

Advocacy, regulations create economic disparities based on size when they have a significant economic impact on a substantial number of small entities.

U.S. livestock importers, breeders, and producers would be entities that are directly affected by this rule. There are no specific data available on numbers of cattle importers; however, there are approximately 2,000 wholesale livestock traders (North American Industry Classification System [NAICS] code 422520), many of whom may also be cattle importers. It is likely that the majority of these firms are small entities according to the SBA's criterion of 100 or fewer employees. There are approximately 1 million livestock producers and breeders (NAICS code 112111) in the United States, approximately 99 percent of which are small entities according to SBA's criterion of annual receipts of \$750,000 or less.

However, given that (1) imported Mexican cattle account for less than 1 percent of the value of the U.S. cattle supply, and (2) the volume of Holstein cross steers and Holstein cross spayed heifers imported from Mexico is believed to represent a small fraction of total cattle imports from Mexico, we expect that the economic effects on the U.S. livestock industry of the prohibition will be negligible. The prohibition also will not have a significant effect on U.S. cattle importers, breeders, or producers because such persons may easily substitute other breeds of cattle for Mexican Holstein cross steers and spayed heifers.

This prohibition on the importation of Holstein cross steers and Holstein cross spayed heifers will benefit the U.S. livestock industry and U.S. consumers by helping to prevent the introduction of bovine tuberculosis into the United States.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This final rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 93

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR part 93 as follows:

PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

■ 1. The authority citation for part 93 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 2. In § 93.427, paragraph (c)(4) is revised to read as follows:

§ 93.427 Cattle from Mexico.

* * * * *

(c) * * *

(4) The importation of Holstein steers, Holstein spayed heifers, Holstein cross steers, and Holstein cross spayed heifers from Mexico is prohibited.

* * * * *

Done in Washington, DC, this 26th day of February 2004.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 04–4598 Filed 3–1–04; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–CE–22–AD; Amendment 39–13504; AD 2003–22–07 R1]

RIN 2120–AA64

Airworthiness Directives; Mitsubishi Heavy Industries, Ltd., MU–2B Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: The FAA is revising Airworthiness Directive (AD) 2003–22–

07, which applies to all Mitsubishi Heavy Industries, Ltd. (Mitsubishi) MU–2B series airplanes. AD 2003–22–07 requires incorporating information into the Limitations Section of the Airplane Flight Manual (AFM) that requires pilot training before flight into known or forecast icing conditions after a certain date. AD 2003–22–07 resulted from the development of a new training video that includes information that is critical to safety of the MU–2B series airplanes. This AD revision is the result of the FAA incorrectly stating in the actions required by AD 2003–22–07 that on or before June 15, 2004 (the effective date of AD 2003–22–07), no person may serve as pilot-in-command (PIC) of a MU–2B series airplane in a flight into known or forecast icing conditions, unless the PIC has received the required training. Consequently, this AD will correct the actions required in AD 2003–22–07 to require those actions on or after June 15, 2004. We are issuing this AD to ensure that the Icing Awareness Training (IAT) requirement continues after June 15, 2004, in order to decrease the chance of icing-related incidents or accidents of the MU–2B series airplanes due to pilot error.

DATES: This AD becomes effective on April 16, 2004.

ADDRESSES: You may view the AD docket at FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2003–CE–22–AD, 901 Locust, Room 506, Kansas City, Missouri 64106. Office hours are 8 a.m. to 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Contact one of the following for questions or more information related to this subject:

—*For General Icing Related Questions:*

Mr. Paul Pellicano, Aerospace Engineer (Icing Specialist), Atlanta Aircraft Certification Office, FAA, One Crown Center, 1895 Phoenix Boulevard, Suite 450, Atlanta, Georgia 30349; telephone: (770) 703–6064; facsimile: (770) 703–6097;

—*For Questions Relating to Airplanes on Type Certificate Data Sheet (TCDS)*

A2PC: Mr. Carl Fountain, Aerospace Engineer, Los Angeles Aircraft Certification Office, FAA, 3960 Paramount Boulevard, Lakewood, California 90712; telephone: (562) 627–5222; facsimile: (562) 627–5228; or

—*For Questions Relating to Airplanes on TCDS A10SW:* Mr. Werner Koch, Aerospace Engineer, FAA, Airplane Certification Office, 2601 Meacham Boulevard, Fort Worth, Texas 76193–

0150; telephone: (817) 222-5133;
facsimile: (817) 222-5960.

