PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

1. The authority citation for Part 200 continues to read in part as follows:

Authority: 15 U.S.C. 77s, 78d-1, 78d-2, 78w, 78ll(d), 79t, 77sss, 80a-37, 80b-11, unless otherwise noted.

* * * * *

2. Section 200.30–14 is amended by adding paragraph (k) to read as follows:

§ 200.30–14 Delegation of authority to the General Counsel.

* * * * *

(k) To refer matters and information concerning possible professional misconduct to state bar associations and other state professional boards or societies.

Dated: October 30, 1996.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–28386 Filed 11–4–96; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 93F–0101]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to correct an error in the Chemical Abstracts Service (CAS) registry number for a component of a food additive. This document corrects that error.

EFFECTIVE DATE: November 5, 1996.

FOR FURTHER INFORMATION CONTACT: John R. Bryce, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3023.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 21, 1995 (60 FR 43370), the agency amended the food additive regulations to provide for the safe use of monomethyltin/dimethyltin isooctylmercaptoacetates as a stabilizer in rigid polyvinyl chloride and rigid vinyl chloride copolymers for use in contact with food. The CAS registry number for dimethyltin bis(2-ethylhexylmercaptoacetate was incorrectly published as ''(CAS Reg. No. 57583–35–43)'' instead of ''(CAS Reg. No. 57583–35–4)''. Accordingly, the agency is amending 21 CFR 178.2010 to correct the error.

Publication of this document constitutes final action on this change under the Administrative Procedure Act (5 U.S.C. 553). Notice and public comment are unnecessary because FDA is merely correcting a nonsubstantive error.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

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

1. 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).

§ 178.2010 [Amended]

2. Section 178.2010 *Antioxidants and/or stabilizers for polymers* is amended in the table in paragraph (b) under the heading ''Substances'' in the entry for ''Dimethyltin/monomethyltin isooctylmercaptoacetates'' by removing ''CAS Reg. No. 57583–35–43'' and adding in its place ''CAS Reg. No. 57583–35–4''.

Dated: October 16, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–28290 Filed 11–4–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 520 and 556

Animal Drugs, Feeds, and Related Products; Enrofloxacin Oral 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 new animal drug application (NADA) filed by Bayer Corp. The NADA provides for the use of drinking water medicated with enrofloxacin for the control of mortality associated with certain bacteria in chickens and turkeys.

EFFECTIVE DATE: November 5, 1996.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

SUPPLEMENTARY INFORMATION: Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201, filed NADA 140–828 that covers Baytril® (enrofloxacin) 3.23% Concentrate Antimicrobial Solution. The concentrate is added to drinking water to produce a final concentration of 25 to 50 parts per million. The medicated drinking water is used in chickens for the control of mortality associated with *Escherichia coli* susceptible to enrofloxacin and in turkeys for the control of mortality associated with *E. coli* and *Pasteurella multocida* (fowl cholera) susceptible to enrofloxacin. The NADA is approved as of October 4, 1996, and the regulations are amended by adding new § 520.813 to reflect the approval. The regulations are also amended to provide for a tolerance for enrofloxacin residues in chickens and turkeys in new § 556.228. The drug product is available on a prescription basis. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information (FOI) 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 (FOI summary) may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday. The FOI summary is also electronically available on the Center for Veterinary Medicine's home page on the World Wide Web (http://www.cvm.fda.gov/). The summaries are located in the section entitled, ''FDA CVM Documents and Databases—Information and Resources Library.''

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 3 years of marketing exclusivity beginning October 4, 1996, because the NADA contains reports of new clinical or field investigations and new human food safety studies (other than bioequivalence or residue studies) essential to the approval of the

application and 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

21 CFR Part 520

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 parts 520 and 556 are 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 520.813 is added to read as follows:

§ 520.813 Enrofloxacin oral solution.

(a) *Specifications.* Each milliliter of concentrate solution contains 32.3 milligrams of enrofloxacin.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.228 of this chapter.

