

with a comment period of February 8, 2013 through March 11, 2013 (78 FR 9330). No comments on the proposed regulatory amendments were received by AMS. The proposed rule may be viewed at www.regulations.gov.

List of Subjects in 7 CFR Part 27

Commodity futures, Cotton.

For the reasons set forth in the preamble, 7 CFR part 27 is amended as follows:

PART 27—[Amended]

- 1. The authority citation for 7 CFR part 27 continues to read as follows:

Authority: 7 U.S.C. 15b, 7 U.S.C. 473b, 7 U.S.C. 1622(g).

- 2. In § 27.93, definitions of the Southeastern market and the East Texas and Oklahoma market are revised to read as follows:

§ 27.93 Bona fide Spot Markets.

* * * * *

Southeastern

All counties in the states of Alabama, Florida, Georgia, North Carolina, South Carolina, and Virginia and all counties in the state of Tennessee east of and including Stewart, Houston, Humphreys, Perry, Wayne and Hardin counties.

* * * * *

East Texas and Oklahoma

All counties in the states of Kansas and Oklahoma and the Texas counties east of and including Montague, Wise, Parker, Erath, Comanche, Mills, San Saba, Mason, Sutton, Edwards, Kinney, Maverick, Webb, Zapata, Star and Hidalgo counties.

* * * * *

- 3. In § 27.94, paragraph (a) is revised to read as follows:

§ 27.94 Spot Markets for Contract Settlement Purposes.

* * * * *

(a) For cotton delivered in settlement of any No. 2 contract on the Intercontinental Exchange (ICE); Southeastern, North and South Delta, Eastern Texas and Oklahoma, West Texas, and Desert Southwest.

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Dated: April 25, 2013.

David R. Shipman,

Administrator, Agricultural Marketing Service.

[FR Doc. 2013–10114 Filed 4–29–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 558

[Docket No. FDA–2013–N–0002]

New Animal Drugs; Dexmedetomidine; Lasalocid; Melengestrol; Monensin; and Tylosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, Technical Amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval actions for new animal drug applications and abbreviated new animal drug applications during March 2013. FDA is also informing the public of the availability of summaries the basis of approval and of environmental review documents, where applicable.

DATES: This rule is effective April 30, 2013.

FOR FURTHER INFORMATION CONTACT:

George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9019, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during March 2013, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents 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. Persons with access to the Internet may obtain these documents at the CVM FOIA Electronic Reading Room: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm>.

In addition, the animal drug regulations are being amended at 21 CFR 522.558 to add a new strength of dexmedetomidine hydrochloride injectable solution for use in dogs and cats. This change is being made to improve the accuracy of the regulations.

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.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING MARCH 2013

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR section	FOIA sum- mary	NEPA review
200–532	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.	TYLOVET 100 (tylosin phosphate) and MGA (melegestron acetate) Type A medicated articles.	Original approval as a generic copy of NADA 139–192.	558.342	yes	CE ¹
200–533	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.	TYLOVET 100 (tylosin phosphate) and RUMENSIN (monensin) and DECCOX (decoquinat) Type A medicated articles.	Original approval as a generic copy of NADA 141–149.	558.195	yes	CE ¹

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING MARCH 2013—Continued

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR section	FOIA sum- mary	NEPA review
200–535	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.	TYLOVET 100 (tylosin phosphate) and BOVATEC (lasalocid) and MGA (melegestron acetate) Type A medicated articles.	Original approval as a generic copy of NADA 138–992.	558.342	yes	CE ¹

¹ The Agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an environmental assessment (EA) or an environmental impact statement (EIS) because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

List of Subjects

21 CFR Part 522

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feed.

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 parts 522 and 558 are 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. In § 522.558, revise paragraph (a) to read as follows:

§ 522.558 Dexmedetomidine.

(a) *Specifications.* Each milliliter of solution contains 0.5 or 1.0 milligrams dexmedetomidine hydrochloride.

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 4. In § 558.195, in the table, in paragraph (e)(2)(v), revise the last sentence in the “Limitations” column and revise the “Sponsor” column to read as follows:

§ 558.195 Decoquinatone.

* * * * *

(e) * * *

(2) * * *

Decoquinatone in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(v) * * *			* * * Monensin as provided by No. 000986, and tylosin as provided by Nos. 000986 and 016592 in § 510.600(c) of this chapter.	016592, 046573
* * *	* * *	* * *	* * *	* * *

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■ 5. In § 558.342, in the table, in paragraphs (e)(1)(iv) and (e)(1)(ix), revise the last sentence in the

“Limitations” column and revise the “Sponsor” column 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
(iv) * * *			* * * Lasalocid provided by No. 046573, and tylosin provided by Nos. 000986 and 016592 in § 510.600(c) of this chapter.	000009, 000986, 016592
(ix) * * *			Tylosin provided by Nos. 000986 and 016592 in § 510.600(c) of this chapter.	000009, 000986, 016592

* * * * *

Dated: April 25, 2013.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2013–10152 Filed 4–29–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 5, 200, 207, and 232

[Docket No. FR-5465-F-03]

RIN-2502-AJ05

Federal Housing Administration (FHA): Section 232 Healthcare Facility Insurance Program—Strengthening Accountability and Regulatory Revisions Update Final Rule Amendment—Revision of Date of Applicability

AGENCY: Federal Housing Commissioner, Office of the Assistant Secretary for Housing, HUD.

