(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

Dated: March 10, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-6732 Filed 3-17-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 5, 211, and 250

Editorial Amendments

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is editorially amending sections of the regulations to update various references.

EFFECTIVE DATE: March 18, 1983.

FOR FURTHER INFORMATION CONTACT: Malcolm B. Reddoch, Bureau of Foods (HFF-312), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-3092.

SUPPLEMENTARY INFORMATION: The changes below update various references in the regulations and are nonsubstantive.

List of Subjects

21 CFR Part 5

Authority delegations (Government agencies), Organization and functions (Government agencies).

21 CFR Part 211

Drugs, manufacturing, Labeling, Laboratories, Packaging and containers, Warehouses.

21 CFR Part 250

Drugs.

Therefore, under section 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(a)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Chapter I of 21 CFR is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

§ 5.10 [Amended]

1. In § 5.10 *Delegations from the Secretary, the Assistant Secretary of Health, and Public Health Service Officials*, in paragraph (a)(4) change "(except in interstate transportation of etiological agents under 42 CFR 72.25)" to "(except in interstate transportation of etiologic agents under 42 CFR Part 72)."

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

§ 211.48 [Amended]

2. In § 211.48 *Plumbing*, in paragraph (a) by revising the second sentence to read as follows: "Potable water shall meet the standards prescribed in the Environmental Protection Agency's Primary Drinking Water Regulations set forth in 40 CFR Part 141."

PART 250—SPECIAL REQUIREMENTS FOR SPECIFIC HUMAN DRUGS

§ 250.203 [Amended]

3. In § 250.203 *Status of fluoridated water and foods prepared with fluoridated water*, in paragraph (a) by inserting "(Centers for Disease Control)" immediately following "through the Public Health Service"; and in paragraph (c) by changing "Public Health Service" to "Environmental Protection Agency".

Effective date. March 18, 1983.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)).)

Dated: March 14, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-7216 Filed 3-17-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 133

[Docket No. 77N-0331]

Nine Natural Cheeses; Revision Based on International Standards of Identity; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration is correcting a final rule that amended its regulations on cheese and related cheese products.

EFFECTIVE DATE: March 18, 1983.

FOR FURTHER INFORMATION CONTACT: Eugene T. McGarrahan, Bureau of Foods (HFF-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1155.

SUPPLEMENTARY INFORMATION: In FR Doc. 83-1842 appearing at page 2736 in the **Federal Register** of Friday, January 21, 1983, the following corrections are made:

1. On page 2737, second column, in the second paragraph of comment 6 the fifth sentence is changed to read "The regulations set forth below provide for the use of 'safe and suitable' ingredients consistent with this policy."

2. On page 2738, third column, in the second paragraph of comment 15 the following changes are made:

a. In the second sentence, "standard" is changed to read "standards".

b. In the third sentence, "standard" is changed to read "standards".

c. In the fourth sentence, "That standard permits" is changed to read "Those standards permit".

3. On page 2742 in § 133.3 *Definitions* in paragraph (d), the following changes are made:

a. In the first line of the table, "90 min." is changed to read "30 min.".

b. In the second line of the footnote to the table, "increased by 6° F" is changed to read "increased by 5° F".

4. On page 2742 in § 133.5 *Methods of analysis* in paragraph (b), "Milk fat" is changed to read "Milkfat".

5. On page 2743 in § 133.113 *Cheddar cheese* in paragraph (a), the following changes are made:

a. In the first sentence, the reference "paragraph (a)(4)" is changed to read "paragraph (a)(3)".

b. In the second sentence, the number "31" is changed to read "50".

6. On page 2743 in § 133.138 *Edam cheese* in paragraph (a), the following changes are made:

a. The second sentence is changed to read "The minimum milkfat content is 40 percent by weight of the solids and the maximum moisture content is 45 percent by weight, as determined by the methods described in § 133.5."

b. The last sentence is changed to read "If the dairy ingredients used are not pasteurized, the cheese is cured at a temperature of not less than 35° F for at least 60 days."

7. On page 2744 in § 133.149 *Gruyere cheese*, the following changes are made:

a. In paragraph (a)(1), the third sentence is changed to read "The minimum milkfat content is 45 percent by weight of the solids and the maximum moisture content is 39 percent by weight, as determined by the methods described in § 133.5."

b. In paragraph (b)(3)(i), "0.002 percent" is changed to read "0.02 percent".

c. In paragraph (d), "part 101" is changed to read "Part 101".

8. On page 2744 in § 133.152 *Limburger cheese* in paragraph (a)(1), the last sentence is changed to read "If the dairy ingredients used are not pasteurized, the cheese is cured at a temperature of not less than 35° F for at least 60 days."

