under paragraph 3 of SFAR 77 does not relieve the operator of the responsibility of ensuring compliance with all rules and regulations of other U.S. Government agencies that may apply to the operation, including, but not limited to, the Transportation Security Regulations issued by the Transportation Security Administration, Department of Homeland Security.

Approval Conditions

If the FAA approves the requested operation, then AVR will issue an approval directly to the carrier through the use of Operations Specifications (large air carriers) or a letter of authorization (general aviation operations). AVR will send a letter to the authorizing agency that stipulates the specific conditions under which the FAA approves the air carrier or other covered persons for the requested operations in Iraq. Specifically:

1. Any approval will stipulate those procedures and conditions that limit to the greatest degree possible the risk to the operator while still allowing the operator to achieve its operational objectives;

2. Any approval shall specify that the operation is not eligible for coverage through a premium insurance policy issued by the FAA under section 44302 of chapter 443 of title 49 of the United States Code. The operator shall not request such coverage, and the FAA shall not issue a policy providing insurance; and

3. If the operator already is covered by a premium insurance policy issued by the FAA,3 the applicant shall be required to request the FAA to issue an endorsement to its premium insurance policy that specifically excludes coverage for any operations into, from, or within the territory or airspace of Iraq pursuant to a flight plan that contemplates landing or taking off from Iraqi territory, and the operator shall expressly waive any claims against the U.S. Government in the event of injury, death or loss resulting from any such operation as a condition for an approval or an exemption issued in accordance with Paragraph 3 of SFAR 77. If approved by the FAA, such an endorsement to the premium insurance policy must be issued and effective prior to the effective date of the approval. Additionally, the operator

must notify the FAA in writing of its agreement to release the U.S. Government from all claims and liabilities, as well as its agreement to indemnify the U.S. Government with respect to any third party claims and liabilities relating to any and all events arising from or related to any such operation. If the operation includes the carriage of passengers, the operator shall obtain signed statements from each passenger that—(1) contain a statement that the passenger knowingly accepts the risk of the operation and consents to that risk, and (2) releases the U.S. Government from all claims and liabilities relating to any and all events arising from or related to any such operation.

Issued in Washington, DC, on April 19, 2004.

Marion C. Blakey,
Administrator.

[FR Doc. 04–9209 Filed 4–20–04; 11:19 am]
BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 232

[Release Nos. 33–8409; 34–49580; 35–27836; 39–2419; IC–26420]
RIN 3235–AG96

Adoption of Updated EDGAR Filer Manual

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission (the Commission) is adopting revisions to the Electronic Data Gathering, Analysis, and Retrieval System (EDGAR) Filer Manual to reflect updates to the EDGAR system. The revisions are being made primarily to support the mandatory electronic filing of Form ID, the application for access codes to file on EDGAR, via a new EDGAR Filer Management Web site and to support the initial period of our proposal to expand the information that we require certain open-end management investment companies and insurance company separate accounts to submit to us electronically through EDGAR regarding their series and classes (or contracts, in the case of separate accounts).


FOR FURTHER INFORMATION CONTACT: In the Office of Information Technology, Rick Heroux, at (202) 942–8800; for questions concerning the Division of Investment Management filings, in the Division of Investment Management, Ruth Armfield Sanders, Senior Special Counsel, at (202) 942–0978; and for questions concerning the Division of Corporation Finance filings, in the Division of Corporation Finance, Herbert Scholl, Office Chief, EDGAR and Information Analysis, at (202) 942–2940; in the Office of Filings and Information Services, Margaret A. Favor, (202) 942–8900.

