

Dated: March 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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

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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)(i)(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

exception of smoking which is to be part of an authorized religious activity). The supplemental notice further allowed the Warden to eliminate outdoor smoking. The Regional Director's concurrence would be required either for the Warden's initial decision to eliminate outdoor smoking or for a subsequent decision to reinstate outdoor smoking. After due consideration of comments received, the Bureau is adopting as final the regulations proposed in the supplemental notice, with one change: After internal consideration, to promote accuracy of our regulations, we retain the original language in § 551.160, Purpose and Scope.

The supplemental notice contained a response to comments received on the original proposed rule. The Bureau received further comments on the supplemental notice. This final rule contains a response to comments received on the supplemental notice together with the response to comments received on the original proposed rule.

One commenter objected to the provisions in the supplemental notice, stating that he believed that the regulations currently in effect which govern smoking at Bureau facilities are adequate to protect inmates and staff from second-hand smoke. The commenter believed eliminating all indoor smoking will create hardships for staff and inmates alike and that Wardens should not be given the discretion to designate an institution as totally smoke-free. The commenter suggests that a resulting lack of uniformity in the smoking policy among the Bureau's various institutions would be tolerable if inmate requests for a transfer based upon a smoking preference would be allowed. The commenter further believes elimination of tobacco products at an institution will have an adverse economic effect on businesses and vendors who serve an institution's commissary as well as funds from tobacco sales, which as with other commissary sales, may be used for any purpose accruing to the benefit of the inmate body.

This same commenter, in response to another proposed rule on inmate discipline sanctions involving the smoking policy, states that nicotine addiction should be recognized as a serious medical condition requiring treatment and therapy and that smoking cessation programs and nicotine patches should be offered to assist those inmates who wish to quit smoking instead of elevating the severity level of the offense.

Four other commenters objected to the supplemental notice, proposing instead a total ban on the possession

and use of lighted tobacco products for all prisoners, staff, management and visitors. Several of these commenters expressed dissatisfaction with the enforcement of the current smoking policy. One of these commenters alternately proposed separate smoking and non-smoking housing units. This commenter recommended limitations on dispensing cigarettes to ensure that the cigarette would be consumed under staff supervision at the point of purchase.

Commenters on the original proposed rule expressed a general belief that prohibiting indoor smoking within Bureau facilities will have little impact on reducing smoking and improving the air quality. Specifically, four commenters stressed that the current restrictions on smoking are rarely enforced. One commenter, alleging that most staff are smokers, expressed concern that the proposed regulations are not clear as to whether staff must also adhere to the ban on indoor smoking. This commenter included statements from four individuals concurring with his views.

As a practical alternative, three commenters on the original proposed rule support non-smoking units instead of a total prohibition against indoor smoking. One commenter expressed concern that tobacco use not be restricted for religious purposes. The supplemental notice was clarified to address this concern. One commenter expressed concern over the availability of health services support (including nicotine patches and nicotine gum) to those wishing to quit smoking. Four commenters objected to eliminating the Warden's authority to designate indoor smoking areas. These commenters believed that designated outdoor smoking areas would lack protection from adverse weather. They requested that the proposed rule specifically assure the availability of a protective environment for designated outdoor smoking areas. One commenter on the original proposed rule suggested installing smoke detectors in all cells. Two commenters on the original proposed rule suggested that all tobacco products be banned and no tobacco products be sold in federal prisons.

In response, the Bureau wishes to emphasize its intention to protect the health and safety of both staff and inmates. The hazards associated with tobacco smoke and second-hand inhalation of smoke by nonsmokers is well documented and the known health risks associated with smoking support implementation of stricter smoking/no smoking rules. The Bureau believes that adopting the provisions in the

supplemental notice is the most practicable step toward promoting a clean air environment and protecting the health and safety of staff and inmates. Under the provisions in the supplemental notice, a Warden must designate a smoking area for use in instances where smoking is to be part of an authorized religious activity. The Warden may designate only outdoor smoking areas for general use (that is, for smoking which is not part of an authorized religious activity). Designating living units within an institution as smoking and non-smoking will not eliminate the health risks associated with passive inhalation of second-hand smoke indoors. By further allowing the Warden the discretion not to designate any smoking areas for general use if the Regional Director concurs, the Bureau is essentially adopting the recommendations of several of the commenters. If an institution did not have designated smoking areas for general use, that institution's commissary would not have corresponding tobacco products available for sale. The Bureau does not believe that removing tobacco products from the institution's commissary will have a significant economic impact as defined by the controlling statutes noted below. While there may be some impact on commissary profits, the Bureau believes that the health benefits outweigh any potential drop in such profits.

