

Exchange Act ("CEA"). The Commissions' joint margin rules provide that stock futures may be held in either a securities or a futures account. Under Regulation T, stock futures transactions may be effected and carried in a margin account because they are securities under the SEA. Under Regulation T, transactions involving contracts of sale for future delivery are recorded in the good faith account,⁶ which is not subject to the restrictions of the margin account. The Board is proposing to amend section 220.6(e) of Regulation T to provide explicitly that stock futures may be effected and carried in the good faith account.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506; 5 CFR 1320 Appendix A.1), the Board reviewed the proposed rule under the authority delegated to the Board by the Office of Management and Budget. No collections of information pursuant to the Paperwork Reduction Act are contained in the proposed rule.

Regulatory Flexibility Act

The Board certifies that the proposed amendments, if adopted, will not have a significant economic impact on a substantial number of small entities. The only substantive effect of the proposed amendments is to eliminate a potential conflict with other federal margin regulations promulgated by the CFTC and SEC.

List of Subjects in 12 CFR Part 220

Brokers, Reporting and recordkeeping requirements, Securities.

Authority and Issuance

For the reasons set forth in the preamble, the Board proposes to amend 12 CFR part 220 to read as follows:

PART 220—CREDIT BY BROKERS AND DEALERS (REGULATION T)

1. The authority citation for Part 220 continues to read as follows:

Authority: 15 U.S.C. 78c, 78g, 78q, and 78w.

2. Section 220.4 is amended as follows:

- a. By revising paragraph (b)(1); and
- b. By adding a new paragraph (e)(4).

The revision and addition read as follows:

§ 220.4 Margin account.

(b) *Required margin.*—(1) *Applicability.* The required margin for

each long or short position in securities (except for security futures products) is set forth in § 220.12 (the Supplement) and is subject to the following exceptions and special provisions.

* * * * *

(e) *Withdrawals of cash or securities.*

* * *

(4) The provisions of this paragraph (e) shall not apply to a withdrawal of cash to meet variation settlement obligations for security futures products held in a margin account.

* * * * *

3. Section 220.6(e)(1) introductory text and (e)(1)(i) are revised to read as follows:

§ 220.6 Good faith account.

* * * * *

(e) *Nonpurpose credit and security futures products.* (1) A creditor may:

(i) Effect and carry transactions in commodities, including transactions in security futures products;

* * * * *

By order of the Board of Governors of the Federal Reserve System, September 30, 2002.

Jennifer J. Johnson,

Secretary of the Board.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000-CE-05-AD]

RIN 2120-AA64

Airworthiness Directives; MORAVAN a.s. Model Z-242L Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to all MORAVAN a.s. (Moravan) Model Z-242L airplanes. This proposed AD would establish a technical service life for these airplanes by restricting Acrobatic and Utility category operations and requiring replacement of the wings after a certain operational time period. This proposed AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for the Czech Republic. The actions specified by this proposed AD are intended to prevent structural failure of the wing due to fatigue

cracking. Such failure could result in a wing separating from the airplane with consequent loss of airplane control.

DATES: The Federal Aviation Administration (FAA) must receive any comments on this proposed rule on or before November 8, 2002.

ADDRESSES: Submit comments to FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2000-CE-05-AD, 901 Locust, Room 506, Kansas City, Missouri 64106. You may view any comments at this location between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays. You may also send comments electronically to the following address: 9-ACE-7-Docket@faa.gov. Comments sent electronically must contain "Docket No. 2000-CE-05-AD" in the subject line. If you send comments electronically as attached electronic files, the files must be formatted in Microsoft Word 97 for Windows or ASCII text.

You may get service information that applies to this proposed AD from Moravan, Inc., 765 81 Otrokovice, Czech Republic; telephone: +420 67 767 3940; facsimile: +420 67 792 2103. You may also view this information at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4059; facsimile: (816) 329-4090.

SUPPLEMENTARY INFORMATION:

Comments Invited

How Do I Comment on This Proposed AD?

The FAA invites comments on this proposed rule. You may submit whatever written data, views, or arguments you choose. You need to include the rule's docket number and submit your comments to the address specified under the caption **ADDRESSES**. We will consider all comments received on or before the closing date. We may amend this proposed rule in light of comments received. Factual information that supports your ideas and suggestions is extremely helpful in evaluating the effectiveness of this proposed AD action and determining whether we need to take additional rulemaking action.

Are There Any Specific Portions of This Proposed AD I Should pay Attention to?

The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this proposed rule that might suggest a need to modify the rule. You may view all comments we receive

⁶ Section 220.6(e).

before and after the closing date of the rule in the Rules Docket. We will file a report in the Rules Docket that summarizes each contact we have with the public that concerns the substantive parts of this proposed AD.

How Can I be Sure FAA Receives my Comment?

If you want FAA to acknowledge the receipt of your mailed comments, you must include a self-addressed, stamped postcard. On the postcard, write "Comments to Docket No. 2000-CE-05-AD." We will date stamp and mail the postcard back to you.