(d) *Conditions of use.* It is used in drinking water as follows:

(1) *Chickens and turkeys*—(i) *Amount.* 25 to 50 parts per million of enrofloxacin in drinking water.

(ii) *Indications.* Chickens: Control of mortality associated with *Escherichia coli* susceptible to enrofloxacin. Turkeys: Control of mortality associated with *E. coli* and *Pasteurella multocida* (fowl cholera) susceptible to enrofloxacin.

(iii) *Limitations.* Do not use in laying hens producing eggs for human consumption. Administer medicated water continuously as sole source of drinking water for 3 to 7 days. Prepare fresh stock solution daily. Effects on the reproductive function of turkeys have not been determined. Treated animals must not be slaughtered for food within 2 days of the last treatment. Individuals with a history of hypersensitivity to quinolones should avoid exposure to this product. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: Secs. 402, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 360b, 371).

4. New § 556.228 is added to subpart B to read as follows:

§ 556.228 Enrofloxacin.

A tolerance of 0.3 part per million is established for residues of enrofloxacin (marker residue) in muscle (target tissue) of chickens and turkeys.

Dated: October 28, 1996.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 96–28291 Filed 11–4–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA–152P]

Schedules of Controlled Substances: Placement of Remifentanil Into Schedule II

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Acting Deputy Administrator of the Drug Enforcement Administration (DEA) places the narcotic drug, remifentanil and salts thereof, into Schedule II of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). This rule imposes the regulatory controls and criminal sanctions of a Schedule II narcotic substance under the CSA on the manufacture, distribution, dispensing, importation, and exportation of remifentanil and salts thereof. Remifentanil hydrochloride was recently approved by the Food and Drug Administration (FDA) for marketing as an intravenous analgesic agent.

EFFECTIVE DATE: November 5, 1996.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: 202–307–7183.

SUPPLEMENTARY INFORMATION: Remifentanil is a narcotic drug pharmacologically similar to, but shorter acting than, fentanyl, alfentanil and sufentanil. Remifentanil hydrochloride will be marketed under the trade name of ULTIVA as an intravenous analgesic agent for use during the induction and maintenance of general anesthesia and monitored anesthesia care. The Assistant Secretary for Health, acting on behalf of the Secretary of the Department of Health and Human Services (DHHS), by letter dated August 23, 1996, recommended to the Deputy Administrator of the DEA that remifentanil, and its salts, be placed into Schedule II of the CSA. The Deputy Administrator of the DEA, in a September 16, 1996, Federal Register notice (61 FR 48655) proposed placing remifentanil, and salts thereof, into Schedule II of the CSA. Interested parties were given until October 16, 1996, to submit comments, objections or requests for a hearing regarding the proposal. None were received.

Based on the scientific and medical evaluation and scheduling recommendation contained in the August 23, 1996, letter from the Assistant Secretary for Health, DHHS, the Acting Deputy Administrator of the DEA, pursuant to the provisions of 21 U.S.C. 811 (a) and (b) and 812(b), finds that:

(1) Remifentanil has a high potential for abuse;

(2) Remifentanil has a currently accepted medical use in treatment in the United States; and

(3) Abuse of remifentanil may lead to severe psychological or physical dependence.

The above findings are consistent with the placement of remifentanil into Schedule II of the CSA. The Acting Deputy Administrator further finds that remifentanil is an opiate as defined in 21 U.S.C. 802(18) since it has an addiction-forming and addiction-sustaining liability similar to morphine. Consequently, remifentanil is a narcotic since the definition of narcotics, as stated in 21 U.S.C. 802(17)(A), includes; ''Opium, opiates, derivatives of opium and opiates.''

In order to make a remifentanil pharmaceutical product available for medical use as soon as possible, the Schedule II control of remifentanil will be effective November 5, 1996. In the event that this poses special hardships on any registrant, the DEA will entertain any justified request of an extension of