SUPPLEMENTARY INFORMATION:

Discussion

Has FAA taken any action to this point? Analysis that the training level of the pilots-in-command (PIC) of the MU-2B series airplanes made it difficult for them to recognize adverse operating conditions and operate safely while flying in icing conditions caused FAA to issue AD 97-20-14, Amendment 39-10150, and AD 2003-22-07, Amendment 39-13355.

AD 97-20-14 required incorporating information into the Limitations Section of the Airplane Flight Manual (AFM) that requires pilot training before further flight into known or forecast icing conditions after a certain date.

AD 2003-22-07 also requires incorporating information into the Limitations Section of the Airplane Flight Manual (AFM) that requires pilot training before further flight into known or forecast icing conditions after a certain date based on a new training video developed by Mitsubishi.

What has happened since AD 2003-22-07 to initiate this action? We incorrectly stated in the AFM Limitation that on or before June 15, 2004 (the effective date of AD 2003-22-07), no person may serve as pilot-in-command (PIC) of a MU-2B series airplane in a flight into known or forecast icing conditions, unless the PIC has received the required training.

Stating on or before June 15, 2004, means that after June 15, 2004, there is no longer a requirement to get the IAT training. This was not the intent of the FAA or Mitsubishi.

The correct statement in the AFM Limitation should be that on or after June 15, 2004, no person may serve as pilot-in-command (PIC) of a MU-2B series airplane in a flight into known or forecast icing conditions, unless the PIC has received the required training.

What is the potential impact if FAA took no action? If the language in the AFM Limitation Section is not corrected, no one would be required to have the mandatory pilot IAT training after June 15, 2004. Lack of mandatory pilot IAT training could result in an increased chance of icing-related incidents or accidents of the MU-2B series airplanes due to pilot error.

FAA's Determination and Requirements of the AD

What has FAA decided? We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other products of this same type design.

Since the unsafe condition described previously is likely to exist or develop in Mitsubishi MU-2B series airplanes when the PIC is not proficient in the operating conditions of these airplanes, we are issuing this AD to decrease the chance of icing-related incidents or accidents of the MU-2B series airplanes due to pilot error.

What does this AD require? This AD requires you to incorporate information into the Limitations Section of the Airplane Flight Manual (AFM) that requires pilot training before further flight into known or forecast icing conditions after a certain date. That AFM limitation consists of the following:

On or after June 15, 2004, no person may serve as pilot-in-command (PIC) of a Mitsubishi MU-2B series airplane in a flight into known or forecast icing conditions, unless the PIC has received the following training since the beginning of the 24th calendar month before the scheduled flight: FAA-approved Mitsubishi Icing Awareness Training (IAT) video YET-01295. One exception is that if training mandated by AD 97-20-14 has been received in the 24 months before June 15, 2004, then the new training must be done no later than 24 months after the date of the AD 97-20-14 training. This two-hour training has been available since July 2, 2002, and is provided by Mitsubishi Heavy Industries at no cost, as part of the Mitsubishi Systems Review (MSR) program. To sign up for the planned training schedules or to arrange training at a more convenient time and location, contact Turbine Aircraft Services at (972) 934-5480. Training is also available at the Sim Com and Reese Howell Enterprises training facilities and some local Flight Standards District Offices (FSDOs). Pilot logbook endorsements are available after completing this training from: Sim Com, Reese Howell Enterprises, Turbine Aircraft Services (TAS), an FAA Aviation Safety Inspector, or other FAA authorized personnel. Please note that all operators of the affected airplanes must initiate action to notify and ensure that flight crewmembers are aware of this requirement.

Changes to 14 CFR Part 39—Affect on the AD

How does the revision to 14 CFR part 39 affect this AD? On July 10, 2002, we published a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs FAA's AD system. This regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. This material previously was included in each individual AD. Since this material is included in 14 CFR part 39, we will not include it in future AD actions.

Compliance Time of This AD

What will be the compliance time of this AD? The compliance time of this

AFM incorporation is "within the next 10 days after the effective date of this AD." The actual viewing of the training video will be incorporated into the current schedule of the video required by AD 97-20-14.

Why is the compliance time presented in calendar time instead of hours time-in-service (TIS)? The unsafe condition described in this AD is not a direct result of airplane design or operation, but is attributed to the expertise and knowledge of the PIC. For this reason, FAA has determined that a compliance time based upon calendar time will be used instead of a certain number of hours TIS.