SUPPLEMENTARY INFORMATION: Today we are adopting an updated EDGAR Filer Manual (Filer Manual). The Filer Manual describes the technical formatting requirements for the preparation and submission of electronic filings through the EDGAR system.1 It also describes the requirements for filing using modernized EDGARLink.2

The Filer Manual contains all the technical specifications for filers to submit filings using the EDGAR system. Filers must comply with the applicable provisions of the Filer Manual in order to assure the timely acceptance and processing of filings made in electronic format.3 Filers should consult the Filer Manual in conjunction with our rules governing mandated electronic filing when preparing documents for electronic submission.4

2 This is the filer assistance software we provide for filers filing on the EDGAR system.
3 See Rule 301 of Regulation S–T (17 CFR 232.301).
4 See Release Nos. 33–6977 (Feb. 23, 1993) [58 FR 14628], IC–19284 (Feb. 23, 1993) [58 FR 14848], 35–25746 (Feb. 23, 1993) [58 FR 14999], and 33–6980 (Feb. 23, 1993) [58 FR 15007] in which we comprehensively discuss the rules we adopted to govern mandated electronic filing. See also Release No. 33–7122 (Dec. 19, 1994) [59 FR 67752], in which we made the EDGAR rules final and applicable to all domestic registrants; Release No. 33–7477 (July 1, 1997) [62 FR 36450], in which we adopted minor amendments to the EDGAR rules; Release No. 33–7472 (Oct. 24, 1997) [62 FR 56847], in which we announced that, as of January 1, 1998,
We will implement EDGAR Release 8.7 on April 26, 2004, to support the mandatory electronic filing of Form ID5, via the new EDGAR Filer Management Web site; and to support the initial period of our proposal to expand the information that we require certain open-end management investment companies and insurance company separate accounts to submit to us electronically through EDGAR regarding their series and classes (or contracts, in the case of separate accounts).6 The initial period being supported in this revision will allow these investment companies, which we refer to as “S/C Funds,” to enter series and class (contract) information using the new Series and Classes (Contracts) Information page on the EDGAR Filer Web site (https://www.edgarfiling.sec.gov) to obtain series and class (contract) identifiers.

In addition, the new release will include EDGAR company naming convention updates. It will increase the company name length from 60 characters to 100 characters and support the use of additional ASCII characters in the company name and the ability to store and disseminate mixed-case company names instead of in all uppercase. The use of additional ASCII characters in the company name and the ability to select the Information Exchange (ASCII 44), period (ASCII 46), colon (ASCII 58), open parenthesis (ASCII 40), right parenthesis (ASCII 41), comma (ASCII 35), dollar sign (ASCII 36), left parenthesis (ASCII 43), exclamation point (ASCII 33), pound/number sign (ASCII 34), and underscore (ASCII 45).7 

Along with adoption of the Filer Manual, we are amending Rule 301 of Regulation S-T to provide for the incorporation by reference into the Code of Federal Regulations of today’s revisions. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51.

You may obtain paper copies of the updated Filer Manual at the following address: Public Reference Room, U.S. Securities and Exchange Commission, 450 Fifth Street, NW., Washington DC 20549–0102. We will post electronic format copies on the Commission’s Web site; the address for the Filer Manual is <http://www.sec.gov/info/edgar.shtml>. You may also obtain copies from Thomson Financial Inc, the paper and microfiche contractor for the Commission, at (800) 638–8241.

Since the Filer Manual relates solely to agency procedures or practice, publication for notice and comment is not required under the Administrative Procedure Act (APA).8 It follows that the requirements of the Regulatory Flexibility Act9 do not apply.

The effective date for the updated Filer Manual and the rule amendments is April 26, 2004. In accordance with the APA,10 we find that there is good cause to establish an effective date less than 30 days after publication of these rules. The EDGAR system upgrade to Release 8.7 is scheduled to become available on April 26, 2004. The Commission believes that it is necessary to coordinate the effectiveness of the updated Filer Manual with the scheduled system upgrade.

