paragraph (a) of this section, including failure to follow the certification agency's own procedures and policies as approved by FDA, FDA shall notify the certification agency that it has a specified period of time to take particular corrective measures as directed by FDA or to submit to FDA for approval the certification agency's own plan of corrective action addressing the minor deficiencies. If the approved corrective actions are not being implemented satisfactorily or within the established schedule, FDA may place the agency on probationary status for a period of time determined by FDA, or may withdraw approval of the certification agency.

(1) If FDA places a certification agency on probationary status, the certification agency shall notify all facilities certified or seeking certification by it of its probationary status within a time period and in a manner approved by FDA.

(2) Probationary status shall remain in effect until such time as the certification agency can demonstrate to the satisfaction of FDA that it has successfully implemented or is implementing the corrective action plan within the established schedule, and that the corrective actions have substantially eliminated all identified problems, or

(3) If FDA determines that a certification agency that has been placed on probationary status is not implementing corrective actions satisfactorily or within the established schedule, FDA may withdraw approval of the certification agency. The certification agency shall notify all facilities certified or seeking certification by it, as well as the appropriate accreditation bodies with jurisdiction in the State, of its loss of FDA approval, within a timeframe and in a manner approved by FDA.

(c) *Transfer of records.* A certification agency that has its approval withdrawn shall transfer facility records and other related information as required by FDA to a location and according to a schedule approved by FDA.

§ 900.25 Hearings and appeals.

(a) Opportunities to challenge final adverse actions taken by FDA regarding approval of certification agencies or withdrawal of approval of certification agencies shall be communicated through notices of opportunity for informal hearings in accordance with part 16 of this chapter.

(b) A facility that has been denied certification is entitled to an appeals process from the certification agency. The appeals process shall be specified in writing by the certification agency and shall have been approved by FDA in accordance with §§ 900.21 and 900.22.

Dated: October 26, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–2750 Filed 2–5–02; 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; Oxytetracycline Hydrochloride Soluble Powder; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Agri Laboratories, Ltd. The ANADA provides for a revised withdrawal time for use of oxytetracycline (OTC) hydrochloride (HCl) soluble powder in the drinking water of turkeys and swine.

DATES: This rule is effective February 6, 2002.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503, filed a supplement to ANADA 200–066 that provides for use of AGRIMYCIN 343 (oxytetracycline HCl) Soluble Powder for making medicated drinking water for the treatment of various bacterial diseases of livestock. The supplemental ANADA provides for a zero-day withdrawal time after the use of the product in the drinking water of turkeys and swine. The supplemental application is approved as of October 4, 2001, and the regulations are amended in 21 CFR 520.1660d to reflect the approval.

Section 520.1660d is also being amended to reflect approval of a 5-pound pail size, which was approved under ANADA 200–066 on June 15, 1994.

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, 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(a)(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 520.1660d is amended in paragraph (a)(6) by adding ''; pail: 5 lb'' after ''oz.''; in paragraphs (d)(1)(ii)(A)(*3*), (d)(1)(ii)(B)(*3*), and (d)(1)(ii)(C)(*3*) in the sixth sentence by removing '', 057561,'' and in the eighth sentence by numerically adding ''057561,''; and in paragraph (d)(1)(iii)(C) by revising the last sentence to read as follows:

§ 520.1660d Oxytetracycline hydrochloride soluble powder.

* * * * *

(d) * * *

(1) * * *

(iii) * * *

(C) * * * Administer up to 5 days; do not use for more than 5 consecutive days; withdraw zero days prior to slaughter those products sponsored by Nos. 046573, 057561, and 061133.

* * * * *

Dated: January 11, 2002.

Claire M. Lathers,

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

[FR Doc. 02–2589 Filed 2–5–02; 8:45 am]

BILLING CODE 4160–01–S