ACTION: Final rule amendment.

SUMMARY: On September 7, 2012, HUD published a final rule that revised the regulations governing the insurance of healthcare facilities under section 232 of the National Housing Act (Section 232). HUD's Section 232 program insures mortgage loans to facilitate the construction, substantial rehabilitation, purchase, and refinancing of nursing homes, intermediate care facilities, board and care homes, and assisted-living facilities. The amendments made by the September 7, 2012, final rule updated the Section 232 regulations to reflect current policy and practices, improve accountability and strengthen risk management in the program. The final rule provided an applicability date of April 9, 2013, for certain of the updated requirements. This final rule amendment changes the applicability date to July 12, 2013, for the purpose of allowing more time to transition to the new requirements.

DATES: *Effective date:* May 30, 2013.

FOR FURTHER INFORMATION CONTACT: Kelly Haines, Director, Office of Residential Care Facilities, Office of Healthcare Programs, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 6264, Washington, DC 20410-8000; telephone number 202-708-0599 (this is not a toll-free number). Persons with hearing- or speech-impairments may access this number through TTY by calling the toll-free Federal Relay Service at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:

I. Background

On September 7, 2012, at 77 FR 55120, HUD published in the **Federal Register** a final rule that revised its Section 232 program regulations to bring the regulations up-to-date to

reflect current policy and practices in healthcare facility transactions and to strengthen risk management and improve accountability in the program. The September 7, 2012, final rule followed a proposed rule published in the **Federal Register** on May 3, 2012, at 77 FR 26218, in which HUD submitted its proposed revisions for public comment. The final rule took effect on October 9, 2012. However, to allow time to transition to the updated requirements, the final rule established an applicability date of April 9, 2013 for certain of the requirements.

On May 3, 2012, at 77 FR 26304, HUD also published a notice that proposed revisions to documents used in the insurance of healthcare facilities, and solicited public comment for a period of 60 days. This notice was issued in accordance with the Paperwork Reduction Act of 1995, and was followed by a second notice, published on November 21, 2012, at 77 FR 69870, that solicited public comment for a period of 30 days. The Office of Management and Budget approved the Section 232 documents under the Paperwork Reduction Act in March 2013, and the approval was announced by notice published in the **Federal Register** on March 14, 2013, at 78 FR 16279.

Following issuance of the March 14, 2013, notice, lenders and other parties that would be involved in upcoming Section 232 program transactions stated that the delayed approval presented barriers to full compliance with some of the requirements in the revised Section 232 regulations that would become applicable on April 9, 2013. The affected parties involved in upcoming financing or refinancing of a loan to be insured under Section 232 advised that they have already expended substantial time and expense in preparing the transaction based on reasonable reliance on the previously applicable Section 232 documents.

II. This Final Rule

Given that the delayed approval of the Section 232 documents has caused difficulties for parties involved in upcoming Section 232 healthcare facility transactions to comply with the updated requirements in the Section 232 regulations because of the April 9, 2013, applicability date, this final rule changes the applicability date to July 12, 2013. An additional delayed applicability date of over 90 days following publication of this final rule should allow parties involved in Section 232 healthcare facility transactions to

prepare for such transactions based on the new Section 232 regulations and related Section 232 documents.

III. Justification for Final Rulemaking

In general, HUD publishes a rule for public comment before issuing a rule for effect, in accordance with HUD's regulations on rulemaking at 24 CFR part 10. Part 10, however, provides in § 10.1 for exceptions from that general rule where HUD finds good cause to omit advance notice and public participation. The good cause requirement is satisfied when the prior public procedure is "impracticable, unnecessary or contrary to the public interest."

HUD finds that good cause exists to publish this rule for effect without first soliciting public comment because prior public comment would be contrary to the public interest. HUD's Section 232 program plays an important role in today's economy as the need for residential care facilities has increased and requests to FHA to provide mortgage insurance for such facilities also increased. By reducing the cost of capital needed by residential care facilities to finance the construction, renovation, acquisition, or refinancing of facilities, the Section 232 program helps to improve access to quality healthcare and decrease overall healthcare costs.

Affected parties involved in upcoming Section 232 transactions have advised that efforts to comply with the April 9, 2013, applicability date would result in a delay in completion of a Section 232 transaction and considerable increased expense due to delay. Given the need for quality and affordable care in many communities across the country, HUD recognizes that a delay in completion of a Section 232 transaction whether for acquisition or refinancing for a healthcare facility not only affects the parties involved in the transaction but the community in which the healthcare facility would be purchased, constructed, or refinanced. For this reason, HUD extends the applicability date in the September 7, 2012, final rule from April 9, 2013, to July 12, 2013.

IV. Findings and Certifications

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory