the adoption of Statement 143 impacts its accounting for oil and gas operations. This disclosure is expected to address each area of accounting that is impacted or expected to be impacted and should specifically address each way that the company's application of full cost accounting has changed as a result of adoption of Statement 143. These disclosures and discussions should include, but are not limited to, how the company's calculation of the ceiling test and depreciation, depletion, and amortization are affected by the adoption of Statement 143.

b. Impact of Statement 143 on the Calculation of Depreciation, Depletion, and Amortization

Facts: Regarding the base for depreciation, depletion, and amortization (DD&A) of proved reserves, Rule 4–10(c)(3)(i) of Regulations S–X states that ''[c]osts to be amortized shall include (A) all capitalized costs, less accumulated amortization, other than the cost of properties described in paragraph (ii) below;[4] (B) the estimated future expenditures (based on current costs) to be incurred in developing proved reserves; and (C) estimated dismantlement and abandonment costs, net of estimated salvage values.'' Statement 143 requires that upon initial recognition of an ARO, the associated asset retirement costs be included in the capitalized costs of the company. Therefore, subsequent to the adoption of Statement 143, the estimated dismantlement and abandonment costs described in (C) above may be included in the capitalized costs described in (A) above, at least to the extent that an ARO has been incurred as a result of acquisition, exploration and development activities to date. Future development activities on proved reserves may result in additional asset retirement obligations when such activities are performed and the associated asset retirement costs will be capitalized at that time.

Question: Following the adoption of Statement 143, should the costs to be amortized under Rule 4–10(c)(3) of Regulation S–X include an amount for estimated dismantlement and abandonment costs, net of estimated salvage values, that are expected to result from future development activities?

Interpretive Response: Yes. To the extent that estimated dismantlement and abandonment costs, net of estimated salvage values, have not been included as capitalized costs in the base for computing DD&A because they have not yet been capitalized as asset retirement costs under Statement 143, compliance with Rule 4–10(c)(3) of Regulation S–X continues to require that they be included in the base for computing DD&A. Companies should estimate the amount of dismantlement and abandonment costs that will be incurred as a result of future development activities on proved reserves and include those amounts in the costs to be amortized.

c. Transition

Question: When will registrants be expected to comply with the accounting and disclosures described in this bulletin?

Interpretive Response: All registrants are expected to apply the accounting and disclosures described in this bulletin prospectively as of the beginning of the first fiscal quarter beginning after the publication of this bulletin in the **Federal Register**. If a registrant files financial statements with the Commission before applying the guidance in this bulletin, disclosures similar to those described in Staff Accounting Bulletin Topic 11–M should be provided.

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BILLING CODE 8010–01–P

[4] The reference to ''cost of properties described in paragraph (ii) below'' relates to the costs of investments in unproved properties and major development projects, as defined.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin 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 supplemental new animal drug application (NADA) filed by Merial Ltd. The supplemental NADA provides revised labeling for ivermectin oral paste used in horses.

DATES: This rule is effective October 4, 2004.

FOR FURTHER INFORMATION CONTACT: Martine Hartogensis, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–7815, e-mail: *martine.hartogensis@fda.gov*.

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640, filed a supplement to NADA 134–314 for EQVALAN (ivermectin 1.87 percent) Paste for Horses. The supplemental application provides for revisions to the labeled indications. Specifically, under the sub-heading ''Small Strongyles,'' the labeling has been revised to separate the listing of adult species from the fourth-stage larvae. The supplemental NADA is approved as of August 9, 2004, and 21 CFR 520.1192 is amended 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 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(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 520.1192 is amended by revising paragraph (e)(1) to read as follows:

§ 520.1192 Ivermectin paste.

* * * * *

(e) *Conditions of use*—(1) *Horses*—(i) *Amount.* 200 micrograms per kilogram (91 micrograms per pound) of body weight.

(ii) *Indications for use.* For treatment and control of:

(A) 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 (adults, including those resistant to some benzimidazole class compounds): *Coronocyclus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocyclus* 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*, and *Petrovinema poculatum*; Small Strongyles (fourth-stage larvae); 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.

(B) Large Strongyles (adult) (*Strongylus equinus*), (adult and arterial larval stages) (*Strongylus vulgaris*), (adult and migrating tissue stages) (*Strongylus edentatus*), (adult) (*Triodontophorus* spp.); Small Strongyles, including those resistant to some benzimidazole class compounds (adult and fourth-stage larvae) (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicodontophorus* spp., *Cylicostephanus* spp.); Pinworms (adult and fourth-stage larvae) (*Oxyuris equi*); Ascarids (third- and fourth-stage larvae and adults) (*Parascaris equorum*); hairworms (adult) (*Trichostrongylus axei*); Large mouth Stomach Worms (adult) (*Habronema muscae*); Stomach Bots (oral and gastric stages) (*Gastrophilus* spp.); 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; and Dermatitis caused by neck threadworm microfilariae (*Onchocerca* sp.).

(iii) *Limitations.* For oral use only. Do not use in horses intended for human consumption.

* * * * *

Dated: September 14, 2004.

Daniel G. McChesney,

Director, Office of Surveillance and Compliance, Center for Veterinary Medicine.

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BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 2003N–0561]

Orthopedic Devices; Effective Date of Requirement for Premarket Approval for Hip Joint Metal/Polymer or Ceramic/Polymer Semiconstrained Resurfacing Cemented Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis. The agency also is summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices. This action implements certain statutory requirements.

DATES: This rule is effective October 4, 2004. Under this final rule, a PMA or a notice of completion of a PDP is required to be filed on or before January 3, 2005, for any hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis.

FOR FURTHER INFORMATION CONTACT: Pei Sung, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295) and the Safe Medical Devices Act of 1990 (Public Law 101–629), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) established the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved PMA or a notice of completion of a PDP until 90 days after FDA issues a final rule requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the act, whichever is later. Also, a preamendments device subject to the rulemaking procedure under section 515(b) of the act is not required to have an approved investigational device exemption (IDE) (see part 812 (21 CFR part 812)) contemporaneous with its interstate distribution until the date identified by FDA in the final rule requiring the submission of a PMA for the device. At that time, an IDE is required only if a PMA has not been submitted or a PDP completed.

When a rule to require premarket approval for a preamendments device is finalized, section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)) requires that a PMA or notice of completion of a PDP for any such device be filed within 90 days of the date of issuance of the final rule or 30 months after the final classification of the device under section 513 of the act, whichever is later. If a PMA or notice of completion of a PDP is not filed by the latter of the two dates, commercial distribution of the device must cease.

The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or notice of completion of a PDP is not filed by the latter of the two dates, and no IDE is in effect, the device is deemed to be adulterated within the meaning of