

before adopting these SIAPs and/or Weather Takeoff Minimums are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs and/or Weather Takeoff Minimums effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR part 97

Air Traffic Control, Airports, Incorporation by reference, and Navigation (Air).

Issued in Washington, DC on October 21, 2005.

James J. Ballough,

Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, under Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures and Weather Takeoff Minimums effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

2. Part 97 is amended to read as follows:

* * * *Effective December 22, 2005*

Atmore, AL, Atmore Muni, RNAV (GPS) RWY 18, Orig

Atmore, AL, Atmore Muni, RNAV (GPS) RWY 36, Orig

Atmore, AL, Atmore Muni, Takeoff Minimums & Textual DP, Orig

St. Paul Island, AK, St. Paul Island, RNAV (GPS) RWY 36, Orig

St. Paul Island, AK, St. Paul Island, GPS

RWY 36, Orig, CANCELLED

St. Paul Island, AK, St. Paul Island, ILS OR LOC/DME RWY 36, Amdt 2

St. Paul Island, AK, St. Paul Island, LOC/DME BC RWY 18, Amdt 3

St. Paul Island, AK, St. Paul Island, NDB–A, Amdt 1

St. Paul Island, AK, St. Paul Island, Takeoff Minimums & Textual DP, Amdt 2

Yakutat, AK, Yakutat, RNAV (GPS) RWY 11, Amdt 1

Yakutat, AK, Yakutat, RNAV (GPS) RWY 29, Amdt 1

Yakutat, AK, Yakutat, VOR/DME RWY 2, Amdt 3

Yakutat, AK, Yakutat, VOR/DME RWY 29, Amdt 2

Yakutat, AK, Yakutat, LOC/DME BC RWY 29, Amdt 4

Springdale, AR, Springdale Muni, RNAV (GPS) RWY 18, Amdt 1A

Oakdale, CA, Oakdale, VOR–A, Orig

Oakdale, CA, Oakdale, RNAV (GPS) RWY 10, Orig

Oakdale, CA, Oakdale, RNAV (GPS) RWY 28, Orig

Oakdale, CA, Oakdale, GPS RWY 10, Orig, CANCELLED

Oakdale, CA, Oakdale, Takeoff Minimums and Textual DP, Orig

Jacksonville, FL, Cecil Field, RADAR–1, Orig, CANCELLED

Jacksonville, FL, Jacksonville Intl, RNAV (GPS) RWY 31, Amdt 1

Boise, ID, Boise Air Terminal/Gowen Fld, RNAV (GPS) RWY 28R, Amdt 1

Sheldon, IA, Sheldon Muni, RNAV (GPS) RWY 15, Orig

Sheldon, IA, Sheldon Muni, RNAV (GPS) RWY 33, Orig

Sheldon, IA, Sheldon Muni, NDB RWY 33, Amdt 7

Sheldon, IA, Sheldon Muni, VOR OR GPS RWY 33, Amdt 1A, CANCELLED

Parsons, KS, Tri-City, NDB RWY 17, Amdt 9A

London, KY, London-Corbin Arpt-Magee Fld, ILS RWY 6, Orig

London, KY, London-Corbin Arpt-Magee Fld, Takeoff Minimums and Textual DP, Amdt 3

Paducah, KY, West Kentucky Airpark, GPS RWY 4, Orig, CANCELLED

Paducah, KY, West Kentucky Airpark, GPS RWY 22, Orig, CANCELLED

Grand Isle, LA, Grand Isle, VOR OR GPS–A, Amdt 8, CANCELLED

Grand Isle, LA, Grand Isle, VOR/DME OR GPS–C, Amdt 7, CANCELLED

Frankfort, MI, Frankfort Dow Memorial Field, VOR/DME–A, Orig

Frankfort, MI, Frankfort Dow Memorial Field, VOR OR GPS–A, Amdt 3, CANCELLED

Freemont, MI, Fremont Muni, RNAV (GPS) RWY 18, Orig

Fremont, MI, Fremont Muni, RNAV (GPS) RWY 36, Orig

Fremont, MI, Fremont Muni, VOR RWY 18, Orig

Fremont, MI, Fremont Muni, VOR RWY 36, Amdt 7

Fremont, MI, Fremont Muni, GPS RWY 18, Orig, CANCELLED

Kennett, MO, Kennett Memorial, RNAV (GPS) RWY 2, Orig

Kennett, MO, Kennett Memorial, RNAV

(GPS) RWY 20, Orig

Kennett, MO, Kennett Memorial, NDB RWY 2, Orig

Kennett, MO, Kennett Memorial, NDB RWY 20, Orig

Kennett, MO, Kennett Memorial, VOR/DME RWY 20, Orig

Kennett, MO, Kennett Memorial, NDB OR GPS RWY 18, Amdt 3, CANCELLED

Kennett, MO, Kennett Memorial, Takeoff Minimums and Textual DP, Amdt 1

Albuquerque, NM, Albuquerque Intl Sunport, ILS OR LOC RWY 3, Amdt 2

Eugene, OR, Mahlon Sweet Field, ILS OR LOC Y RWY 16R, Orig

Eugene, OR, Mahlon Sweet Field, ILS OR LOC/DME Z RWY 16R, Amdt 35, ILS RWY 16R (CAT II), ILS RWY 16R (CAT III), Amdt 35

