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

§ 558.128 [Amended]

6. Section 558.128 *Chlortetracycline* is amended in paragraph (a)(4) and in the table in paragraph (d)(1) in the ''sponsor'' column by removing ''012286'' each time it appears and adding in its place ''017519''.

§ 558.274 [Amended]

7. Section 558.274 *Hygromycin B* is amended in paragraph (a)(7) and in the table in paragraph (c)(1), under the ''sponsor''column, by removing ''012286'' each time it appears and adding in its place, ''017519''.

§ 558.485 [Amended]

8. Section 558.485 *Pyrantel tartrate* is amended in paragraph (a)(11) by removing ''012286'' and adding in its place''017519''.

§ 558.625 [Amended]

9. Section 558.625 *Tylosin* is amended in paragraphs (b)(10) and (b)(52) by removing ''012286'' and adding in its place ''017519''.

§ 558.630 [Amended]

10. 558.630 *Tylosin and sulfamethazine* is amended in paragraphs (b)(3), (b)(8), and (b)(10) by removing ''012286'' and adding in its place ''017519''.

Dated: May 7, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–13269 Filed 5–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation and Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection

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 Pfizer Animal Health. The supplemental NADA provides for subcutaneous use of oxytetracycline injection in addition to intramuscular and intravenous use in beef cattle and nonlactating dairy cattle, and calves including preruminating (veal) calves.

EFFECTIVE DATE: May 21, 1997.

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: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed supplemental NADA 113–232 that provides for use of Liquamycin® LA–200® (oxytetracycline injection) for subcutaneous in addition to intramuscular and intravenous treatment of beef cattle, nonlactating dairy cattle, and calves including preruminating (veal) calves. The supplemental NADA is approved as of April 23, 1997, and the regulations are amended in § 522.1660 (21 CFR 522.1660) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Section 522.1660(c) is redesignated as paragraph (d) and new paragraph (c) is added to provide for more uniform regulations and future expansion.

Also § 522.1660 is amended in new paragraph (d)(1) to add the phrase ''and calves including preruminating (veal) calves'' after the phrase ''nonlactating cattle'' in the title and an additional sentence following the text of newly redesignated paragraph (d)(1)(iii) to provide for subcutaneous use for this sponsor.

Furthermore, § 522.1660 is amended to correct several typographical errors. The errors are: In § 522.1660(d)(1)(ii), *Haemophilis* is misspelled, *Staphylococcus* is not capitalized, and in § 522.1660(d)(2)(ii), *multocida* is misspelled.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, 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 for food-producing animals qualifies for 3 years of marketing exclusivity beginning April 23, 1997, because the supplement contains substantial evidence of effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant. Exclusivity applies only to the subcutaneous route of administration.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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.

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. Section 522.1660 is amended by redesignating paragraph (c) as (d) and reserving paragraph (c), in newly redesignated paragraph (d)(1) by revising the heading, in newly redesignated paragraph (d)(1)(ii) by removing the word ''*Hemophilis*'' and adding in its place ''*Haemophilis*'' and by removing the word ''*staphylococcus*'' and adding in its place ''*Staphylococcus*'', in newly redesignated paragraph (d)(2)(ii) by removing the word ''*multicida*'' and adding in its place ''*multocida*'', and by adding a new sentence at the end of newly redesignated paragraph (d)(1)(iii) to read as follows:

§ 522.1660 Oxytetracycline injection.

* * * * *

(c) [Reserved]

(d) * * *

(1) *Beef cattle, nonlactating dairy cattle and calves including preruminating (veal) calves.* * * *

(iii) * * * For sponsor 000069, use subcutaneously with a maximum of 10 milliliters per injection site in adult cattle as well as intramuscularly and intravenously.

* * * * *

Dated: May 7, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–13268 Filed 5–20–97; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[DEA–154E]

RIN 1117–AA42

Temporary Exemption From Chemical Registration for Distributors of Combination Ephedrine Products; Extension of Application Deadline

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Interim rule.

