

isobutylene-isoprene copolymers" by removing the phrase "Division of Food and Color Additives," and by removing the mail code "(HFF-335)" and adding in its place "(HFS-200)".

§ 177.1345 [Amended]

46. Section 177.1345 *Ethylene/1,3-phenylene oxyethylene isophthalate/terephthalate copolymer* is amended in paragraph (b)(1) by removing the phrase "Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF-330)" and adding in its place "Center for Food Safety and Applied Nutrition's Library".

§ 177.1390 [Amended]

47. Section 177.1390 *Laminate structures for use at temperatures of 250 °F and above* is amended in paragraph (c)(3)(i)(a)(1) by removing the phrase "Division of Food and Color Additives," and by removing the mail code "(HFF-334)" and adding in its place "(HFS-200)".

§ 177.1480 [Amended]

48. Section 177.1480 *Nitrile rubber modified acrylonitrile-methyl acrylate copolymers* is amended in paragraph (b)(2) by removing the phrase "Division of Food and Color Additives," and by removing the mail code "(HFF-334)" and adding in its place "(HFS-200)".

§ 177.1500 [Amended]

49. Section 177.1500 *Nylon resins* is amended in paragraph (c)(5)(i) by removing the phrase "Division of Food and Color Additives," and by removing the mail code "(HFF-335)" and adding in its place "(HFS-200)".

§ 177.1520 [Amended]

50. Section 177.1520 *Olefin polymers* is amended in the table in paragraph (b) by removing the phrase "Division of Petition Control," each time it appears and by removing the mail code "(HFS-216)" each time it appears and adding in its place "(HFS-200)".

§ 177.1550 [Amended]

51. Section 177.1550 *Perfluorocarbon resins* is amended in paragraph (d)(2)(ii) by removing the phrase "Division of Food and Color Additives (HFF-330)" and adding in its place "Center for Food Safety and Applied Nutrition (HFS-200)".

§ 177.2450 [Amended]

52. Section 177.2450 *Polyamide-imide resins* is amended in paragraphs (b)(2) and (b)(3) by removing the phrase "Division of Food and Color Additives (HFF-330)" and by adding in its place "Center for Food Safety and Applied Nutrition (HFS-200)".

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

53. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

§ 178.3297 [Amended]

54. Section 178.3297 *Colorants for polymers* is amended in paragraph (c) by removing the phrase "Division of Petition Control (HFS-215)," and adding in its place "(HFS-200)".

§ 178.3780 [Amended]

55. Section 178.3780 *Polyhydric alcohol esters of long chain monobasic acids* is amended in paragraph (b)(1) by removing the phrase "Division of Food and Color Additives," and by removing the mail code "(HFF-334)" and adding in its place "(HFS-200)".

PART 508—EMERGENCY PERMIT CONTROL

56. The authority citation for 21 CFR part 508 continues to read as follows:

Authority: Secs. 402, 404, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 344, 371).

§ 508.35 [Amended]

57. Section 508.35 *Thermal processing of low-acid animal foods packaged in hermetically sealed containers* is amended in paragraph (c)(1) by moving the phrase "Food and Drug Administration," the first time it appears in the second sentence to appear before "200 C St.", by removing the phrase "Industry Programs Branch, HFF-326" and adding in its place "(HFS-565)", by removing the phrase "Food and Drug Administration," the first time it appears in the third sentence, by removing the phrase "Division of Food Chemistry and Technology, HFF-410" and adding in its place "(HFS-617), Food and Drug Administration"; in the introductory text of paragraph (c)(2) by removing "Food and Drug Administration," the first time it appears in the third sentence and in the fourth sentence by removing "Industry Programs Branch, HFF-326" and adding in its place "(HFS-565), Food and Drug Administration", by removing "Division of Food Chemistry and Technology, HFF-410" and adding in its place "(HFS-617), Food and Drug Administration", in paragraph (c)(2)(ii) by removing "Food and Drug Administration," in the third sentence by adding the mail code "(HFS-617)" in front of the comma after the word

"Nutrition", and by removing the mail code "HFF-410,".

PART 730—VOLUNTARY FILING OF COSMETIC PRODUCT EXPERIENCES

58. The authority citation for 21 CFR part 730 continues to read as follows:

Authority: Secs. 201, 301, 601, 602, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 361, 362, 371, 374).

§ 730.3 [Amended]

59. Section 730.3 *How and where to file* is amended by removing the phrase "Division of Cosmetics Technology (HFF-444)," and by adding the mail code "(HFS-100)" in front of the comma and after the word "Nutrition".

