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.
*	*	*

* * * * *

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.

* * * * *

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]

BILLING CODE 4160–01–S

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 detections 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

order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a guidance document that is the special control for this device.

DATES: This rule is effective April 15, 2004. The classification was effective December 17, 2003.

FOR FURTHER INFORMATION CONTACT: Elizabeth Mansfield, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the 1976 amendments, generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving written notice classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification (513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued a notice on December 5, 2003, classifying the Factor V Leiden Kit into class III because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On December 8, 2003, Roche Diagnostics Corp. submitted a petition requesting classification of the Factor V Leiden Kit under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II.

In accordance with 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the Factor V Leiden system intended for use for the detection of the G1691A mutation in patients with suspected thrombophilia can be classified in class II with the establishment of special controls. FDA believes these special controls, in addition to the general controls, will provide reasonable assurance of safety and effectiveness of the device.

The device is assigned the generic name Factor V Leiden DNA mutation detection system and is identified as a device that consists of different reagents and instruments, which include polymerase chain reaction (PCR) primers, hybridization matrices, thermal cyclers, imagers, and software packages. The detection system is intended as an aid in the diagnosis of patients with suspected thrombophilia.

FDA has identified no direct risks to patient health when tests are used as an aid to diagnosis. However, failure of the test to perform as indicated or error in interpretation of results may lead to improper medical management of patients with clotting disorders. A false negative interpretation could lead to undermanagement of the patient, with increased risk of future thrombotic events. A false positive result could lead to inappropriate treatment and alteration of present and future drug selection and treatment. Consequently, FDA has identified the following risks to health associated specifically with this type of device: (1) Improper medical management; and (2) misdiagnosis and improper treatment, and drug selection and dosing. Therefore, in addition to the general controls of the act, the device is subject to special controls, identified as the guidance document entitled ''Class II Special Controls Guidance Document: Factor V Leiden DNA Mutation Detection Systems.''

The class II special controls guidance document provides information on how to meet premarket (510(k)) submission requirements for the device, including recommendations on instrumentation validation, reproducibility, use of control materials, and clinical studies or literature summaries. The premarket notification should describe the risk analysis method. FDA believes that following the class II special controls guidance document addresses the risks to health identified in the previous paragraph. Therefore, on December 17, 2003, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this classification by adding § 864.7280.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a Factor V Leiden DNA mutation detection systems device will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness; therefore, the device is not exempt from premarket notification requirements. The device is used to test for the Factor V Leiden DNA mutation in the Factor V gene as an aid in the diagnosis of patients with suspected thrombophilia. FDA review of key performance characteristics, test methodology, and other relevant performance data, with regard to the test's sensitivity, specificity, and reproducibility, will ensure that acceptable levels of performance for both safety and effectiveness will be addressed before market clearance. Thus, persons who intend to market this type of device must submit to FDA a premarket notification containing information on the Factor V Leiden DNA mutation detection systems device before marketing the device.

FDA is also adding paragraph (d) to 21 CFR 864.1 to advise interested persons where to find guidance documents referenced in 21 CFR part 864, including the special controls

guidance document identified in this rule.

II. Environmental Impact

The agency has determined under 21 CFR 25.22 and 25.34(b) 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.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so it is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Classification of these devices into class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs. The agency, therefore, certifies that the final rule will not have a significant impact on a substantial number of small entities. In addition, this final rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate and, therefore, a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act is not required.

IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

V. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Roche Diagnostics Corp., dated December 8, 2003.

List of Subjects in 21 CFR Part 864

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 864 is amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 864 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 864.1 is amended by adding paragraph (d) to read as follows:

§ 864.1 Scope.

* * * * *

(d) Guidance documents referenced in this part are available on the Internet at *http://www.fda.gov/cdrh/guidance.html*.

■ 3. Section 864.7280 is added to subpart H to read as follows:

§ 864.7280 Factor V Leiden DNA mutation detection systems.

(a) *Identification.* Factor V Leiden deoxyribonucleic acid (DNA) mutation detection systems are devices that consist of different reagents and instruments which include polymerase chain reaction (PCR) primers, hybridization matrices, thermal cyclers, imagers, and software packages. The detection of the Factor V Leiden mutation aids in the diagnosis of patients with suspected thrombophilia.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance entitled ''Class II Special Controls Guidance Document: Factor V Leiden DNA Mutation Detection Systems.'' (See § 864.1(d) for the availability of this guidance document.)

Dated: March 5, 2004.

Beverly Chernaik Rothstein,

Acting Deputy Director for Policy and Regulations, Center for Devices and Radiological Health.

[FR Doc. 04–5864 Filed 3–15–04; 8:45 am]

BILLING CODE 4160–01–S

PEACE CORPS

22 CFR Part 302

Organization

AGENCY: Peace Corps.

ACTION: Final rule.

SUMMARY: The Peace Corps is removing from the Code of Federal Regulations its regulation on Peace Corps' organization. The regulation is outdated and unnecessary. Information on the Peace Corps' organization is already published and updated annually in the *United States Government Manual,* a special **Federal Register** publication.

DATES: The rule will be effective on April 15, 2004.

FOR FURTHER INFORMATION CONTACT: Tyler S. Posey, General Counsel, (202) 692–2150.

SUPPLEMENTARY INFORMATION: This final rule removes 22 CFR part 302 from the Code of Federal Regulations because it is outdated and unnecessary. Information on Peace Corps' organization is annually updated and published in the **Federal Register's** ''United States Government Manual.'' *See* FOIA Update, Summer 1992 (Office of Information and Privacy, Department of Justice).

Matters of Regulatory Procedure. Executive Order 12866. The Peace Corps has determined that this final rule does not constitute a ''significant regulatory action'' for the purposes of Executive Order 12866.

Regulatory Flexibility Act. Pursuant to section 605(b) of the Regulatory Flexibility Act, the Peace Corps certifies that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Accordingly, no regulatory flexibility analysis is required.