

PART 229—STANDARD INSTRUCTIONS FOR FILING FORMS UNDER SECURITIES ACT OF 1933, SECURITIES EXCHANGE ACT OF 1934 AND ENERGY POLICY AND CONSERVATION ACT OF 1975—REGULATION S-K

■ 1. The authority citation for part 229 continues to read in part as follows:

Authority: 15 U.S.C. 77e, 77f, 77g, 77h, 77j, 77k, 77s, 77z-2, 77z-3, 77aa(25), 77aa(26), 77ddd, 77eee, 77ggg, 77hhh, 77iii, 77jjj, 77nnn, 77sss, 78c, 78i, 78j, 78l, 78m, 78n, 78o, 78u-5, 78w, 78ll, 78mm, 79e, 79j, 79n, 79t, 80a-8, 80a-9, 80a-20, 80a-29, 80a-30, 80a-31(c), 80a-37, 80a-38(a), 80a-39, 80b-11, and 7201 *et seq.*; and 18 U.S.C. 1350, unless otherwise noted.

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■ 2. Amend § 229.512 to revise the introductory text of paragraph (h) to read as follows:

§ 229.512 (Item 512) Undertakings.

* * * * *

(h) *Request for acceleration of effective date or filing of registration statement becoming effective upon filing.* Include the following if acceleration is requested of the effective date of the registration statement pursuant to Rule 461 under the Securities Act (§ 230.461 of this chapter), if a Form S-3 or Form F-3 will become effective upon filing with the Commission pursuant to Rule 462 (e) or (f) under the Securities Act (§ 230.462 (e) or (f) of this chapter), or if the registration statement is filed on Form S-8, and:

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PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

■ 3. The authority citation for part 230 continues to read in part as follows:

Authority: 15 U.S.C. 77b, 77c, 77d, 77f, 77g, 77h, 77j, 77r, 77s, 77z-3, 77sss, 78c, 78d, 78j, 78l, 78m, 78n, 78o, 78t, 78w, 78ll(d), 78mm, 79t, 80a-8, 80a-24, 80a-28, 80a-29, 80a-30, and 80a-37, unless otherwise noted.

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■ 4. Amend § 230.139 to revise paragraph (a)(1)(i)(A)(1) to read as follows:

§ 230.139 Publications or distributions of research reports by brokers or dealers distributing securities.

- (a) * * *
- (1) * * *
- (i) * * *

(A)(1) At the later of the time of filing its most recent Form S-3 (§ 239.13 of this chapter) or Form F-3 (§ 239.33 of this chapter) or the time of its most recent amendment to such registration

statement for purposes of complying with section 10(a)(3) of the Act or, if no Form S-3 or Form F-3 has been filed, at the date of reliance on this section, meets the registrant requirements of such Form S-3 or Form F-3 and:

(i) At such date, meets the minimum float provisions of General Instruction I.B.1 of such Forms; or

(ii) At the date of reliance on this section, is, or if a registration statement has not been filed, will be, offering securities meeting the requirements for the offering of investment grade securities pursuant to General Instruction I.B.2 of Form S-3 or Form F-3; or

(iii) At the date of reliance on this section is a well-known seasoned issuer as defined in Rule 405 (§ 230.405), other than a majority-owned subsidiary that is a well-known seasoned issuer by virtue of paragraph (1)(ii) of the definition of well-known seasoned issuer in Rule 405; and

* * * * *

§ 230.405 [Amended]

■ 5. Amend § 230.405, definition of “Well-known seasoned issuer”, paragraph (1)(i)(B)(3) to revise the cite “paragraph (1)(i)(B)(2)” to read “paragraph (1)(i)(B)(1)”.

■ 6. Amend § 230.433 by adding a sentence to the end of paragraph (b)(2)(ii) to read as follows:

§ 230.433 Conditions to permissible post-filing free writing prospectuses.

* * * * *

- (b) * * *
- (2) * * *

(ii) * * * For purposes of paragraph (f) of this section, the prospectus included in the registration statement relating to the offering that has been filed does not have to include a price range otherwise required by rule.

* * * * *

Dated: February 6, 2006.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 06-1286 Filed 2-10-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Moxidectin Solution

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 Fort Dodge Animal Health. The supplemental NADA provides for use of an injectable moxidectin solution in cattle for the treatment and control of an additional three species of internal parasites and an additional three life stages of previously-approved internal parasites.

DATES: This rule is effective February 13, 2006.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: joan.gotthardt@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to NADA 141-220 that provides for use of CYDECTIN (moxidectin) Injectable Solution for Beef and Nonlactating Dairy Cattle for the treatment and control of an additional three species of internal parasites and an additional three life stages of previously-approved internal parasites. The NADA is approved as of January 10, 2006, and the regulations are amended in 21 CFR 522.1450 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3

years of marketing exclusivity beginning January 10, 2006.

FDA 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.

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 522

Animal drugs.

