Dated: November 16, 2009.

Steven D. Vaughn,

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

[FR Doc. E9–28009 Filed 11–20–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2009–N–0665]

New Animal Drugs for Use in Animal Feeds; Melengestrol; Monensin; Tylosin

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 new animal drug application (NADA) filed by Pharmacia & Upjohn Co., a Division of Pfizer, Inc. The supplemental NADA provides for use of the same dose levels approved for single-ingredient Type C medicated feeds containing melengestrol acetate, monensin, or tylosin phosphate for heifers fed in confinement for slaughter in three-way, combination drug Type C medicated feeds containing melengestrol acetate, monensin, and tylosin phosphate.

DATES: This rule is effective November 23, 2009.

FOR FURTHER INFORMATION CONTACT: Suzanne J. Sechen, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8105, e-mail: *suzanne.sechen@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 138–870 for use of MGA (melengestrol acetate), RUMENSIN (monensin, USP), and TYLAN (tylosin phosphate) single-ingredient Type A medicated articles to make three-way, combination drug Type C medicated feeds for heifers fed in confinement for slaughter. The supplemental NADA provides for use of the same dose levels approved for single ingredient Type C medicated feeds containing melengestrol acetate, monensin, or tylosin phosphate in the three-way, combination drug Type C medicated feeds. The supplemental application is approved as of October 19, 2009, and the regulations are amended in 21 CFR 558.342 to reflect the approval.

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.

The agency has determined under 21 CFR 25.33 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 558

Animal drugs, Animal feeds.

■ 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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 2. In § 558.342, add paragraph (e)(1)(xi) to read as follows:

§ 558.342 Melengestrol.

* * * * *

(e) * * *

(1) * * *

Melengestrol acetate in mg/head/day	Combination in mg/head/day	Indications for use	Limitations	Sponsor
*	* *	* *	* *	
(xi) 0.25 to 0.5	Monensin 50 to 480, plus tylosin 60 to 90.	Heifers fed in confinement for slaughter: As in paragraph (e)(1)(i) of this section; for the prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*.	Feed continuously as sole ration (liquid or dry) at a rate of 0.5 to 2.0 lb/head/day to provide 0.25 to 0.5 mg/head/day melengestrol acetate; 0.14 to 0.42 mg monensin/lb body weight/day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day; and 60 to 90 mg/head/day tylosin. The melengestrol acetate portion of this Type C medicated feed must be mixed into a complete feed containing 10 to 40 g/ton monensin and 8 to 10 g/ton tylosin in the amount of complete feed consumed by an animal per day. Monensin and tylosin phosphate provided by No. 000986 in § 510.600(c) of this chapter.	000009

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Dated: November 17, 2009.

Steven D. Vaughn,

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

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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Parts 538 and 560

Sudanese Sanctions Regulations; Iranian Transactions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Interim final rule with request for comments.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (''OFAC'') is adopting an interim final rule which makes technical changes to certain sections of the Sudanese Sanctions Regulations and the Iranian Transactions Regulations, 31 CFR parts 538 and 560, respectively, relating to the Trade Sanctions Reform and Export Enhancement Act of 2000, as amended (''TSRA''). The preamble to this interim final rule clarifies OFAC's policy with respect to the process for issuing one-year licenses to export agricultural commodities, medicine, and medical devices to Sudan and Iran pursuant to section 906 of TSRA.

DATES: The interim final rule is effective November 23, 2009. Written comments may be submitted on or before January 22, 2010.

ADDRESSES: You may submit comments by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov.

Follow the instructions for submitting comments.

