

subpart F of part 23, the earliest that an SD or MSP would be required to comply with such requirements is December 31, 2012. The changes to compliance dates for § 23.201 will extend the compliance date for certain provisions of this rule until May 1, 2013.

The changes to compliance dates being adopted do not change the substance of the rules; rather, they merely provide additional time by which parties can comply. As such, the costs and benefits of the Commission's action relate only to the additional time provided.

2. Costs

The Commission does not anticipate there being any new, quantifiable costs attributable to these changes to compliance dates being adopted because it is only extending the compliance dates for certain requirements in part 23 of the Commission's regulations. At the same time, however, the Commission is mindful that a delay in the protections afforded by the regulations could result in costs to the public, even if the same is not amenable to quantification. The Commission believes, however, that these costs are mitigated by the maintenance of various other provisions relating to (i) prohibitions on fraud, manipulation and abusive practices, (ii) fair dealings in communications, and (iii) reasonable diligence regarding recommended swaps. These provisions are unaffected by delayed compliance from this extension. The Commission invites comments from the public on any costs, quantitative and qualitative, arising from the delay granted by the changes to compliance dates being adopted.

3. Benefits

The additional time for compliance provided for in this release will yield substantial benefit for market participants and the public alike. Absent this extension, market participants would be required to implement temporary solutions while the more permanent, industry wide solutions described earlier are finalized. The Commission believes that this duplication of efforts to achieve compliance would impose extensive burdens and costs on parties without any concomitant benefit to the public. Moreover, the Commission is concerned that based on the representations made by market participants, absent the changes to compliance dates being adopted, market participants might exit the market or curtail their swaps activity due to a lack of legal certainty and protection afforded by Commission relief. If that were to occur, the

Commission expects that reduced market liquidity would increase the costs of hedging, which would then be passed on the public in the form of higher costs.

4. Section 15(a)

Section 15(a) of the CEA requires the Commission to consider the effects of its actions in light of the following five factors:

a. Protection of Market Participants and the Public

The Commission believes that by extending the compliance date for certain regulations in part 23, market participants will be able to continue to participate in the swaps market without concerns about potential consequences of failure to comply with the specified regulations. This will, in turn, protect the public by ensuring that the economy does not suffer as a result of any unintended consequences that may have arisen if market participants exited the swaps market. The Commission recognizes that any delay in compliance with the aforementioned business conduct and documentation requirements continues to leave the public without the protections and attendant benefits of those requirements. However, the Commission believes that delaying compliance for only certain business conduct and documentation requirements, while retaining the original compliance dates for fundamental counterparty protections relating to (i) prohibitions on fraud, manipulation and abusive practices, (ii) fair dealings in communications, and (iii) reasonable diligence regarding recommended swaps, will mitigate those effects while avoiding this risk that market participants will exit the market due to legal uncertainty.

b. Efficiency, Competitiveness, and Financial Integrity of Markets

The Commission believes that extending the compliance dates for the aforementioned rules will help protect the efficiency and competitiveness of the markets by obviating the need to stop transacting in swaps due to delay in complying with specific Commission regulations. It will also strengthen the financial integrity of markets by ensuring that market participants do not transact in the swaps markets while not being in full compliance with these regulations.

c. Price Discovery

If concerns regarding non-compliance results in a reduction in participation by a large number of market participants,

such a decrease in swaps activity will adversely impact the price discovery process of the swaps markets.

d. Sound Risk Management

If counterparties refrain from transacting in swaps, the ability of other market participants to hedge their risks using these instruments may suffer. By mitigating the concerns of market participants regarding compliance with Commission rules, the changes to compliance dates being adopted herein help ensure that, while firms diligently complete the compliance requirements, they can continue entering into swap transactions to hedge their business and investment risks.

e. Other Public Interest Considerations

The Commission has not identified an impact on other public interest considerations, other than those mentioned above, as a result of the changes to compliance dates being adopted herein, but seeks comment as to any potential impact on this and other 15(a) factors.