9. On page 2745 in § 133.185 *Samsoe cheese* in the last sentence of paragraph (a)(1), the word "cheese" is added after "Samsoe".

10. On page 2746 in § 133.195 *Swiss and emmentaler cheese* in paragraph (d) in the introductory text, "part 101" is changed to read "Part 101".

Dated: March 14, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-7112 Filed 3-17-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 211, 314, and 700

[Docket No. 82N-0330]

Tamper-Resistant Packaging Requirements for Certain Over-the-Counter Human Drug and Cosmetic Products

Correction

In FR Doc. 82-30645 beginning on Page 50442 in the issue of Friday, November 5, 1982, make the following corrections.

1. On page 50448, first column, first line, "alternating" should read "alerting".

2. On page 50451, second column, paragraph "(el)" of § 700.25 should read "(e)".

3. On page 50451, third column, twentieth line from the bottom of the last paragraph, "700.25(c)" should read "700.25(e)".

BILLING CODE 1505-01-M

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21 CFR Part 314

New Drug Applications; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is issuing a correction to the final rule that amended the new drug regulations.

EFFECTIVE DATE: March 18, 1983.

FOR FURTHER INFORMATION CONTACT: Marilyn L. Watson, National Center for Drugs and Biologics (HFN-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; 301-443-3640.

SUPPLEMENTARY INFORMATION: FDA is correcting a document published in the Federal Register of Friday, January 21, 1983, to include a cross reference change in § 314.1(c)(2) that was inadvertently omitted. Therefore, in FR Doc. 83-1647 at page 2755 in the Federal Register of Friday, January 21, 1983, the following correction is made in the center column: Amendment 2.a. is corrected to read "a. In § 314.1 by removing paragraph (f), by revising the first sentence of paragraph (a)(1) to read as follows, and by changing in paragraph (c)(2), form FD-356H, the reference '§ 314.1(f)' to '§ 314.2:' "

Dated: March 15, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-7246 Filed 3-17-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 436, 442, and 450

Drugs for Human Use; Antibiotics; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction

SUMMARY: The Food and Drug Administration is correcting errors in certain antibiotic regulations that published in the Federal Register in May and September of 1974 during the recodificaton of Subchapter D—Drugs for Human Use—of Title 21 of the Code of Federal Regulations.

FOR FURTHER INFORMATION CONTACT: Joan Eckert, National Center for Drugs and Biologics (HFN-140), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4290.

SUPPLEMENTARY INFORMATION: The following corrections are made:

PART 436—TESTS AND METHODS OF ASSAY OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

§ 436.311 [Corrected]

1. In § 436.311 *Thin layer chromatography identity test for amoxacillin* in paragraph (d), the seventh sentence reading "Pour developing solvent into the glass trough" is removed. (The error first appeared in FR Doc. 74-21842 at page 34032 in the Federal Register of Monday, September 23, 1974.)

PART 442—CEPHA ANTIBIOTIC DRUGS

§ 442.25a [Corrected]

2. In § 442.25a *Sterile cephalothin sodium* in paragraph (a)(4)(i), the first six words "Results of tests and assays of" are changed to read "Results of test and assay on." (The error first appeared in FR Doc. 74-12338 at page 19042 in the Federal Register of Thursday, May 30, 1974.)

PART 450—ANTITUMOR ANTIBIOTIC DRUGS

§ 450.240 [Corrected]

3. In § 450.240 *Mithramycin for injection* in paragraph (b)(3), the reference "§ 436.32" is changed to "§ 436.32(b)." (The error first appeared in FR Doc. 74-12338 at page 19148 in the Federal Register of Thursday, May 30, 1974.)

Dated: March 9, 1983.

James C. Morrison,

Assistant Director for Regulatory Affairs.

[FR Doc. 83-6734 Filed 3-17-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 510

New Animal Drugs; Change of Sponsor Name

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor name for a new animal drug application (NADA) from Endo Laboratories, Inc., to DuPont Pharmaceuticals. DuPont Pharmaceuticals submitted a supplemental NADA advising the agency of the change.

EFFECTIVE DATE: March 18, 1983.

FOR FURTHER INFORMATION CONTACT: John R. Markus, Bureau of Veterinary Medicine (HFV-145), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3442.

SUPPLEMENTARY INFORMATION: DuPont Pharmaceuticals, One Rodney Square, Wilmington, DE 19898, has revised NADA 30-525 (oxymorphone hydrochloride injection) to reflect a change of sponsor name from Endo Laboratories, Inc., to DuPont Pharmaceuticals. This intracorporate transfer of sponsorship does not involve any changes in manufacturing facilities, equipment, procedures, or production personnel. The regulations are amended to reflect the name change.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Reporting requirements.