Comments Invited

Will I have the opportunity to comment before you issue the rule? This AD is a final rule that involves requirements affecting flight safety and was not preceded by notice and an opportunity for public comment; however, we invite you to submit any written relevant data, views, or arguments regarding this AD. Send your comments to an address listed under **ADDRESSES**. Include "AD Docket No. 2003-CE-22-AD" in the subject line of your comments. If you want us to acknowledge receipt of your mailed comments, send us a self-addressed, stamped postcard with the docket number written on it; we will date-stamp your postcard and mail it back to you. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify it. If a person contacts us through a nonwritten communication, and that contact relates to a substantive part of this AD, we will summarize the contact and place the summary in the docket. We will consider all comments received by the closing date and may amend the AD in light of those comments.

Regulatory Findings

Will this AD impact various entities? We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Will this AD involve a significant rule or regulatory action? For the reasons discussed above, I certify that this AD:

1. Is not a "significant regulatory action" under Executive Order 12866;

2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a summary of the costs to comply with this AD and placed it in the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES**. Include "AD Docket No. 2003-CE-22-AD" in your request.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. FAA amends § 39.13 by removing Airworthiness Directive (AD) 2003-22-07, Amendment 39-13355 (68 FR 61613, October 29, 2003), and by adding a new AD to read as follows:

2003-22-07 R1 Mitsubishi Heavy Industries, Ltd.: Amendment 39-13504; Docket No. 2003-CE-22-AD; Revises AD 2003-22-07, Amendment 39-13355.

When Does This AD Become Effective?

(a) This AD becomes effective on April 16, 2004.

What Other ADs Are Affected by This Action?

(b) This AD revises AD 2003-22-07, Amendment 39-13355.

What Airplanes Are Affected by This AD?

(c) This AD affects Models MU-2B, MU-2B-10, MU-2B-15, MU-2B-20, MU-2B-25, MU-2B-26, MU-2B-26A, MU-2B-30, MU-2B-35, MU-2B-36, MU-2B-36A, MU-2B-

40, and MU-2B-60 airplanes, all serial numbers, that are certificated in any category.

Note: This AD also applies to owners and operators who are operating an MU-2B that is under the Alternative Method of Compliance (AMOC) to Item (d)(2) of AD 2000-09-15 R1, for non-air carrier pilots, that requires *annual* viewing of the Icing Awareness Video YET-01295. This AMOC stated that Mitsubishi Heavy Industries America (MHIA) produced icing training video reference YET-97336A may optionally be used as an alternative to the YET 01295 until November 24, 2004, provided it is a valid method of compliance to AD 97-20-14. As of June 15, 2004, YET-97336A will now no longer be a valid method of compliance for this AMOC.

What Is the Unsafe Condition Presented in This AD?

(d) This AD is the result of Mitsubishi developing a new training video that includes information that is critical to safety of the MU-2B series airplanes. The actions specified in this AD are intended to decrease the chance of icing-related incidents or accidents of the MU-2B series airplanes due to pilot error.

What Must I Do To Address This Problem?

(e) To address this problem, you must accomplish the following:

Actions	Compliance	Procedures
<p>Incorporate information into the Limitations Section of the Airplane Flight Manual (AFM) that requires pilot training before further flight into known or forecast icing conditions after a certain date. This AFM limitation consists of the following: "On or after June 15, 2004, no person may serve as pilot-in-command (PIC) of a Mitsubishi MU-2B series airplane in a flight into known or forecast icing conditions, unless the PIC has received the following training since the beginning of the 24th calendar month before the scheduled flight: FAA-approved Mitsubishi Icing Awareness Training (IAT) video YET-01295. One exception is that if training mandated by AD 97-20-14 has been received in the 24 months before June 15, 2004, then the new training must be done no later than 24 months after the date of the AD 97-20-14 training. This two-hour training has been available since July 2, 2002, and is provided by Mitsubishi Heavy Industries at no cost. To sign up for the planned training schedules or to arrange training at a more convenient time and location, contact Turbine Aircraft Services at (972) 934-5480. Training is also available at Sim Com and Reese Howell Enterprises training facilities and some local Flight Standards District Offices (FSDOs). Pilot logbook endorsements are available after completing this training from: Sim Com, Reese Howell Enterprises, Turbine Aircraft Services (TAS), an FAA Aviation Safety Inspector, or other FAA authorized personnel. Please note that all operators of the affected airplanes must initiate action to notify and ensure that flight crewmembers are aware of this requirement."</p>	<p>Do the AFM incorporation within the next 10 days after April 16, 2004 (the effective date of this AD).</p>	<p>The owner/operator holding at least a private pilot certificate as authorized by section 43.7 of the Federal Aviation Regulations (14 CFR 43.7) may accomplish the AFM incorporation requirement of this AD. Make an entry into the aircraft records showing compliance with this portion of the AD in accordance with § 43.9 of the Federal Aviation Regulations (14 CFR 43.9). Inserting a copy of this AD into the Limitations Section of the AFM accomplishes this portion of the AD.</p>

What About Alternative Methods of Compliance?

