Dated: March 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–6480 Filed 3–23–04; 8:45 am]

BILLING CODE 4160–01–S

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, Div. of Ivy Animal Health, Inc. The supplemental ANADA provides for the addition of tylosin tartrate to an approved subcutaneous implant containing trenbolone and estradiol used for increased rate of weight gain in feedlot heifers.

DATES: This rule is effective March 24, 2004.

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0232, e-mail: *edubbin@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to ANADA 200–346 for COMPONENT TE–IH (trenbolone acetate and estradiol) with TYLAN, a subcutaneous implant used for increased rate of weight gain in heifers fed in confinement for slaughter. The supplemental ANADA provides for the addition of a pellet containing 29 milligrams tylosin tartrate to the approved implant. The supplemental application is approved as of February 23, 2004, 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 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 Division of Dockets Management (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 qualifies for 3 years of marketing exclusivity beginning February 23, 2004.

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 the 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 by revising paragraph (b)(1) and by adding paragraph (d)(2)(i)(E) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(b) * * *

(1) No. 021641 for use as in paragraphs (d)(1), (d)(2)(i)(A), (d)(2)(i)(B), (d)(2)(i)(C), (d)(2)(i)(E), (d)(2)(iii), and (d)(3) of this section.

* * * * *

(d) * * *

(2) * * *

(i) * * *

(E) 80 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 5 pellets, each of 4 pellets containing 20 mg trenbolone acetate and 2 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose for use as in paragraph (d)(2)(ii)(B) of this section.

* * * * *

Dated: March 11, 2004.

Steven D. Vaughn,

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

[FR Doc. 04–6483 Filed 3–23–04; 8:45 am]

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DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 551

[BOP–1084–F]

RIN 1120–AA79

Smoking/No Smoking Areas

AGENCY: Bureau of Prisons, Justice.

ACTION: Final rule.

SUMMARY: In this document, the Bureau of Prisons (Bureau) revises its regulations pertaining to smoking/no smoking areas in Bureau facilities. The revised regulations require the Warden to designate a smoking area for use in instances where smoking is to be part of an authorized religious activity. If the Warden designates smoking areas for general use (that is, for smoking which is not part of an authorized religious activity), the area must be in visibly designated outdoor locations. The amendment also requires the concurrence of the Regional Director if the Warden chooses not to designate smoking areas for general use. Once this occurs, the Regional Director's concurrence is also required if the Warden later chooses to designate smoking areas for general use at the institution. We intend this amendment to promote a clean air environment and to protect the health and safety of staff and inmates.

EFFECTIVE DATE: This rule will be effective on July 15, 2004.

ADDRESSES: Rules Unit, Office of General Counsel, Bureau of Prisons, 320 First Street, NW., Washington, DC 20534.

FOR FURTHER INFORMATION CONTACT: Sarah Qureshi, Office of General Counsel, Bureau of Prisons, phone (202) 307–2105.

SUPPLEMENTARY INFORMATION: The Bureau adopts as final a revision of its regulations in 28 CFR part 551, subpart N on smoking. We published a proposed rule on this subject on November 25, 1998 (63 FR 65502), which we modified in a supplemental notice on May 6, 1999 (64 FR 24468).

Both the original proposed rule and the supplemental notice would eliminate indoor smoking (with the