Discussion

What Events Have Caused This Proposed AD?

The Civil Aviation Authority Czech Republic (CAA CZ), which is the airworthiness authority for the Czech Republic, notified FAA that an unsafe condition may exist on all Moravan Model Z-242L airplanes. The CAA CZ reports that these airplanes are operated over the load spectrum that was used at certification. The CAA CZ further reports that a technical service life for these airplanes is needed.

The affected airplanes fall into two different groups:

—Group 1: those airplanes with a serial number in the range of 0001 through 0656 with the original wings installed; and

—Group 2: those airplanes with stronger wings installed either through modification (serial numbers 0001 through 0656) or at manufacture (all serial numbers beginning with 0657).

Based on analysis, the CAA CZ reports that the technical service life should be:

	Acrobatic and utility category operations	All operations
Group 1	190 hours time-in-service (TIS) only in these categories. Operation only in the Normal category thereafter.	3,500 hours TIS. New wings must be installed prior to further operation.

	Acrobatic and utility category operations	All operations
Group 2	450 hours TIS only in these categories. Operation only in the Normal category thereafter.	5,500 hours TIS. New wings must be installed prior to further operation.

What Are the Consequences if the Condition Is not Corrected?

Fatigue cracks in the wing, if not detected and corrected or prevented, could result in structural failure of the wing. Such failure could result in a wing separating from the airplane with consequent loss of airplane control.

Is There Service Information That Applies to This Subject, and What Are the Provisions of This Service Information?

- Moravan has issued the following:
- Mandatory Service Bulletin Z 242L/27a—Rev. 1, dated October 31, 2000: This service bulletin includes procedures for installing strengthened wings on airplanes with a serial number in the range of 0001 through 0656; and
 - Mandatory Service Bulletin Z 242L/37a (Z 142C/17a), Rev. 1, and Mandatory Service Bulletin Z 242L/38a (Z 142C/18a), both dated October 31, 2000: These service bulletins include criteria for a new technical service life of the affected airplanes and specify operational limitations for Acrobatic and Utility category operations.

What Action Did the CAA Take?

The CAA classified these service bulletins as mandatory and issued Czech Republic AD Number CAA-AD-T-099/2000R1, dated June 28, 2001, in order to ensure the continued airworthiness of these airplanes in the Czech Republic.

Was This in Accordance With the Bilateral Airworthiness Agreement?

This airplane model is manufactured in the Czech Republic and is type

certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement.

Pursuant to this bilateral airworthiness agreement, the CAA has kept FAA informed of the situation described above.

The FAA's Determination and an Explanation of the Provisions of this Proposed AD

What has FAA Decided?

The FAA has examined the findings of the CAA; reviewed all available information, including the service information referenced above; and determined that:

- The unsafe condition referenced in this document exists or could develop on other Moravan Model Z-242L airplanes of the same type design that are on the U.S. registry;
- The actions specified in the previously-referenced service information should be accomplished on the affected airplanes; and
- AD action should be taken in order to correct this unsafe condition.

What Would This Proposed AD Require?

This proposed AD would establish a technical service life for these airplanes by restricting Acrobatic and Utility category operations and requiring replacement of the wings after a certain operational time period.

Cost Impact

How Many Airplanes Would This Proposed AD Impact?

We estimate that this proposed AD would affect 39 airplanes in the U.S. registry.

What Would Be the Cost Impact of This Proposed AD on Owners/Operators of the Affected Airplanes?

We estimate the following costs to replace the wings after the technical service life is reached:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
60 workhours × \$60 per hour = \$3,600.	\$17,400 per set of wings	\$21,000	\$819,000.

We have no way of determining the monetary cost of the inconvenience of restricting flight to Normal category operations.

Regulatory Impact

Would This Proposed AD Impact Various Entities?

The regulations proposed herein would 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. Therefore, it is determined that this proposed rule would not have federalism implications under Executive Order 13132.

Would This Proposed AD Involve a Significant Rule or Regulatory Action?

For the reasons discussed above, I certify that this proposed action (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) if

promulgated, 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. A 5 copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 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 adding a new airworthiness directive (AD) to read as follows:

Moravan A.S.: Docket No. 2000-CE-05-AD

(a) *What airplanes are affected by this AD?* This AD affects Model Z 242L airplanes, all serial numbers, that are certificated in any category.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the airplanes identified in paragraph (a) of this AD must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to prevent structural failure of the wing due to fatigue cracking. Such failure could result in a wing separating from the airplane with consequent loss of airplane control.