(f) You may request a different method of compliance or a different compliance time for this AD by following the procedures in 14 CFR 39.19. Unless FAA authorizes otherwise, send your request to your principal inspector. The principal inspector may add comments and will send your request to the Manager, Standards Office, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4110; facsimile: (816) 329-4090.

(1) For information on any already approved alternative methods of compliance, contact Mr. Paul Pellicano, Aerospace Engineer (Icing Specialist), Atlanta Aircraft Certification Office, FAA, One Crown Center, 1895 Phoenix Boulevard, Suite 450, Atlanta, Georgia 30349; telephone: (770) 703-6064; facsimile: (770) 703-6097.

(2) Alternative methods of compliance approved in accordance with AD 2003-22-07, which is revised by this AD, are approved as alternative methods of compliance with this AD.

Issued in Kansas City, Missouri, on February 24, 2004.

James E. Jackson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04-4512 Filed 3-1-04; 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; Levamisole Powder for Oral Solution

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 Schering-Plough Animal Health Corp. The supplemental NADA revises the description of various internal parasites in labeling for levamisole powder, used to make a drench solution for oral administration to cattle and sheep.

DATES: This rule is effective March 2, 2004.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578, e-mail: jmessenh@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095

Morris Ave., Union, NJ 07083, filed a supplement to NADA 112-051 for LEVASOLE (levamisole) Soluble Drench Powder revising the description of various internal parasites in labeling for levamisole powder, used to make a drench solution for oral administration to cattle and sheep. The supplemental NADA is approved as of December 23, 2003, and the regulations are revised in 21 CFR 520.1242a to reflect the approval and a current format. The basis of approval is discussed in the freedom of information summary.

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(a)(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 520.1242a is revised to read as follows:

§ 520.1242a Levamisole powder for oral solution.

(a) *Specifications.* Each package of powder contains 9.075, 11.7, 18.15, 46.8, or 544.5 grams (g) levamisole hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) for use as follows:

(1) No. 000061 for use of 46.8- and 544.5-g packages as in paragraph

(e)(1)(i), (e)(1)(ii)(B), and (e)(1)(iii) of this section; for 11.7-, 46.8-, and 544.5-g packages as in paragraph (e)(2)(i), (e)(2)(ii)(B), and (e)(2)(iii) of this section; and for an 18.15-g package as in paragraph (e)(3) of this section.

(2) No. 053501 for use of a 46.8-g package as in paragraph (e)(1)(i), (e)(1)(ii)(a), and (e)(1)(iii) of this section; for 11.7- and 46.8-g packages as in paragraph (e)(2)(i), (e)(2)(ii)(A), and (e)(2)(iii) of this section; and for 9.075- and 18.15-g packages as in paragraph (e)(3) of this section.

(3) No. 057561 for use of 46.8- and 544.5-g packages as in paragraphs (e)(1)(i), (e)(1)(ii)(A), and (e)(1)(iii) and (e)(2)(i), (e)(2)(ii)(A), and (e)(2)(iii) of this section.

(4) No. 059130 for use of an 18.15-g package as in paragraph (e)(3) of this section.

(c) *Related tolerances.* See § 556.350 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use.* It is used as an anthelmintic as follows:

(1) *Cattle*—(i) *Amount.* 8 milligrams per kilogram (mg/kg) body weight as a drench.

(ii) *Indications for use*—(A) Effective against the following nematode infections: Stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*); intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*); and lungworms (*Dictyocaulus*).

(B) Effective against the following adult nematode infections: Stomach worms (*Haemonchus placei*, *Ostertagia ostertagi*, *Trichostrongylus axei*); intestinal worms (*T. longispicularis*, *Cooperia oncophora*, *C. punctata*, *Nematodirus spathiger*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*); and lungworms (*Dictyocaulus viviparus*).

(iii) *Limitations.* Do not slaughter for food within 48 hours of treatment. Not for use in dairy animals of breeding age. Conditions of constant helminth exposure may require retreatment 2 to 4 weeks after the first treatment. Consult your veterinarian before using in severely debilitated animals.

(2) *Sheep*—(i) *Amount.* 8 mg/kg body weight as a drench.

(ii) *Indications for use*—(A) Effective against the following nematode infections: Stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*); intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*, *Chabertia*); and lungworms (*Dictyocaulus*).