Issued in Washington, DC on December 18, 2012, by the Commission.

Sauntia S. Warfield,

Assistant Secretary of the Commission.

Appendix to Business Conduct and Documentation Requirements for Swap Dealers and Major Swap Participants—Commission Voting Summary

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendix 1—Commission Voting Summary

On this matter, Chairman Gensler and Commissioners Sommers, Chilton, O'Malia and Wetjen voted in the affirmative; no Commissioner voted in the negative.

[FR Doc. 2012–30885 Filed 12–31–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 558

[Docket No. FDA–2012–N–0002]

New Animal Drugs; Meloxicam; Nicarbazin

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 actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during October 2012. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable.

DATES: This rule is effective January 2, 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 original and supplemental approval actions during October 2012, as listed in table 1 of this document. 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 Center for Veterinary Medicine FOIA Electronic Reading Room: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm>.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAs AND ANADAs APPROVED DURING OCTOBER 2012

NADA/ANADA	Sponsor	New animal drug product name	Action	21 CFR section	FOIA summary	NEPA review
009-476	Phibro Animal Health Corp., GlenPointe Centre East, Third floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666.	NICARB 25% (nicarbazin) Type A medicated article.	Supplement revising nicarbazin dosage to a range consistent with dosage approved for use in combination feeds.	558.366	No	CE ¹
098-378	Phibro Animal Health Corp., GlenPointe Centre East, Third floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666.	NICARB 25% (nicarbazin) and bacitracin methylene disalicylate Type A medicated articles.	Supplement revising nicarbazin dosage to a range consistent with dosage approved for use in combination feeds.	558.366	No	CE ¹
200-496	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.	AMPROMED P for Poultry (amprolium) 9.6% Oral Solution.	Original approval as a generic copy of NADA 13-149.	520.100	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 or an environmental impact statement because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

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

21 CFR Part 520

Animal drugs.

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 parts 520 and 558 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. In § 520.100, revise paragraph (b)(4) and the introductory text in paragraph (d)(1) to read as follows:

§ 520.100 Amprolium.

* * * * *

(b) * * *

(4) No. 061623 for use of products described in paragraphs (a)(1) and (a)(2) of this section as in paragraph (d) of this section.

* * * * *

(d) * * * (1) *Growing chickens, turkeys, and laying hens.* It is used in drinking water as follows:

* * * * *

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 § 558.366, in paragraph (d), amend the table as follows:

■ a. Revise the entries for “90.8 to 181.6 (0.01 to 0.02 pct)”.

■ b. In the entry for “113.5 (0.0125 pct)”, in the entry for “Chickens; aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina*, *E. maxima*, *E. necatrix*, and *E. brunetti*)

coccidiosis”, remove “066104” from the “Sponsor” column.
 ■ c. In the entry for “113.5 (0.0125 pct)”, in the entry for “Bacitracin

methylene disalicylate 30”, remove “066104” from the “Sponsor” column.
 The revisions read as follows:

§ 558.366 Nicarbazin.
 * * * * *
 (d) * * *

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
90.8 to 181.6 (0.01 to 0.02 pct).	Broiler chickens: As an aid in preventing outbreaks of cecal (<i>Eimeria tenella</i>) and intestinal (<i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i>) coccidiosis.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton.	066104
	Bacitracin methylene disalicylate 4 to 50 and roxarsone 22.7 to 45.4.	Broiler chickens: As an aid in preventing outbreaks of cecal (<i>Eimeria tenella</i>) and intestinal (<i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i>) coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for outbreaks of coccidiosis. Discontinue medication 5 days before marketing the birds for human consumption to allow for elimination of the drug from edible tissue. Do not feed to laying hens in production. Nicarbazin as provided by No. 066104; bacitracin methylene disalicylate and roxarsone by No. 046573 in §510.600(c) of this chapter.	066104
	Bacitracin methylene disalicylate 30.	Broiler chickens: As an aid in preventing outbreaks of cecal (<i>Eimeria tenella</i>) and intestinal (<i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i>) coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton.	066104
	Penicillin 2.4 to 50 ..	Broiler chickens: As an aid in preventing outbreaks of cecal (<i>Eimeria tenella</i>) and intestinal (<i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i>) coccidiosis, and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for outbreaks of coccidiosis. Do not use in flushing mashers. Do not feed to chickens producing eggs for human consumption. Discontinue medication 5 days before marketing the birds for human consumption to allow for elimination of the drug from edible tissue. Penicillin as procaine penicillin G. Nicarbazin and penicillin as provided by No. 066104 in §510.600(c) of this chapter.	066104

