

State party	Cultural property	Decision No.
Honduras	Archaeological Material of Pre-Colombian cultures ranging approximately from 1200 B.C. to 1500 A.D.	CBP Dec. 04—08.

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Robert C. Bonner,
Commissioner, Customs and Border Protection.

Approved: March 12, 2004.

Timothy E. Skud,
Deputy Assistant Secretary of the Treasury.
[FR Doc. 04-6017 Filed 3-12-04; 2:31 pm]

BILLING CODE 4820-02-M

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, Division 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 and improved feed efficiency in feedlot steers.

DATES: This rule is effective March 16, 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, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to ANADA 200-221 for COMPONENT TE-IS (trenbolone acetate and estradiol) with TYLAN, a subcutaneous implant used for increased rate of weight gain and improved feed efficiency in steers 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 13, 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 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this supplemental 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 supplemental approval qualifies for 3 years of marketing exclusivity beginning February 13, 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 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 adding paragraph (d)(1)(i)(F) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(F) 80 mg trenbolone acetate and 16 mg estradiol (one implant consisting of 5 pellets, each of 4 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

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Dated: March 2, 2004.

Steven D. Vaughn,
Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 04-5863 Filed 3-15-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 864

[Docket No. 2004P-0044]

Medical Devices; Hematology and Pathology Devices; Classification of the Factor V Leiden DNA Mutation Detection Systems Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the Factor V Leiden deoxyribonucleic acid (DNA) mutation detection systems device into class II (special controls). The special control that will apply to the device is the guidance document entitled "Class II Special Controls Guidance Document: Factor V Leiden DNA Mutation Detection Systems." The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (SMDA), the Food and Drug Administration Modernization Act of 1997 (FDAMA), and the Medical Device User Fee and Modernization Act of 2002. The agency is classifying this device into class II (special controls) in