puppies, cats, and kittens that are 4 weeks of age and older and 2 lb of body weight or greater. The NADA is approved as of October 20, 2000, and the regulations are amended in part 520 (21 CFR part 520) by adding § 520.1510 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning October 20, 2000, because no active ingredient (including any ester or salt of the drug) has been previously approved in any other application filed under section 512(b)(1) of the act.

The agency has determined under 21 CFR 25.33(d)(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 520.1510 is added to read as follows:

§ 520.1510 Nitenpyram.

(a) *Specifications.* Each tablet contains 11.4 or 57 milligrams of nitenpyram.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use—Dogs and cats*—(1) *Amount.* One tablet given orally, as needed.

(2) *Indications for use.* For the treatment of flea infestations on dogs, puppies, cats, and kittens 4 weeks of age and older and 2 pounds of body weight or greater.

Dated: November 8, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–30047 Filed 11–24–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

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

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 abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Inc. The supplemental ANADA provides for adding tylosin tartrate as a local antibacterial to an approved subcutaneous cattle ear implant containing trenbolone and estradiol used in pasture cattle for increased rate of weight gain.

DATES: This regulation is effective November 27, 2000.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Inc., 8857 Bond St., Overland Park, KS 66214, filed supplemental ANADA 200–221 for COMPONENT® TE–G (trenbolone acetate/estradiol) with Tylan®, a subcutaneous ear implant containing 40 of milligrams (mg) trenbolone acetate and 8 mg of estradiol, in 2 pellets, each pellet containing 20 mg of trenbolone acetate and 4 mg of estradiol, and an additional pellet containing 29 mg of tylosin tartrate as a local antibacterial. The implants are used in pasture cattle (slaughter, stocker, and feeder steers and heifers) for increased rate of weight gain. The supplemental application is approved as of September 18, 2000, and the regulations are amended in 21 CFR 522.2477 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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.

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 approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning September 18, 2000, because the application contains substantial evidence of the 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 the approval and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the addition of tylosin tartrate to the implant for which the supplemental application was approved.

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 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: 21 U.S.C. 360b.

2. Section 522.2477 is amended in the first sentence of paragraph (b) by removing ''(d)(3)'' and by adding in its place ''(d)(3)(i)(A), (d)(3)(ii), and (d)(3)(iii)''; in the second sentence of paragraph (b) by removing ''(d)(3)'' and by adding in its place ''(d)(3)(i)(A), (d)(3)(i)(B), (d)(3)(ii), and (d)(3)(iii)''; and by revising paragraph (d)(3)(i) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(d) * * *

(3) * * *

(i) *Amount.* (A) 40 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 2 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(B) 40 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 3 pellets, each of 2 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

* * * * *

Dated: October 11, 2000.

Claire M. Lathers,

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

[FR Doc. 00–30049 Filed 11–24–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Parole Commission

28 CFR Part 2

Paroling, Recommitting, and Supervising Federal Prisoners: Prisoners Serving Sentences Under the District of Columbia Code

AGENCY: United States Parole Commission, Justice.

ACTION: Final rule.

SUMMARY: The U.S. Parole Commission is revising the guidelines that govern its decisions to grant and deny parole in the case of prisoners serving sentences for felony crimes under the District of Columbia Code. The revised guidelines convert the rehearing ranges into a single range indicating the total prison time that may be served by the inmate, and authorizes the setting of presumptive release dates up to 36 months from the date of the parole hearing. However, the Point Assignment Table remains the basis upon which the guidelines are determined. The Commission is adopting this rule change to improve understanding by inmates and the public as to the impact that the guidelines will have in individual cases, and to facilitate successful release planning in advance of parole.

EFFECTIVE DATE: January 2, 2001.

FOR FURTHER INFORMATION CONTACT: Office of General Counsel, U.S. Parole Commission, 5550 Friendship Blvd., Chevy Chase, Maryland 20815, telephone (301) 492–5959. Questions about this publication are welcome, but public inquiries concerning individual cases cannot be answered.

SUPPLEMENTARY INFORMATION: The Commission has voted to revise 28 CFR 2.80 so as to make the guidelines for D.C. Code offenders more understandable to inmates and the public, fairer and easier to administer. The revised rule will (1) enhance the ability of inmates and the public, including victims of crime, to understand the guidelines and their impact in individual cases by allowing each inmate's Base Point Score to determine an overall guideline range showing the total time the inmate is expected to serve before release on parole; (2) provide more information to inmates as to their actual expected release dates by authorizing presumptive release dates up to 36 months from the date of the most recent parole hearing (contingent upon good conduct and development of an adequate release plan); (3) facilitate release planning by setting such presumptive release dates; (4) eliminate anomalies in the current system that disadvantage inmates whose rehearings are delayed through no fault of their own or who are encouraged by staff to waive parole reconsideration until they complete institutional programs; and (5) reduce the maximum allowable time between parole consideration hearings from five years to three years (except for an offense in which death results and the offender is more than three years below his or her applicable guideline range). Moreover, the revised rule contains a presumptive credit for ''ordinary program achievement,'' which currently must be determined on a case-by-case basis, in the guideline range itself. Hence, inmates will now receive the benefit of having their ''ordinary program achievement'' points credited in advance.

Public comment was received on this rule in response to the proposals published at 65 FR 26789 (May 8, 2000). In general, the comment was favorable as to the establishing of presumptive release dates and the general limitation of continuances to 36 months. However, there were complaints that the proposed rule was difficult to understand and apply. Confusion was, in all likelihood, caused by the Commission having published alternative options of the proposal for public comment. The Commission believes that the version adopted herein (Option 2, modified by increasing the credit for superior program achievement from 25 percent to 33⅓ percent) is straightforward and will be readily understood by prisoners and their representatives.

Summary of the Final Rule

The revised version of § 2.80 eliminates the Total Point Score from the Point Assignment Table (*i.e.,* the system of adding or subtracting points for post-incarceration factors), and eliminates the system of determining at each hearing (based on the Total Point Score) whether the inmate qualifies for parole at that time. It substitutes the following decisionmaking procedure.

Under Step 1, a Base Guideline Range is determined from the Base Point Score. There is no change from the Base Point Score used in § 2.80. The time expected for the inmate to qualify for parole (assuming no disciplinary infractions and ordinary program achievement) is simply made explicit.[1] Under Step 2, the Parole Eligibility Date is recorded. Under Step 3, a Disciplinary Guideline Range is determined (if there are any disciplinary infractions) based on the time ranges prescribed at § 2.36. Under Step 4, a Superior Program Achievement Award (if superior program achievement is found) is determined. The Superior Program Achievement Award is based on the number of months of superior program achievement on the inmate's prison record (*i.e.,* program achievement that would have qualified for a two-point deduction under the current system that this rule will replace).

Under Step 5, Base Point Guideline Range, Parole Eligibility Date, Disciplinary Range, and the Superior Program Achievement Award are combined, at the initial hearing, into a

[1] Multiplying (A) the rehearing range in the current D.C. guidelines by (B) [the Base Point Score minus 3 points] (the number of rehearings required before parole assuming no disciplinary infractions and ordinary program achievement) produces the Base Point Range. For example, an inmate with a Base Point Score of 6 with no disciplinary infractions and ordinary program achievement at each hearing would have two rehearing range of 18–24 months each before the guidelines indicated parole. This translates to a guideline range of the Parole Eligibility Date plus 36–48 months. For most cases, the results under the current system lumps together certain dissimilar cases; for example, under the current system, an offender with a case point score of 5 who has outstanding program achievement and no disciplinary infractions will serve the same amount of time as an offender with ordinary program achievement.