PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

■ 1. The general authority citation for Part 239 continues to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 77z–2, 77sss, 78c, 78*l*, 78m, 78n, 78o(d), 78u–5, 78w(a), 78*ll*(d), 79e, 79f, 79g, 79j, 79*l*, 79m, 79n, 79q, 79t, 80a–8, 80a–24, 80a–26, 80a–29, 80a–30, and 80a–37, unless otherwise noted.

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PART 274—FORMS PRESCRIBED UNDER THE INVESTMENT COMPANY ACT OF 1940

■ 2. The authority citation for part 274 continues to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 78c(b), 78*l*, 78m, 78n, 78o(d), 80a–8, 80a–24, 80a–26, and 80a–29, unless otherwise noted.

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■ 3. Instruction 1(a) to Item 21(d)(1) of Form N–1A (referenced in §§ 239.15A and 274.11A) is amended to read as follows:

Note: The text of Form N–1A does not and this amendment will not appear in the *Code of Federal Regulations*.

Form N–1A

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Item 21. Financial Statements

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(d) * * *

(1) * * *

Instructions.

1. *General.*

(a) Round all figures in the table to the nearest cent.

* * * * *

Dated: August 9, 2004.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 04–18449 Filed 8–11–04; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 17

[Docket No. 2003N–0308]

Civil Money Penalties Hearings; Maximum Penalty Amounts and Compliance With the Federal Civil Penalties Inflation Adjustment Act; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that published in the **Federal Register** of July 20, 2004 (69 FR 43299). The document issued a regulation to adjust for inflation the maximum civil money penalty amounts for various civil money penalty authorities within our jurisdiction. The document published with some errors and this document corrects those errors.

DATES: The rule is effective September 20, 2004.

FOR FURTHER INFORMATION CONTACT: Joyce A. Strong, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville MD, 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 04–16388, appearing on page 43299 in the **Federal Register** of Tuesday, July 20, 2004, the following corrections are made:

§ 17.2 [Corrected]

1. On pages 43301 and 43302, in the last column of the table (in dollars), paragraphs (a)(4), (a)(11), and (a)(12) are corrected to read: 16,500, 1,100, and 330,000, respectively. For the convenience of the reader, the table is republished in its entirety:

CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS

U.S.C. Section	Description of Violation	Former Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty	Adjusted Maximum Penalty Amount (in dollars)
(a) 21 U.S.C.					
(1) 333(b)(2)(A)	Violation of certain requirements of the Prescription Drug Marketing Act (PDMA)	50,000	For each of the first two violations in any 10-year period	2004	55,000
(2) 333(b)(2)(B)	Violation of certain requirements of the PDMA	1,000,000	For each violation after the second conviction in any 10-year period	2004	1,100,000
(3) 333(b)(3)	Violation of certain requirements of the PDMA	100,000	Per violation	2004	110,000
(4) 333(f)(1)(A)	Violation of certain requirements of the Safe Medical Devices Act (SMDA)	15,000	Per violation	2004	16,500
(5) 333(f)(1)(A)	Violation of certain requirements of the SMDA	1,000,000	For the aggregate of violations	2004	1,100,000
(6) 333(f)(2)(A)	Violation of certain requirements of the Food Quality Protection Act of 1996 (FQPA)	50,000	Per individual	2004	55,000
(7) 333(f)(2)(A)	Violation of certain requirements of the FQPA	250,000	Per ''any other person''	2004	275,000
(8) 333(f)(2)(A)	Violation of certain requirements of the FQPA	500,000	For all violations adjudicated in a single proceeding	2004	550,000

CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS—Continued

U.S.C. Section	Description of Violation	Former Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty	Adjusted Maximum Penalty Amount (in dollars)
(9) 335b(a)	Violation of certain requirements of the Generic Drug Enforcement Act of 1992 (GDEA)	250,000	Per violation for an individual	2004	275,000
(10) 335b(a)	Violation of certain requirements of the GDEA	1,000,000	Per violation for ''any other person''	2004	1,100,000
(11) 360pp(b)(1)	Violation of certain requirements of the Radiation Control for Health and Safety Act of 1968 (RCHSA)	1,000	Per violation per person	2004	1,100
(12) 360pp(b)(1)	Violation of certain requirements of the RCHSA	300,000	For any related series of violations	2004	330,000
(b) 42 U.S.C.					
(1) 263b(h)(3)	Violation of certain requirements of the Mammography Quality Standards Act of 1992 and the Mammography Quality Standards Act of 1998	10,000	Per violation	2004	11,000
(2) 300aa–28(b)(1)	Violation of certain requirements of the National Childhood Vaccine Injury Act of 1986	100,000	Per occurrence	2004	110,000

Dated: August 5, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–18407 Filed 8–11–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin and Praziquantel 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 and praziquantel oral paste used in horses for the treatment and control of various internal parasites.

DATES: This rule is effective August 12, 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 141–214 for ZIMECTERIN GOLD (ivermectin 1.55 percent/praziquantel 7.75 percent) Paste for horses. This supplement amends product labeling to separate parasite life stages in the indications section, to remove the 8-week retreatment interval from the dosage and administration section, and to add a new precaution statement. The supplemental NADA is approved as of July 13, 2004, and 21 CFR 520.1198 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 520.1198 is amended by revising paragraphs (d)(2)(i) and (d)(3) to read as follows:

§ 520.1198 Ivermectin and praziquantel paste.

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(d) * * *

(2) * * *