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Penicillin 2.4 to 50 and roxarsone 22.7 to 45.4.	Broiler chickens: As an aid in preventing outbreaks of cecal (<i>Eimeria tenella</i>) and intestinal (<i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i>) coccidiosis, and for increased rate of weight gain and improved feed efficiency, and improved pigmentation.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for outbreaks of coccidiosis. Feed as the sole source of organic arsenic; drug overdose or lack of water may result in leg weakness; do not use in flushing mashers. Discontinue medication 5 days before marketing the birds for human consumption to allow for elimination of the drug from edible tissue. Do not feed to laying hens in production. Penicillin as procaine penicillin G. Nicarbazin and penicillin as provided by No. 066104; roxarsone by No. 046573 in § 510.600(c) of this chapter.	066104
*	*	*	*	*

Dated: December 21, 2012

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2012-31234 Filed 12-31-12; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[USCG-2012-1074]

RIN 1625-AA11

Regulated Navigation Area; Reporting Requirements for Barges Loaded With Certain Dangerous Cargoes, Inland Rivers, Eighth Coast Guard District; Extension of Stay (Suspension)

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Commander, Eighth Coast Guard District is extending the previously published stay (suspension) of reporting requirements under the Regulated Navigation Area (RNA) established by 33 CFR 165.830 for barges loaded with certain dangerous cargoes (CDC barges) in the inland rivers of the Eighth Coast Guard District. A two year stay was previously published at 76 **Federal Register** (FR) 1360 (January 10, 2011), which expires January 15, 2013. This extension is necessary because the Coast Guard continues to analyze future reporting needs and evaluate possible changes in CDC reporting requirements. This extension of the suspension of the CDC reporting requirements in no way relieves towing vessel operators and fleeting area managers responsible for

CDC barges in the RNA from their dangerous cargo or vessel arrival and movement reporting obligations currently in effect under other regulations or placed into effect under appropriate Coast Guard authority.

DATES: Effective midnight January 15, 2013, 33 CFR 165.830(d), (e), (f), (g), and (h) are stayed until midnight September 30, 2013.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2012-1074. To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions about this temporary rule, call or email LT Jason Doherty, Coast Guard; telephone 504-671-2266, email: Jason.C.Doherty@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

CDC Certain Dangerous Cargo
DHS Department of Homeland Security
FR **Federal Register**
NPRM Notice of Proposed Rulemaking

A. Regulatory History and Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(3)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it would be impracticable, unnecessary, and contrary to the public interest.

The contract for the CDC barge reporting system at the Inland River Vessel Movement Center (IRVMC) expired in January 2011. Due to the expiration of this contract, the Coast Guard would not be able to receive and process reports, therefore, in late December 2010, the Coast Guard decided to suspend the IRVMC reporting requirements for a two-year period. This suspension was published in the **Federal Register** at 76 FR 1360 (January 10, 2011), and expires on January 15, 2013.

At this time, the contract for the CDC barge reporting system has not been renewed, and the Coast Guard is still considering whether to enter into a new contract and lift the suspension, modify the reporting requirements in the RNA, or repeal the RNA completely. An extension of the stay is necessary while the Coast Guard continues to consider these options.

We believe prior notice and comment is unnecessary because we expect the affected public will have no objection to