Fax: Attn: Request for Comments (Trade Sanctions Reform and Export Enhancement Act) (202) 622–1657

Mail: Attn: Request for Comments (Trade Sanctions Reform and Export Enhancement Act): Office of Foreign Assets Control, Department of the Treasury, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Instructions: All submissions received must include the agency name and the **Federal Register** Doc. number that appears at the end of this document. Comments received will be made available to the public via regulations.gov or upon request, without change and including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Assistant Director for Compliance, Outreach and Implementation, tel.: 202/622–2490, Assistant Director for Licensing, tel.: 202/622–2480, Assistant Director for Policy, tel.: 202/622–4855, Office of Foreign Assets Control, or Chief Counsel (Foreign Assets Control), tel.: 202/622–2410, Office of the General Counsel, Department of the Treasury (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site (*http://www.treas.gov/ofac*). Certain general information pertaining to OFAC's sanctions programs is also available via facsimile through a 24-hour fax-on-demand service, tel.: 202/622–0077.

Procedural Requirements

Because the amendment of 31 CFR parts 538 and 560 involves a foreign affairs function, the provisions of Executive Order 12866 and the Administrative Procedure Act (5 U.S.C. 553), requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Although a prior notice of proposed rulemaking is not required, OFAC is soliciting comments on this interim final rule in order to consider how it might make improvements to these sections of the Sudanese Sanctions Regulations and the Iranian Transactions Regulations, 31 CFR parts 538 and 560, respectively. Comments must be submitted in writing. The addresses and deadline for submitting comments appear near the beginning of this notice. OFAC will not accept comments accompanied by a request that all or part of the submission be treated confidentially because of its business proprietary nature or for any other reason. All comments received by the deadline will be a matter of public record and will be made available to the public via regulations.gov.

Background

The Office of Foreign Assets Control (''OFAC'') today is adopting an interim final rule which makes technical changes to certain sections of the Sudanese Sanctions Regulations, 31 CFR part 538 (the ''SSR''), and the Iranian Transactions Regulations, 31 CFR part 560 (the ''ITR''), relating to the Trade Sanctions Reform and Export Enhancement Act of 2000, as amended (22 U.S.C. 7201 *et seq.*) (''TSRA''). This interim final rule and accompanying preamble serve to clarify OFAC's policy with respect to the process for issuing one-year licenses to export agricultural commodities, medicine, and medical devices to Sudan and Iran, and the considerations relevant to such licensing decisions.

TSRA provides that, with certain exceptions, the President may not impose a unilateral agricultural sanction or unilateral medical sanction against a foreign country or foreign entity unless, at least 60 days before imposing such a sanction, the President submits a report to Congress describing the proposed sanction and the reasons for it and Congress enacts a joint resolution approving the report. Section 906 of TSRA, however, requires that the export of agricultural commodities, medicine, and medical devices to Cuba, or to the government of a country that has been determined by the Secretary of State, pursuant to, *inter alia,* section 6(j) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j)), to have repeatedly provided support for acts of international terrorism, or to any entity in such a country, shall only be made pursuant to one-year licenses issued by the United States Government. Section 906 also requires that procedures shall be in place to deny licenses for exports to any entity within such country that promotes international terrorism.

Effective July 26, 2001, OFAC promulgated amendments to the SSR and the ITR to implement section 906 of TSRA. See 66 FR 36683 (July 12, 2001) (the ''2001 interim rule''). The preamble to the 2001 interim rule described an expedited process for the issuance of the one-year license required by section 906 for all exports and reexports of agricultural commodities, medicine, and medical devices to Sudan or Iran.

OFAC published the 2001 interim rule describing the expedited licensing process in July 2001. As OFAC has stated publicly, circumstances developed almost immediately after publication of the 2001 interim rule that seriously limited OFAC's ability to process applications as expeditiously as had been hoped. See Clarification of Policy With Respect to the Process for Issuing One-Year Licenses to Export Agricultural Commodities, Medicine, and Medical Devices to Sudan and Iran, 72 FR 12980 (March 20, 2007). To begin with, the terrorist attacks of September 11, 2001, magnified concerns about international terrorism and proliferation of weapons of mass destruction. These concerns prompted greater scrutiny on