

automatic shelf registration statement, consistent with our belief that well-known seasoned issuers are the most widely followed in the marketplace. However, the reference in the rule to only primary offerings meeting the transactional requirements of General Instruction I.B.1 or I.B.2 of Form S-3 or Form F-3 mistakenly excluded certain securities that may be registered by well-known seasoned issuers on Form S-3 or Form F-3 under automatic shelf registration statements pursuant to General Instruction I.D, such as non-investment grade securities. We are, therefore, amending Rule 139(a)(1) to provide that a broker or dealer can rely on the safe harbor if the issuer is a well-known seasoned issuer. The only exception to this provision is for a majority-owned subsidiary that is not eligible on its own as a well-known seasoned issuer and registers its securities on its parent well-known seasoned issuer's registration statement.

B. Rule 405—Definition of Well-Known Seasoned Issuer

In the definition of well-known seasoned issuer, paragraph (1)(i)(B)(3) contains a typographical error—the paragraph contains a cross reference to paragraph (1)(i)(B)(2) that should be a cross reference to paragraph (1)(i)(B)(1). We are correcting that typographical error in this release.

C. Rule 433(f)—Free Writing Prospectuses Published or Distributed By Media

New Rule 433(f) includes certain accommodations where a free writing prospectus is prepared and published or broadcast by persons in the media business that are unaffiliated with the issuer and any other offering participant, and the preparation, publication, or broadcast is not paid for by the issuer or other offering participant. Where the conditions of Rule 433(f) are met, an issuer or offering participant is not required to have a statutory prospectus precede or accompany the media communication. However, a filed registration statement including a statutory prospectus is necessary.

In adopting Rule 433, we stated that the purpose of the media free writing prospectus provision in paragraph (f) is to permit unaffiliated, uncompensated media publications to be published or distributed while an issuer is in registration, without requiring that the statutory prospectus precede or accompany the media publication, so long as the statutory prospectus is on file. Under Rule 433(f), it was our intent that the media publication

accommodations be available without regard to whether the statutory prospectus in an initial public offering includes a *bona fide* price range.⁷

However, Rule 433 inadvertently can be read elsewhere to narrow the availability of the media exclusion for initial public offerings, as Rule 433(b)(2)(ii) requires that a statutory prospectus be on file, which in the context of an initial public offering requires a price range. To address this situation, we are amending paragraph (b)(2)(ii) of Rule 433 to provide that the media accommodations in Rule 433(f) do not require that the filed prospectus, in the context of an initial public offering, include a price range. This change will clarify that the media accommodations included in paragraph (f) of Rule 433 are not limited for initial public offerings.

D. Item 512(h) of Regulation S-K—Inclusion of Statement of Commission's Position on Indemnification for Liabilities in Automatic Shelf Registration Statements

Item 512(h) of Regulation S-K requires an issuer to include a statement regarding the Commission's position on indemnification for liabilities under the Securities Act in registration statements in which acceleration is requested or in registration statements filed on Form S-8. We did not intend to alter the application of Item 512(h) of Regulation S-K; however, we did not amend Item 512(h) of Regulation S-K to include a reference to immediately effective automatic shelf registration statements under amended Rule 462. Absent the corrections we are making today, the amendments to Rule 462 providing that automatic shelf registration statements go effective immediately would inadvertently allow a well-known seasoned issuer to file an automatic shelf registration statement without including a statement of the Commission's position on indemnification in its undertakings. The

⁷ Indeed, in the adopting release (Securities Offering Reform, Release No. 33-8591 [70 FR 44722] (Aug. 3, 2005)), we provided an example of a chief executive officer of a non-reporting issuer giving an interview to a financial news magazine without payment. We included this example to make clear that the accommodation for unaffiliated, uncompensated media publications was available to issuers in initial public offerings. Providing that the unaffiliated, uncompensated media accommodation for issuer and underwriter free writing prospectuses is available in an initial public offering only after the prospectus includes a *bona fide* price range would, we believe, significantly and unintentionally limit the availability of the media accommodation in initial public offerings to a potentially brief time period between the inclusion of a *bona fide* price range in the prospectus and the effective date of the registration statement.

omission of such language was an oversight, as it would otherwise be inconsistent with our long-standing rules to include such statements.

Accordingly, we are correcting this omission under Item 512(h) of Regulation S-K with regard to automatic shelf registration statements and post-effective amendments to automatic shelf registration statements that go effective immediately pursuant to Rule 462(e) and (f). The amendments we are adopting provide for the inclusion of new language in Item 512(h) of Regulation S-K stating that the Item will apply to registration statements that go effective immediately pursuant to Rule 462(e) and (f).

II. Certain Findings

Under the Administrative Procedure Act, a notice of proposed rulemaking is not required when an agency, for good cause, finds “that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.”⁸ The correcting amendments to Item 512 of Regulation S-K, and Rules 139, 405, and 433 under the Securities Act are technical changes that conform the text to the intent of the Commission and correct a cross-reference. For these reasons, the Commission finds that there is no need to publish notice of these amendments.⁹

The Administrative Procedures Act also requires publication of a rule at least 30 days before its effective date unless the agency finds otherwise for good cause.¹⁰ For the same reasons described with respect to opportunity for notice and comment, the Commission finds there is good cause for the amendments to take effect on February 13, 2006.

III. Text of Amendments

List of Subjects in 17 CFR Parts 229 and 230

Reporting and recordkeeping requirements, Securities.

■ Accordingly, 17 CFR parts 229 and 230 are corrected by making the following amendments:

⁸ 5 U.S.C. 553(b)(3)(B).

⁹ For similar reasons, the amendments do not require an analysis under the Regulatory Flexibility Act or analysis of major status under the Small Business Regulatory Enforcement Fairness Act. See 5 U.S.C. 601(2) (for purposes of Regulatory Flexibility Act analyses, the term “rule” means any rule for which the agency publishes a general notice of proposed rulemaking) and 5 U.S.C. 804(3)(C) (for purposes of congressional review of agency rulemaking, the term “rule” does not include any rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties).

¹⁰ See 5 U.S.C. 553(d)(3).

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.

* * * * *

■ 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:

* * * * *

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.

* * * * *

■ 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.

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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