

(ii) Model G58, serial numbers TH-2125 through TH-2281, TH-2283, and TH-2284.

(d) Subject

Joint Aircraft System Component (JASC)/ Air Transport Association (ATA) of America Code 28; fuel.

(e) Unsafe Condition

This AD was prompted by installation of oversized clamps on fuel vapor return and/ or fuel vent lines in the outboard sections of the left and right wings. We are issuing this AD to correct the unsafe condition on these products.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspection

Within the next 50 hours time-in-service after June 21, 2012 (the effective date of this AD) or within the next 6 calendar months after June 21, 2012 (the effective date of this AD), whichever occurs first, inspect the fuel hose clamps for oversized or deformed clamps following Hawker Beechcraft Mandatory Service Bulletin No. SB 28-4039, Revision 1, dated October 2011.

Note 1 to paragraph (g) of this AD: If you have a scheduled inspection before the compliance time of this AD, the FAA recommends you comply with this AD at that time.

(h) Replacement

If any oversized or deformed clamps are found during the inspection required in paragraph (g) of this AD, before further flight, replace the clamps following Hawker Beechcraft Mandatory Service Bulletin No. SB 28-4039, Revision 1, dated October 2011.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Wichita Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/ certificate holding district office.

(j) Related Information

For more information about this AD, contact Thomas Teplik, Aerospace Engineer, Wichita ACO, FAA, 1801 Airport Road, Room 100, Wichita, Kansas 67209; phone: (316) 946-4196; fax: (316) 329-4090; email: thomas.teplik@faa.gov.

(k) Material Incorporated by Reference

(1) You must use Hawker Beechcraft Mandatory Service Bulletin No. SB 28-4039, Revision 1, dated October 2011, to do the actions required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference (IBR) under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Hawker Beechcraft Corporation, B091-A04, 10511 E. Central Ave., Wichita, Kansas 67206; telephone: (800) 429-5372 or (316) 676-3140; fax: (316) 676-8027; email: tmdc@hawkerbeechcraft.com; or Internet: http://www.hawkerbeechcraft.com/customer_support/technical_and_field_support/.

(3) You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Kansas City, Missouri, on May 9, 2012.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012-11812 Filed 5-16-12; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, and 558

[Docket No. FDA-2012-N-0002]

New Animal Drugs; Ceftiofur Sodium; Lincomycin Powder; Naracin; 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 actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during March 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 May 17, 2012.

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, email: george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA's Center for Veterinary Medicine (CVM) is adopting use of a monthly **Federal Register** document to codify approval actions for NADAs and abbreviated ANADAs. CVM will no longer publish a separate rule for each action. This approach will allow a more efficient use of available resources.

In this document, FDA is amending the animal drug regulations to reflect the original and supplemental approval actions during March 2012, as listed in table 1 of this document. FDA is also informing the public of the availability of environmental review documents required under the National Environmental Policy Act (NEPA), where applicable. For actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA) 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.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING MARCH 2012

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR Section	FOIA summary	NEPA review
118-980 ...	Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285.	MONTEBAN (narasin) Type A medicated article.	Supplement increasing the upper dose limit for narasin in broiler feed.	558.363	Yes	Environmental assessment (EA)/Finding of no significant impact (FONSI).
111-636 ...	Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017.	LINCOMIX (lincomycin hydrochloride) Soluble Powder.	Supplement adding an indication for control of American foulbrood in honey bees.	520.1263c	Yes	Categorically excluded (CE). ¹
200-421 ...	Hospira, Inc., 275 N. Field Dr., Lake Forest, IL 60045.	Ceftiofur for Injection (ceftiofur sodium) Sterile Powder.	Original approval of generic copy of NADA 140-338.	522.313c	Yes	CE.
200-455 ...	Cross Vetpharm Group, Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.	TYLOMED-WS (tylosin tartrate) Soluble Powder.	Supplement adding an indication for control of porcine proliferative enteropathies.	520.2640	Yes	CE. ¹
200-473 ...	Huvepharma AD, 33 James Boucher Blvd., Sophia 1407, Bulgaria.	TYLOVET Soluble (tylosin tartrate).	Supplement adding an indication for control of porcine proliferative enteropathies.	520.2640	Yes	CE. ¹

¹ The Agency has determined under 21 CFR 25.33 that this action is CE from the requirement to submit an 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.

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 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520 and 522

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 510, 520, 522, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1), alphabetically add an entry for “Hospira, Inc.”; and in the table in paragraph (c)(2), numerically add an entry for “000409” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
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* * * * *	
Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045	000409

* * * * *

(2) * * *

Drug labeler code	Firm name and address
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* * * * *	
000409	Hospira Inc., 275 North Field Dr., Lake Forest, IL 60045.

* * * * *

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 4. In § 520.1263c, revise paragraph (b) and add paragraph (d)(3) to read as follows:

§ 520.1263c Lincomycin powder.

* * * * *

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 000009 for use as in paragraph (d) of this section.

(2) Nos. 046573, 054925, 061623, and 076475 for use as in paragraphs (d)(1) and (d)(2) of this section.