PART 1250—INTERSTATE CONVEYANCE SANITATION

60. The authority citation for 21 CFR part 1250 continues to read as follows:

Authority: Secs. 215, 311, 361, 368 of the Public Health Service Act (42 U.S.C. 216, 243, 264, 271).

§ 1250.51 [Amended]

61. Section 1250.51 *Railroad conveyances; discharge of wastes* is amended in paragraph (d) by removing the phrase "Food and Drug Administration," and by removing the phrase "Nutrition, Manager, Interstate Travel Sanitation Sub-Program, HFF-312" and adding in its place "Nutrition (HFS-627), Food and Drug Administration".

Dated: March 26, 1996.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 96-7884 Filed 4-1-96; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Parts 172, 173, 175, 176, 177, 178, 180, 181, and 189

Change of Names and Addresses; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to reflect a change in the name and address for the Association of Official Analytical Chemists International. In addition the agency is also amending the regulations to reflect an organizational change within its Center for Food Safety and Applied Nutrition (CFSAN). This action is

editorial in nature, and is intended to provide accuracy and clarity to the agency's regulations.

DATES: Effective April 1, 1996.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2994.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in parts 172, 173, 175, 176, 177, 178, 180, 181, and 189 to reflect a change in the name and address for the Association of Official Analytical Chemists International. The current name and address listed in FDA's regulations is Association of Official Analytical Chemists, 2300 Wilson Blvd., Suite 400, Arlington, VA 22201-3301. The new name and address is Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504.

To reflect an organizational change within CFSAN, FDA is amending the regulations to remove references to the Division of Food and Color Additives.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because these amendments are editorial and nonsubstantive in nature.

List of Subjects

21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

21 CFR Parts 173 and 180

Food additives.

21 CFR Part 175

Adhesives, Food additives, Food packaging.

21 CFR Parts 176, 177, and 178

Food additives, Food packaging.

21 CFR Parts 181 and 189

Food ingredients, Food packaging.

Therefore under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, *et seq*) and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 172, 173, 175, 176, 177, 178, 180, 181, and 189 are amended as follows:

1. In parts 172, 173, 176, 177, 178, and 189 remove the words "Association of Official Analytical Chemists, 2200 Wilson Blvd., suite 400, Arlington, VA 22201-3301" and add in its place the words "Association of Official Analytical Chemists International, 481

North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504" wherever it appears.

2. In parts 172, 173, 175, 176, 177, 178, 180, and 181 remove the phrase "Division of Food and Color Additives," and remove the mail code "(HFF-330)" and add in its place "(HFS-200)" wherever it appears.

Dated: March 26, 1996.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 96-7919 Filed 4-1-96; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone Acetate and Estradiol Benzoate

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 new animal drug application (NADA) filed by Syntex Animal Health. The NADA provides for use of an ear implant containing trenbolone acetate and estradiol benzoate in steers fed in confinement for slaughter for improved feed efficiency.

EFFECTIVE DATE: April 2, 1996.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0217.

SUPPLEMENTARY INFORMATION: Syntex Animal Health, Division of Syntex Agribusiness, Inc., 3401 Hillview Ave., Palo Alto, CA 94304, filed NADA 141-043, which provides for use of an ear implant consisting of 8 pellets, each pellet containing 25 milligrams (mg) of trenbolone acetate and 3.5 mg of estradiol benzoate. The implant is used in steers fed in confinement for slaughter for improved feed efficiency. The NADA is approved as of February 22, 1996, and the regulations are amended by adding new 21 CFR 522.2478 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for a 3-year period of marketing exclusivity beginning on February 22, 1996, because new clinical or field investigations (other than bioequivalence or residue studies), or human food safety studies (other than bioequivalence or residue studies) essential to the approval were conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 522

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 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 522.2478 is added to read as follows:

§ 522.2478 Trenbolone acetate and estradiol benzoate.

(a) *Sponsor.* See 000033 in § 510.600(c) of this chapter.

(b) *Related tolerance.* See §§ 556.240 and 556.739 of this chapter.

(c) *Conditions of use—(1) Steers—(i) Amount.* 200 milligrams of trenbolone acetate and 28 milligrams of estradiol benzoate (one implant consisting of 8 pellets, each pellet containing 25 milligrams of trenbolone acetate and 3.5 milligrams of estradiol benzoate) per animal.

(ii) *Indications for use.* For improved feed efficiency in steers fed in confinement for slaughter.