Statutory Basis

We are adopting the amendments to Regulation S–T under Sections 6, 7, 8, 10, and 19(a) of the Securities Act,11 Sections 3, 12, 15, 14, 15, 23, and 35A of the Securities Exchange Act of 1934,12 Section 20 of the Public Utility Holding Company Act of 1935,13 Section 319 of the Trust Indenture Act of 1939,14 and Sections 8, 30, 31, and 38 of the Investment Company Act of 1940.15

List of Subjects in 17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

Text of the Amendment

In accordance with the foregoing, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

1. The authority citation for Part 232 continues to read in part as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77ss(a), 78(b)(1), 78l, 78m, 78n, 78o(d), 78w(a), 78j(d), 79(a), 80a–8, 80a–29, 80a–30 and 80a–37.

2. Section 232.301 is revised to read as follows:


Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets out the technical formatting requirements for electronic submissions. The requirements for filers using modernized EDGARLink are set forth in the EDGAR Release 8.7 EDGARLink Filer Manual Volume I, dated April 2004. Additional provisions applicable to Form N–SAR filers and Online Forms filers are set forth in the EDGAR Release 8.7 N–SAR Supplement Filer Manual Volume II, dated April 2004, and the EDGAR Release 8.7 OnlineForms Filer Manual Volume III, dated April 2004. All of these provisions have been incorporated by reference into the Code of Federal Regulations, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. You must comply with these requirements in

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5 5 U.S.C. 552(b).
7 5 U.S.C. 553(d)(3).
8 Applicable EDGAR filers can do this by selecting the Information Exchange—Retrieve/Edit Data option from the EDGAR Filer Web site.
9 5 U.S.C. 552(a) and 1 CFR Part 51.
11 5 U.S.C. 77s(a).
12 5 U.S.C. 78c, 78l, 78m, 78n, 78o(d), 78w(a), 78j(d), 79(a), 80a–8, 80a–29, 80a–30, and 80a–37.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Moxidectin and Praziquantel Gel

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, Division of Wyeth. The supplemental NADA provides for oral use of a moxidectin and praziquantel gel in horses and ponies for the treatment and control of an additional species of small strongyles.

DATES: This rule is effective April 23, 2004.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine, HHS.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW, Fort Dodge, IA 50501, filed a supplement to NADA 141–216 for QUEST PLUS (moxidectin 2.0%/praziquantel 12.5%) Gel, used for the treatment and control of various species of internal parasites in horses and ponies. The supplement provides for the speciation of adult small strongyles in product labeling. The supplemental NADA is approved as of March 17, 2004, and 21 CFR 520.1453 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(5)(A) because it is a rule of a type that does not individually or cumulatively have a significant effect on the human environment. 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:


2. Section 520.1453 is amended by revising paragraph (d)(2) to read as follows:

§ 520.1453 Moxidectin and praziquantel gel.

(d) * * * * *

(2) Indications for use. For the treatment and control of strongyles: Strongylus vulgaris (adults and L4/L5 arterial stages), S. edentatus (adult and tissue stages), Triodontophorus brevicauda (adults), and T. serratus (adults); small strongyles (adults); C. cattinatum and C. pateratum; Cylicocyclus spp., including C. insignae, C. leptotomum, and C. nasalis; Cylistostephanus spp., including C. calicus, C. goldi, C. longibursatus, and C. minutus; Coronoclycus spp., including C. coronatus, C. labiatus, and C. labratus; and Gyalophalus capitatus; small strongyles: undifferentiated luminal larvae; encysted cyathostomes (late L3 and L4 mucusal cyathostome larvaes); ascarids: Parascaris equorum (adults and L4 larval stages); pinworms: Oxyuris equi (adults and L4 larval stages); hairworms: Trichostrongylus axei (adults); large-mouth stomach worms: Habronema muscae (adults); horse stomach bots: Gasterophilus intestinalis (2nd and 3rd instars) and G. nasalis (3rd Instars); and tapeworms: Anoplocephala perfoliata (adults). One dose also suppresses strongyle egg production for 84 days.

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

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