The agency is classifying sulfide detection devices into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

EFFECTIVE DATE: December 7, 1998.

FOR FURTHER INFORMATION CONTACT: Robert S. Betz, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of the enactment of the Medical Device Amendments 1976, generally referred to as postamendments devices are classified automatically by statute into class III without any rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the FDA regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such as request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification.

In accordance with section 513(f)(1) of the act, FDA issued an order on May 15, 1998, classifying sulfide detection devices in class III. On May 18, 1998, Diamond General Development Corp. submitted a petition requesting classification into class II of the Diamond Probe®/Perio 2000 System that is intended to measure periodontal pocket probing depths, evaluate the presence or absence of bleeding on probing, and to detect the presence of sulfides in periodontal pockets of adult patients. After reviewing the information submitted in the petition, its amendments, K980749, and medical literature, FDA concludes that this device, and substantially equivalent devices of this generic type, can be classified into class II with the establishment of special controls. In accordance with 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of the safety and effectiveness of the device and there is sufficient information to develop special controls to provide such assurance. After reviewing the information submitted in the petition, FDA determined that sulfide detection devices can be classified into class II with the establishment of special controls. FDA believes that general controls and special controls will provide reasonable assurance of safety and effectiveness of the device.

FDA has identified the following risks to health associated with this type of device: (1) Risks associated with the inability to develop adequate directions for use; (2) risks associated with biocompatibility, electrical safety, and sterility; (3) risks related to inaccurate device performance; and (4) risks associated with improper device use.

FDA determined that the special controls described below address these risks and provide reasonable assurance of the safety and effectiveness of the device. Therefore on July 17, 1998, FDA issued an order to the petitioner classifying the sulfide detection device as described previously into class II subject to the special controls described below.

Additionally, FDA is codifying the classification of this device by adding § 872.1870 *Sulfide detection device.*

In addition to the general controls of the act, the sulfide detection device is subject to the following special controls which, combined with general controls, provide reasonable assurance of the safety and effectiveness of the device: (1) Restriction of the sale, distribution, and use of this device to prescription use in accordance with 21 CFR 801.109; (2) conformance with recognized standards for biocompatibility, electrical safety, and sterility; (3) clinical and analytical testing sufficient to demonstrate that the device accurately measures probing depths, detects the presence or absence of bleeding on probing, and accurately detects the presence of sulfides in periodontal pockets in adult patients; (4) labeling that includes proper instructions for device storage, use, and maintenance.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and efficacy of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device, and therefore, the device is not exempt from the premarket notification requirements. Thus persons who intend to market this device must submit to FDA a premarket notification prior to marketing the device.

II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) 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.

III. Analysis of Impacts

FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Flexibility Act (Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health

and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order, and so it is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Classification of these devices in class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore, certifies that the final rule will not have a significant impact on a substantial number of small entities. In addition, this final rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and, therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Act is not required.

IV. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget, under the Paperwork Reduction Act of 1995 is not required.

V. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD, 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Diamond General Development Corp., dated May 18, 1998.

2. Solis-Gaffar, M. C., T. Fischer, and A. Gaffar, ''Instrumental Evaluation of Odor Produced by Specific Oral Microorganisms,'' *Journal of Cosmetic Chemistry*, vol. 30, pp. 241 to 247, 1979.

3. Solis-Gaffar, M. C., K. N. Rustogi, and A. Gaffar, ''Hydrogen Sulfide Production from Gingival Crevicular Fluid,'' *Journal of Periodontology*, vol. 5 (10), pp. 603 to 606, 1980.

List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 872 is amended as follows:

PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 872.1870 is added to subpart B to read as follows:

§ 872.1870 Sulfide detection device.

(a) *Identification*. A sulfide detection device is a device consisting of an AC-powered control unit, probe handle, probe tips, cables, and accessories. This device is intended to be used in vivo, to manually measure periodontal pocket probing depths, detect the presence or absence of bleeding on probing, and detect the presence of sulfides in periodontal pockets, as an adjunct in the diagnosis of periodontal diseases in adult patients.

(b) *Classification*. Class II (special controls) prescription use in accordance with § 801.109 of this chapter; conformance with recognized standards of biocompatibility, electrical safety, and sterility; clinical and analytical performance testing, and proper labeling.

Dated: August 25, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–29569 Filed 11–4–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 98N–0087]

General Hospital and Personal Use Devices: Classification of the Apgar Timer, Lice Removal Kit, and Infusion Stand

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the Apgar timer, the lice removal kit, and the infusion stand into class I (general controls) based on new information regarding these devices. FDA is also exempting the devices from the requirement of premarket notification and is exempting the Apgar timer from most of the requirements of the good manufacturing practice regulations. This action is taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by Medical Device Amendments of 1976 (the amendments), the Safe Medical Devices Act of 1990 (SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

EFFECTIVE DATE: December 7, 1998.

FOR FURTHER INFORMATION CONTACT: Patricia M. Cricenti, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 10, 1998 (63 FR 11632), FDA issued a proposed rule to classify the Apgar timer, the lice removal kit, and the infusion stand into class I (general controls) and to exempt them from premarket notification procedures based on new information regarding these devices. FDA also proposed to exempt the Apgar timer from the current good manufacturing practice requirements in part 820 (21 CFR part 820), with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons were given until June 8, 1998, to comment on the proposed rule. FDA did not receive any comments on the proposed rule.

II. FDA's Conclusion

FDA has concluded that the Apgar timer, the lice removal kit, and the infusion stand do not present unreasonable risks to the public health and that general controls would provide reasonable assurance of the safety and effectiveness of the devices. On November 21, 1997, the President signed FDAMA into law. Section 206 of FDAMA, in part, added a new section 510(l) to the act (21 U.S.C. 360(l)). Under section 501 of FDAMA, new section 510(l) became effective on February 19, 1998. New section 510(l) provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury (hereinafter referred to as ''reserved criteria''). FDA has determined that these devices do not meet the reserved criteria and, therefore, they are exempt from the premarket notification requirements. FDA is finalizing the classification of these devices, the exemptions from premarket notification