■ 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. In § 522.956, revise paragraph (d)(2) to read as follows:

§ 522.956 Florfenicol and flunixin.

* * * * *

(d) * * *

(2) *Indications for use.* For treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*, and control of BRD-associated pyrexia in beef and non-lactating dairy cattle.

* * * * *

Dated: August 31, 2010.

Elizabeth Rettie,

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

[FR Doc. 2010–22039 Filed 9–2–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2010–N–0002]

New Animal Drugs for Use in Animal Feed; Ractopamine

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 two supplemental new animal drug applications (NADAs) filed by Elanco Animal Health, A Division of Eli Lilly & Co. The supplemental NADAs provide for administering a Type C medicated feed containing ractopamine hydrochloride as a top dress on Type C medicated feeds containing monensin, USP, or monensin, USP, and tylosin phosphate to cattle fed in confinement for slaughter.

DATES: This rule is effective September 3, 2010.

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: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 141–225 that provides for use of OPTAFLEXX (ractopamine hydrochloride) and RUMENSIN (monensin, USP) Type A medicated articles to formulate two-way combination drug Type C medicated feeds for cattle fed in confinement for slaughter. Elanco Animal Health also filed a supplement to NADA 141–224 that provides for use of OPTAFLEXX (ractopamine hydrochloride), RUMENSIN (monensin, USP), and TYLAN (tylosin phosphate) Type A medicated articles to formulate three-way combination drug Type C medicated feeds for cattle fed in confinement for slaughter.

The supplemental NADAs provide for administering ractopamine hydrochloride Type C medicated feeds as a top dress on Type C medicated feeds containing monensin, USP, or monensin, USP, and tylosin phosphate to cattle fed in confinement for slaughter as the means by which the two-way or three-way combinations will be created. Supplemental NADA 141–224 is approved as of June 7, 2010; supplemental NADA 141–225 is approved as of June 17, 2010; and the regulations in 21 CFR 558.500 are amended to reflect the approvals.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summaries of safety and effectiveness data and information submitted to support approval of these applications 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 these actions are of a type that do 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 the 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 § 558.500, add paragraphs (e)(2)(xii) and (e)(2)(xiii) to read as follows:

§ 558.500 Ractopamine.

* * * * *

(e) * * *

(2) * * *

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(xii) Not to exceed 800; to provide 70 to 400 mg/head/day.	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.	Top dress ractopamine in a minimum of 1.0 lb of medicated feed during the last 28 to 42 days on feed. Not for animals intended for breeding. See § 558.355(d).	000986

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xiii) Not to exceed 800; to provide 70 to 400 mg/head/day.	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day, plus tylosin 8 to 10.	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for 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* (*Actinomyces*) *pyogenes*.	Top dress ractopamine in a minimum of 1.0 lb of medicated feed during the last 28 to 42 days on feed. Not for animals intended for breeding. See §§ 558.355(d) and 558.625(c).	000986

* * * * *

Dated: August 31, 2010.

Elizabeth Rettie,

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

[FR Doc. 2010–22071 Filed 9–2–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Ch. II

[Docket No. FR–5404–N–02]

Federal Housing Administration Risk Management Initiatives: New Loan-to-Value and Credit Score Requirements

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

ACTION: Final rule.

SUMMARY: On July 15, 2010, HUD issued a notice seeking comment on three initiatives that HUD proposed would contribute to the restoration of the Mutual Mortgage Insurance Fund (MMIF) capital reserve account. This document is limited to implementation of HUD's proposal to introduce a minimum credit score threshold and reduce the maximum LTV. At the end of the public comment period on August 16, 2010, HUD received 902 comments. The overwhelming majority of these comments focused on HUD's proposal to cap seller concessions. HUD is continuing to review and consider the issues raised by commenters on capping seller concessions as well as those pertaining to HUD's proposal to tighten manual underwriting guidelines. HUD's final decision on these two proposals will be addressed separately.

DATES: *Effective Date:* October 4, 2010.

FOR FURTHER INFORMATION CONTACT: Karin Hill, Director, Office of Single Family Program Development, Office of Housing, Department of Housing and Urban Development, 451 7th Street, SW., Room 9278, Washington, DC 20410; telephone number 202–708–2121 (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 Information Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background—HUD's July 15, 2010 Notice

On July 15, 2010, at 75 FR 41217, HUD issued a proposed rule seeking comment on three initiatives that HUD proposed would contribute to the restoration of the Mutual Mortgage Insurance Fund (MMIF) capital reserve account. The proposed changes were developed to preserve both the historical role of the Federal Housing Administration (FHA) in providing a home financing vehicle during periods of economic volatility and HUD's social mission of helping underserved borrowers. In the July 15, 2010, notice, HUD proposed the following: To reduce the amount of closing costs a seller may pay on behalf of a homebuyer purchasing a home with FHA-insured mortgage financing for the purposes of calculating the maximum mortgage amount; to introduce a credit score threshold as well as reduce the maximum loan-to-value (LTV) for borrowers with lower credit scores who represent a higher risk of default and mortgage insurance claim; and to tighten underwriting standards for mortgage loan transactions that are manually underwritten.

A recently issued independent actuarial study shows that the MMIF capital ratio has fallen below its statutorily mandated threshold.[1] Consistent with HUD's responsibility under the National Housing Act to ensure that the MMIF remains financially sound, HUD published the July 15, 2010 document and sought public comment on the three proposals described above designed to address features of FHA mortgage insurance that have resulted in high mortgage insurance claim rates and present an unacceptable risk of loss to FHA.

Over the past two years, the volume of FHA insurance has increased rapidly as private sources of mortgage finance retreated from the market. FHA's share of the single-family mortgage market today is approximately 30 percent—up from 3 percent in 2007, and the dollar volume of insurance written has jumped from the $56 billion issued in that year to more than $300 billion in 2009. The growth in the MMIF portfolio over such a short period of time coincided with worsening economic conditions that have seen high levels of defaults and foreclosures, and consequently unacceptable risks of loss to the MMIF. Given these conditions and concerns, FHA, in managing the MMIF, must be especially vigilant in monitoring the performance of the portfolio, enhancing risk controls, and tightening standards to address portions of the business that expose homeowners to excessive financial risks. FHA's authorizing statute, the National Housing Act (12 U.S.C. 1701 *et seq.*), envisions that FHA will adjust program standards and practices, as necessary, to operate the MMIF, with reasonable expectations of financial loss. Within the past year, FHA has adjusted several program standards and practices so that the MMIF is preserved and FHA is operating the MMIF with acceptable risks of financial loss, not unacceptable risks.[2]

[1] On November 13, 2009, HUD released an independent actuarial study that reported that FHA will likely sustain significant losses from mortgage loans made prior to 2009, due to the high concentration of seller-financed downpayment assistance mortgage loans and declining real estate values nationwide, and that the MMIF capital reserve relative to the amount of outstanding insurance in force had fallen below the statutorily mandated 2 percent ratio. The capital reserve account serves as a back-up fund, where FHA holds additional capital to cover unexpected losses. The capital ratio generally reflects the reserves available (net of expected claims and expenses), as a percentage of the current portfolio, to address unexpected losses. The report can be found at: *http://www.hud.gov/offices/hsg/fhafy09annualmanagementreport.pdf.*

[2] While the Federal Credit Reform Act of 1990 requires that FHA (and all other government credit agencies) estimate and budget for the anticipated cost of mortgage loan guarantees, the National