Portland, OR, Portland-Hillsboro, VOR/DME–C, Orig

Portland, OR, Portland-Hillsboro, NDB–B, Amdt 2

Portland, OR, Portland-Hillsboro, VOR/DME OR GPS–A, Orig–B, CANCELLED

Portland, OR, Portland-Hillsboro, Takeoff Minimums and Textual DP, Amdt 5

The Dalles, OR, Columbia Gorge Regional/The Dalles Muni, RNAV (GPS)–A, Orig

The Dalles, OR, Columbia Gorge Regional/The Dalles Muni, VOR/DME OR GPS–A, Amdt 4, CANCELLED

Barnwell, SC, Barnwell County, RNAV (GPS) RWY 17, Amdt 1

Barnwell, SC, Barnwell County, NDB RWY 17, Orig

Barnwell, SC, Barnwell County, NDB–A, Amdt 1, CANCELLED

Barnwell, SC, Barnwell County, NDB RWY 4, Amdt 2A, CANCELLED

Delta, UT, Delta Muni, RNAV (GPS) RWY 17, Orig

Delta, UT, Delta Muni, RNAV (GPS) RWY 35, Orig

Delta, UT, Delta Muni, VOR/DME RWY 17, Amdt 2

Delta, UT, Delta Muni, VOR RWY 35, Amdt 3

Delta, UT, Delta Muni, Takeoff Minimums and Textual DP, Orig

Bremerton, WA, Bremerton National, ILS OR LOC RWY 19, Amdt 14

Pinedale, WY, Ralph Wenz Field, Takeoff Minimums and Textual DP, Amdt 1

Pinedale, WY, Ralph Wenz Field, RNAV (GPS) RWY 11, Orig

Pinedale, WY, Ralph Wenz Field, RNAV (GPS) RWY 29, Orig

Pinedale, WY, Ralph Wenz Field, NDB RWY 29, Amdt 1

* * * *Effective February 16, 2006*

Harrisburg, PA, Harrisburg International, COPTER ILS 128, Orig, CANCELLED

Harrisburg, PA, Harrisburg International, COPTER ILS 308, Orig, CANCELLED

[FR Doc. 05–21582 Filed 10–31–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin and Praziquantel Paste

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 Virbac AH, Inc. The supplemental NADA provides revised labeling for ivermectin and praziquantel oral paste used in horses for the treatment and control of various internal parasites.

DATES: This rule is effective November 1, 2005.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7543, e-mail: melanie.berson@fda.gov.

SUPPLEMENTARY INFORMATION: Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137, filed a supplement to NADA 141-215 for EQUIMAX (ivermectin 1.87%/praziquantel 14.03%) Paste for horses. This supplement amends product labeling to separate parasite life stages in the indications section. The supplemental NADA is approved as of September 16, 2005, and the regulations in 21 CFR 520.1198 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary. The current regulations for ivermectin and praziquantel paste are also being revised to remove redundant language. These changes are being made to improve the readability of the regulations.

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(d)(1) 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 520

Animal drugs.

■ 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 520 is 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. Section 520.1198 is amended by revising paragraphs (d)(2)(i) and (d)(2)(ii) to read as follows:

§ 520.1198 Ivermectin and praziquantel paste.

* * * * *

(d) * * *

(2) * * *

(i) Tapeworms—*Anoplocephala perfoliata*; Large strongyles (adults)—*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds)—*Coronocylus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocylus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; Small Strongyles—fourth-stage larvae; Pinworms (adults and fourth-stage larvae)—*Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae)—*Parascaris equorum*; Hairworms (adults)—*Trichostrongylus axei*; Large-mouth Stomach Worms (adults)—*Habronema muscae*; Bots (oral and gastric stages)—*Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae)—*Dictyocaulus arnfieldi*; Intestinal Threadworms (adults)—*Strongyloides westeri*; Summer Sores

caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

(ii) Tapeworms—*Anoplocephala perfoliata*; Large Strongyles (adults)—*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp.; Small Strongyles (adults, including those resistant to some benzimidazole class compounds)—*Cyathostomum* spp., *Cylicocylus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp.; Small Strongyles—fourth-stage larvae; Pinworms (adults and fourth-stage larvae)—*Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae)—*Parascaris equorum*; Hairworms (adults)—*Trichostrongylus axei*; Large-mouth Stomach Worms (adults)—*Habronema muscae*; Bots (oral and gastric stages)—*Gasterophilus* spp.; Lungworms (adults and fourth-stage larvae)—*Dictyocaulus arnfieldi*; Intestinal Threadworms (adults)—*Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

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Dated: October 14, 2005.

Steven D. Vaughn,

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

[FR Doc. 05-21641 Filed 10-31-05; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP Jacksonville 05-140]

RIN 1625-AA87

Security Zone; Sea Buoy at the Entrance of St. Mary's River to Kings Bay, GA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary moving security zone around foreign naval submarines in transit within the area between 12 nautical miles offshore from the baseline, also known as the shoreline, at the mouth of the St. Mary's River to the Kings Bay Naval Submarine Base, Kings Bay, GA. The security zone includes all waters within 500 yards in