* * * * *

(d) * * *

(3) *Honey bees*—(i) *Amount.* Mix 100 milligrams lincomycin with 20 grams confectioners’/powdered sugar and dust over the top bars of the brood chamber once weekly for 3 weeks.

(ii) *Indications for use.* For the control of American foulbrood (*Paenibacillus larvae*).

(iii) *Limitations.* The drug should be fed early in the spring or late in the fall and consumed by the bees before the main honey flow begins to avoid contamination of production honey. Complete treatments at least 4 weeks before main honey flow.

■ 5. In § 520.2640, revise paragraph (b) introductory text to read as follows:

§ 520.2640 Tylosin.

* * * * *

(b) *Sponsors.* See Nos. 000986, 016592, and 061623 in § 510.600(c) of this chapter.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 6. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 7. In § 522.313c, revise paragraphs (b), (e)(2)(ii), (e)(3)(ii), (e)(4)(ii), and (e)(8)(i) to read as follows:

§ 522.313c Ceftiofur sodium.

(b) *Sponsors.* See Nos. 000009, 000409, and 068330 in § 510.600(c) of this chapter.

(e) * * *

(2) * * *

(ii) *Indications for use.* For treatment of bovine respiratory disease (shipping fever, pneumonia) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*. Also, for the treatment of acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.

(3) * * *

(ii) *Indications for use.* For treatment of sheep respiratory disease (sheep pneumonia) associated with *Mannheimia haemolytica* and *Pasteurella multocida*.

(4) * * *

(ii) *Indications for use.* For treatment of caprine respiratory disease (goat pneumonia) associated with *Mannheimia haemolytica* and *Pasteurella multocida*.

(8) * * *

(i) *Amount.* 1.0 mg/lb (2.2 mg/kg) body weight by subcutaneous injection. Treatment should be repeated at 24-hour intervals for 5 to 14 days.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 9. In § 558.363, revise paragraph (d)(1)(i) introductory text to read as follows:

§ 558.363 Narasin.

(d) * * *

(1) * * *

(i) *Amount per ton.* Narasin, 54 to 90 grams.

* * *

Dated: May 7, 2012.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2012-11937 Filed 5-16-12; 8:45 am]

BILLING CODE 4160-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA-HQ-OAR-2009-0277; FRL-9668-3]

RIN 2060-AQ83

Protection of Stratospheric Ozone: The 2012 Critical Use Exemption From the Phaseout of Methyl Bromide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is authorizing uses that qualify for the 2012 critical use exemption and the amount of methyl bromide that may be produced, imported, or supplied from existing pre-phaseout inventory for those uses in 2012. EPA is taking this action under the authority of the Clean Air Act to reflect a recent consensus decision by the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer at the Twenty-Second Meeting of the Parties.

DATES: This rule is effective on May 17, 2012.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2009-0277. All documents in the docket are listed on the www.regulations.gov web site. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and is publicly available only in hard copy form. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the Air and Radiation Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Air and Radiation Docket is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: For further information about this rule, contact Jeremy Arling by telephone at

(202) 343-9055, or by email at arling.jeremy@epa.gov or by mail at U.S. Environmental Protection Agency, Stratospheric Protection Division, Stratospheric Program Implementation Branch (6205J), 1200 Pennsylvania Avenue NW., Washington, DC 20460. You may also visit the methyl bromide section of the ozone layer protection Web site at www.epa.gov/ozone/mbr for further information about the methyl bromide critical use exemption, other stratospheric ozone protection regulations, the science of ozone layer depletion, and related topics.

SUPPLEMENTARY INFORMATION: This rule concerns Clean Air Act (CAA) restrictions on the consumption, production, and use of methyl bromide (a Class I, Group VI controlled substance) for critical uses during calendar year 2012. Under the Clean Air Act, methyl bromide consumption and production were phased out on January 1, 2005, apart from allowable exemptions, such as the critical use exemption and the quarantine and preshipment (QPS) exemption. Consumption is defined under the CAA as production plus imports minus exports. With this action, EPA is authorizing the uses that qualify for the 2012 critical use exemption as well as specific amounts of methyl bromide that may be produced and imported, or sold from pre-phaseout inventory (also referred to as “stocks”) for critical uses in 2012.

Section 553(d) of the Administrative Procedure Act (APA), 5 U.S.C. Chapter 5, generally provides that rules may not take effect earlier than 30 days after they are published in the **Federal Register**. EPA is issuing this final rule under section 307(d)(1) of the Clean Air Act, which states: “The provisions of section 553 through 557 * * * of Title 5 shall not, except as expressly provided in this section, apply to actions to which this subsection applies.” Thus, section 553(d) of the APA does not apply to this rule. EPA is nevertheless acting consistently with the policies underlying APA section 553(d) in making this rule effective on May 17, 2012. APA section 553(d) allows an effective date less than 30 days after publication “as otherwise provided by the agency for good cause found and published with the rule.” Section 5 U.S.C. 553(d)(1) allows an effective date less than 30 days after publication for a rule that “that grants or recognizes an exemption or relieves a restriction.” 5 U.S.C. 553(d)(1). Since today’s action can be considered to either grant an exemption for limited critical uses during 2012 from the general