■ 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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 2. Revise paragraph (d)(2) in § 522.1450 to read as follows:

§ 522.1450 Moxidectin solution.

* * * * *

(d) * * *

(2) *Indications for use.* For treatment and control of gastrointestinal roundworms: *Ostertagia ostertagi* (adults, fourth-stage larvae, and inhibited larvae), *Haemonchus placei* (adults), *Trichostrongylus axei* (adults and fourth-stage larvae), *Trichostrongylus colubriformis* (adults and fourth-stage larvae), *Cooperia oncophora* (adults), *Cooperia pectinata* (adults), *Cooperia punctata* (adults and fourth-stage larvae), *Cooperia spatulata* (adults), *Cooperia surnabada* (adults and fourth-stage larvae), *Nematodirus helvetianus* (adults), *Oesophagostomum radiatum* (adults and fourth-stage larvae), *Trichuris* spp. (adults); lungworms: *Dictyocaulus viviparus* (adults and fourth-stage larvae); grubs: *Hypoderma bovis* and *Hypoderma lineatum*; mites: *Psoroptes ovis* (*Psoroptes communis* var. *bovis*); lice: *Linognathus vituli* and *Solenopotes capillatus*; for protection of cattle from reinfection with *D. viviparus* and *O. radiatum* for 42 days after treatment, with *H. placei* for 35 days after treatment, and with *O. ostertagi* and *T. axei* for 14 days after treatment.

* * * * *

Dated: February 3, 2006.

Steven D. Vaughn,

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

[FR Doc. 06-1264 Filed 2-10-06; 8:45 am]

BILLING CODE 4160-01-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 35

[OECA-2005-0082; FRL-8031-4]

RIN 2070-AJ24

Revision to Toxic Substances Compliance Monitoring Grants (TSCA Section 28) Regulation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This is an amendment to the grant regulations. EPA is amending regulations based on a determination that it is not practicable to award Toxic Substances Control Act (TSCA) compliance monitoring grant funds to States through a competitive process. Instead, EPA will award these grants to States on an allotment basis. Section 28 of TSCA authorizes EPA to award grants to States for the establishment and operation of programs to prevent or eliminate unreasonable risks to health or the environment associated with chemical substances or mixtures within the States with respect to which EPA is unable or not likely to take action for their prevention or elimination.

DATES: This final rule is effective February 13, 2006.

ADDRESSES: Materials related to this rulemaking are contained in EPA Grants Docket OECA 2005-0082. The EPA Docket is located at the Office of Environmental Information Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Avenue, NW., Washington, DC, 20460. The Air Docket is open from 8:30 a.m. until 4:30 p.m., Monday through Friday. Materials related to previous EPA actions on the essential use program are contained in EPA Docket No. OECA-2005-0082.

FOR FURTHER INFORMATION CONTACT: Phyllis Flaherty, Chief, National Compliance Monitoring Policy Branch (NCMPB), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564-2405; fax number: (202) 564-0050; e-mail address: flaherty.phyllis@epa.gov.

SUPPLEMENTARY INFORMATION: Section 28 of TSCA authorizes EPA to award grants

to States for the establishment and operation of programs to prevent or eliminate unreasonable risks to health or the environment associated with chemical substances or mixtures within the States with respect to which EPA is unable or not likely to take action for their prevention or elimination.

This action is necessary to reflect how EPA manages the TSCA compliance monitoring programs for PCB and asbestos compliance monitoring activities through grants to States. EPA manages these grants as continuing environmental programs with awards allocated to participating States annually on a non-competitive basis. For the grants awarded in FY2002, FY2003, FY2004, and FY2005, the EPA Grants Administration Division granted a deviation to allow EPA to award these grants without competition to avoid disruption of ongoing State compliance monitoring programs. As described more fully below, it is not practicable to award these funds competitively. If funds were competed, some States may receive reduced or zero funding which could adversely impact ongoing State compliance monitoring programs and cause layoffs of State personnel. This amendment will eliminate the need for additional deviations by removing the requirement to award these grant funds competitively.

EPA has in the past competitively awarded sector based/multimedia grants which funded discrete projects under the TSCA section 28 grant authority. When 40 CFR 35.312 was promulgated in 2001, the intent was that these project specific funds would be competed and that, as described above, the grants for PCBs and asbestos would continue to be funded as continuing programs and not be competed. EPA no longer awards its sector based/multimedia grants for discrete compliance monitoring projects exclusively under TSCA but awards these as multimedia capacity building and cooperative agreement grants under various statutes including TSCA section 10. EPA continues to compete these grants, as appropriate, which fund discrete projects rather than continuing environmental programs.

Under EPA's grants competition policy, EPA awards grants competitively "to the maximum extent practicable." EPA has determined that it is not practicable to award the TSCA PCB and asbestos compliance monitoring grants to States under 40 CFR 35.312 "through a competitive process" for the following reasons:

1. If the funds were competed, States may receive zero or reduced funding. Such funding reductions could result in layoffs or turnover of qualified and