PART 510—NEW ANIMAL DRUGS

§ 510.600 [Amended]

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 510 is amended in § 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* in paragraph (c)(1) for the entry "Endo Laboratories, Inc." by revising the firm name to read

"DuPont Pharmaceuticals"; and in paragraph (c)(2) for the entry "000056" by revising "Endo Laboratories, Inc." to read DuPont Pharmaceuticals."

Effective date. March 18, 1983.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360(i)).)

Dated: March 9, 1983.

Max L. Crandall,

Associate Director for Surveillance and Compliance.

[FR Doc. 83-7110 Filed 3-17-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 510

New Animal Drugs; Change of Sponsor Name

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor name for a new animal drug application (NADA) from Endo Pharmaceuticals, Inc., to DuPont Pharmaceuticals, Inc. DuPont Pharmaceuticals, Inc., submitted a supplemental NADA advising the agency of the change.

EFFECTIVE DATE: March 18, 1983.

FOR FURTHER INFORMATION CONTACT: John R. Markus, Bureau of Veterinary Medicine (HFV-145), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3442.

SUPPLEMENTARY INFORMATION: DuPont Pharmaceuticals, Inc., P.O. Box 363, Manati, Puerto Rico 00701, has revised NADA 35-825 (naloxone hydrochloride injection) to reflect a change of sponsor name from Endo Pharmaceuticals, Inc., to DuPont Pharmaceuticals, Inc. This intracorporate transfer of sponsorship does not involve any changes in manufacturing facilities, equipment, procedures, or production personnel. The regulations are amended to reflect the name change.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Reporting requirements.

PART 510—NEW ANIMAL DRUGS

§ 510.600 [Amended]

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 510 is amended in § 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* in paragraph (c)(1) for the entry "Endo Pharmaceuticals, Inc.," by changing the firm name to "DuPont Pharmaceuticals, Inc." and placing it in the proper alphabetical sequence; and in paragraph (c)(2) for the entry "000590" by changing the firm name "Endo Pharmaceuticals, Inc." to "DuPont Pharmaceuticals, Inc."

Effective date. March 18, 1983.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: March 9, 1983.

Max L. Crandall,

Associate Director for Surveillance and Compliance.

[FR Doc. 83-7108 Filed 3-17-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 510

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for several new animal drug applications (NADA's) from Hart-Delta, Inc., to AMI, Inc. Supplements to the affected NADA's provide for this change.

EFFECTIVE DATE: March 18, 1983.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Bureau of Veterinary Medicine (HFV-238), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6243.

SUPPLEMENTARY INFORMATION: AMI, Inc., 5055 Choctaw Drive, Baton Rouge, LA 70805, filed supplements to several NADA's providing for a change of sponsor from Hart-Delta, Inc., to AMI, Division of Med-Tech Veterinarian Products, Inc. (AMI, Inc.). By letters, Hart-Delta, Inc, and AMI, Inc., confirmed the change of sponsor. Those NADA's affected are: NADA 92-481, n-Butyl Chloride capsules; NADA 92-837, D.E.C. soluble syrup; NADA 102-020, Tri-Plex worm capsules; and NADA 111-349, Selenium Disulfide shampoo.

This action, the change of sponsor for several NADA's, does not involve changes in manufacturing facilities, equipment, procedures, or personnel. The list of sponsor names and addresses in 21 CFR 510.600(c) is amended to reflect the change of sponsors.

The Bureau has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), § 510.600 is amended in paragraph (c)(1) by removing the entry for "Hart-Delta, Inc.," and by alphabetically adding a new sponsor entry for "AMI, Inc.", and in paragraph (c)(2) in the entry for "015563" by removing the sponsor name "Hart-Delta, Inc.," and inserting in its place "AMI, Inc.," to read as follows:

PART 510—NEW ANIMAL DRUGS

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
AMI, Inc., 5055 Choctaw Drive, Baton Rouge, LA 70805	015563
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
015563	AMI, Inc., 5055 Choctaw Drive, Baton Rouge, LA 70805
* * * * *	

* * * * *

Effective date. March 18, 1983.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: March 9, 1983.

Max L. Crandall,

Associate Director for Surveillance and Compliance.

[FR Doc. 83-7109 Filed 3-17-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 520

Oral Dosage Form New Animal Drugs Not Subject to Certification; Levamisole Gel

AGENCY: Food and Drug Administration.