With respect to concerns raised by various commenters over enforcement of the smoking regulations, the Bureau is committed to investigate reported violations of the smoking policy. To emphasize the Bureau's commitment to reducing the health risks associated with tobacco smoke, the Bureau, in a separate document (64 FR 9432), proposed to elevate violations of the smoking policy from a low moderate category act to a moderate category prohibited act. Maintaining a smoke-free environment necessarily means that staff and visitors will be bound by the restrictions.

With respect to concerns over the availability of health services support for those inmates who wish to stop smoking, the Bureau notes that currently institutions are encouraged to offer smoking cessation programs. Upon implementation of these revised regulations, smoking cessation programs are to be offered at all institutions. Nicotine patches are available at the inmate's expense through commissary purchase.

With respect to the concern over the lack of uniformity in the application of policy system-wide, the Bureau believes

that role of the Regional Director will serve to minimize apparent disparity. The designation of an inmate to any particular institution remains subject to separate procedures designed to assess the inmate's designation needs in light of management variables and public safety factors.

With respect to the more technical comments, the Bureau notes that the effect on businesses and vendors who serve an institution's commissary does not rise to the level of an economically significant action. The Bureau does not believe additional smoke detectors are necessary as a deterrent to violations of the smoking policy because a total ban on indoor smoking simplifies enforcement. The Bureau is in compliance with fire safety codes on smoke detectors in its housing units. Nor does the Bureau believe it to be practicable to impose limitations on the dispensing and consumption of tobacco products as recommended by one commenter. Finally, the Bureau declines to incorporate the recommendation to require in the regulation some provision to accommodate outdoor smokers from adverse weather conditions. Security considerations make a blanket assurance of such accommodations impracticable. However, each Warden may give consideration to this issue based upon the security concerns of the institution and local weather conditions.

Members of the public may submit comments concerning this rule by writing to the previously cited address. These comments will be considered but will receive no response in the **Federal Register**.

Executive Order 12866

This regulation has been drafted and reviewed in accordance with Executive Order 12866, "Regulatory Planning and Review", section 1(b), Principles of Regulation. The Director of the Bureau of Prisons has determined that this rule is not a "significant regulatory action" under Executive Order 12866, section 3(f), and accordingly this rule has not been reviewed by the Office of Management and Budget.

Executive Order 13132

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Regulatory Flexibility Act

The Director of the Bureau of Prisons, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities for the following reasons: This rule pertains to the correctional management of offenders committed to the custody of the Attorney General or the Director of the Bureau of Prisons, and its economic impact is limited to the Bureau's appropriated funds.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 28 CFR Part 551

Prisoner.

Harley G. Lappin,

Director, Bureau of Prisons.

■ Under the rulemaking authority vested in the Attorney General in 5 U.S.C. 552(a) and delegated to the Director, Bureau of Prisons, we amend 28 CFR part 551 as set forth below.

SUBCHAPTER C—INSTITUTIONAL MANAGEMENT

PART 551—MISCELLANEOUS

■ 1. Revise the authority citation for 28 CFR 551 to read as follows:

Authority: 5 U.S.C. 301; 18 U.S.C. 1512, 3621, 3622, 3624, 4001, 4005, 4042, 4081, 4082 (Repealed in part as to offenses committed on or after November 1, 1987), 4161–4166 (Repealed as to offenses committed on or after November 1, 1987), 5006–5024 (Repealed October 12, 1984 as to

offenses committed after that date), 5039; 28 U.S.C. 509, 510; Pub. L. 99–500 (sec. 209); Attorney General's May 1, 1995 Guidelines for Victim and Witness Assistance.

■ 2. Revise subpart N to read as follows:

Subpart N—Smoking/No Smoking Areas

Sec.

551.160 Purpose and scope.

551.161 Definitions.

551.162 Designated smoking areas.

Subpart N—Smoking/No Smoking Areas

§ 551.160 Purpose and scope.

To advance towards becoming a clean air environment and to protect the health and safety of staff and inmates, the Bureau of Prisons will restrict areas and circumstances where smoking is permitted within its institutions and offices.

§ 551.161 Definitions.

For purpose of this subpart, *smoking* is defined as carrying or inhaling a lighted cigar, cigarette, pipe, or other lighted tobacco products.

§ 551.162 Designated smoking areas.

(a) The Warden must designate a smoking area for use in instances where smoking is part of an authorized inmate religious activity.

(b)(1) The Warden may designate only outdoor smoking areas for general inmate use (that is, for smoking which is not part of an authorized religious activity). These smoking areas must be clearly identified.

(2) The Warden, with the Regional Director's concurrence, may choose not to designate smoking areas for general use. Once this occurs, the Regional Director's concurrence is required if the Warden later chooses to designate smoking areas for general use at the institution.

[FR Doc. 04–6495 Filed 3–23–04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[DE 070–1043a; FRL–7639–4]

Approval and Promulgation of Air Quality Implementation Plans; Delaware; Amendments to Regulation 24, Section 10—Aerospace Coatings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve a revision to the State