SUMMARY: DEA is amending its regulations to extend the temporary exemption from the chemical registration requirements from May 12, 1997 to July 12, 1997. Certain segments of the industry that distribute combination ephedrine products did not realize that they would be subject to the registration requirement due to questions regarding the application of the registration requirements to their activities. Persons failing to meet the May 12, 1997 deadline would have been required to cease all distributions of combination ephedrine products until they had obtained a registration. In order to avoid interruption of legitimate distributions of combination ephedrine products, based upon the request of this industry group, DEA is extending the temporary exemption from the registration requirement for the additional period to allow affected persons sufficient time to make application for registration.

EFFECTIVE DATE: May 21, 1997. The new deadline for submitting an application for registration is July 12, 1997.

FOR FURTHER INFORMATION CONTACT: G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Telephone (202) 307–4025.

SUPPLEMENTARY INFORMATION: The Comprehensive Methamphetamine Control Act of 1996 (MCA) removed the exemption from DEA's chemical controls for combination ephedrine drug products, effective October 3, 1996. As a result, these products became subject to the chemical registration, recordkeeping, and reporting requirements set forth in Title 21, Code of Federal Regulations (CFR), parts 1309, 1310, and 1313.

To allow businesses to continue to distribute combination ephedrine products pending issuance of a registration to engage in such activities, DEA amended its regulations by interim rule published in the **Federal Register** on February 10, 1997 (62 FR 5914) to provide that any person who submitted a properly completed application for registration to DEA on or before May 12, 1997, would be exempt from the registration requirement until DEA took final action on such application (21 CFR 1310.09).

Following publication of the interim rule, questions were raised by a segment of the industry distributing combination ephedrine products regarding whether the registration requirements applied to their activities. Following clarification of the chemical registration requirements, a request was received from Food Distributors International for an extension of the application deadline to allow adequate time for the affected distributors to make application for registration. DEA has no objection to granting the request. Therefore, 21 CFR 1310.09 is being amended to provide that the deadline for submitting an application is extended to July 12, 1997.

The Acting Deputy Administrator of the Drug Enforcement Administration hereby certifies that this interim rulemaking will have no significant impact upon entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* This interim rulemaking extends a temporary exemption from the registration requirement for distributors of combination ephedrine products.

This rule is not a significant regulatory action and therefore has not been reviewed by the Office of Management and Budget pursuant to Executive Order 12866.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that the interim rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1310

Drug traffic control, List I and List II chemicals, Reporting and recordkeeping requirements.

For reasons set out above, Title 21, Code of Federal Regulations, part 1310 is amended as follows.

PART 1310—[AMENDED]

1. The authority citation for part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b).

2. Section 1310.09 is revised to read as follows:

§ 1310.09 Temporary exemption from registration.

Each person required by Section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export a combination ephedrine product is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before July 12, 1997. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

Dated: May 14, 1997.

James S. Milford,

Acting Deputy Administrator.

[FR Doc. 97–13313 Filed 5–20–97; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF STATE

Bureau of Consular Affairs

22 CFR Part 42

[Public Notice 2546]

Visas: Documentation of Immigrants Under the Immigration and Nationality Act; Validity of Immigrant Visas

AGENCY: Bureau of Consular Affairs, Department of State.

ACTION: Final rule.

SUMMARY: On September 30, 1996, the Immigration and Nationality Act (INA) was amended to, inter alia, grant authority to the Secretary of State to extend the period of validity of an immigrant visa to six months from the date of issuance. The Secretary of State, hereby, exercises that authority and amends the Department's regulations accordingly.

DATES: This rule is effective October 1, 1997.

ADDRESSES: Chief, Legislation and Regulations Division, Visa Office, Room L603–C, SA–1, Washington, D.C. 20520–0106.

FOR FURTHER INFORMATION CONTACT: Stephen K. Fischel, Chief, Legislation