(d) *What actions must I accomplish to address this problem?* To address this problem, you must establish a technical service life and restrict Acrobatic and Utility category operations. This must be done by accomplishing the following, as applicable:

Actions	Compliance	Procedures
(1) If you have an airplane with a serial number in the range of 0001 through 0656 that does not have strengthened wings installed (both left and right wings) in accordance with Moravan Mandatory Service Bulletin Z 242L/27a—Rev. 1, dated October 31, 2000, accomplish the following: (i) Insert the following information into the Limitations Section of the Airplane Flight Manual (AFM): "Do not operate in the Acrobatic or Utility category. Operate in the Normal category only." (ii) Replace both wings with the following part numbers: (A) L 242.2100 left-hand wing; and (B) L 242.2200 right-hand wing.	<i>AFM incorporation:</i> Upon the accumulation of 190 hours time-in-service (TIS) in the Acrobatic category and/or Utility category or within the next 10 hours TIS in all operations after the effective date of this AD, whichever occurs later; and <i>Replacement:</i> Upon the accumulation of 3,500 hours TIS in all operations or within the next 50 hours TIS in all operations after the effective date of this AD, whichever occurs later.	<i>AFM incorporation:</i> 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 this AFM insertion of this AD. Make an entry into the aircraft records showing compliance with these portions of the AD in accordance with section 43.9 of the Federal Aviation Regulations (14 CFR 43.9). This operational restriction is referenced in Moravan Mandatory Service Bulletin Z 242L/37a (Z 142C/17a), Rev. 1, dated October 31, 2000. <i>Replacement:</i> In accordance with Moravan Mandatory Service Bulletin Z 242L/27a—Rev. 1, dated October 31, 2000.
(2) If you have an airplane with a serial number of 0657 or higher or one in the range of 0001 through 0656 that has strengthened wings (both left and right) installed in accordance with Moravan Mandatory Service Bulletin Z 242L/27a—Rev. 1, dated October 31, 2000, accomplish the following: (i) Insert the following information into the Limitations Section of the Airplane Flight Manual (AFM): "Do not operate the Acrobatic or Utility category. Operate in the Normal category only." (ii) Replace both wings with the following part numbers: (A) L 242.2100 left-hand wing; and (B) L 242.2200 right-hand wing.	<i>AFM incorporation:</i> Upon the accumulation of 450 hours TIS in the Acrobatic category and/or Utility category or within the next 10 hours TIS in all operations after the effective date of this AD, whichever occurs later; and <i>Replacement:</i> Upon the accumulation of 5,500 hours TIS in all operations or within the next 50 hours TIS in all operations after the effective date of this AD, whichever occurs later. You must maintain the AFM requirement until replacement of the wings.	<i>AFM incorporation:</i> 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 this AFM insertion of this AD. Make an entry into the aircraft records showing compliance with these portions of the AD in accordance with section 43.9 of the Federal Aviation Regulations (14 CFR 43.9). This operational restriction is referenced in Moravan Mandatory Service Bulletin Z 242L/38a (Z 142C/18a), Rev. 1, dated October 31, 2000. <i>Replacement:</i> In accordance with Moravan Mandatory Service Bulletin Z 242L/27a—Rev. 1, dated October 31, 2000.
(3) Only install a wing with a part number of L 242.2100 left-hand wing or L 242.2200 right-hand wing.	As of the effective date of this AD.	Not Applicable.

Actions	Compliance	Procedures
(4) When you install new wings (both left and right) on your airplane, the AFM and replacement requirements of paragraph (d)(2) of this AD apply.	<i>AFM incorporation:</i> Upon the accumulation of 450 hours TIS in the Acrobatic category and/or Utility category; and <i>Replacement:</i> Upon the accumulation of 5,500 hours TIS in all operations.	See paragraph (d)(2) of this AD.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Small Airplane Directorate, approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 1: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4059; facsimile: (816) 329-4090.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *How do I get copies of the documents referenced in this AD?* You may get copies of the documents referenced in this AD from Moravan, Inc., 765 81 Otrkovice, Czech Republic; telephone: +420 67 767 3940; facsimile: +420 67 792 2103. You may view these documents at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

Note 2: The subject of this AD is addressed in Czech Republic AD Number CAA-AD-T-099/2000R1, dated June 28, 2001.

Issued in Kansas City, Missouri, on September 26, 2002.

James E. Jackson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02-25208 Filed 10-3-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310 and 358

[Docket No. 02N-0359]

RIN 0910-AA01

Ingrown Toenail Relief Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed rule to establish conditions under which over-the-counter (OTC) ingrown toenail relief drug products containing sodium sulfide 1 percent in a gel vehicle are generally recognized as safe and effective and not misbranded. This rule also proposes to amend the regulation that lists nonmonograph active ingredients in OTC drug products for ingrown toenail relief by removing sodium sulfide from that list. This proposal is part of FDA's ongoing review of OTC drug products.

DATES: Submit written or electronic comments by December 3, 2002. Please see section IX of this document for the effective date of any final rule that may publish based on this proposal.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Nahid Mokhtari, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of September 9, 1993 (58 FR 47602), FDA published a final rule establishing that any ingrown toenail relief drug product for OTC human use is not generally recognized as safe and effective and is misbranded. (See 21 CFR 310.538.) In

that final rule, sodium sulfide 1 percent was considered effective but not safe for the temporary relief of pain associated with ingrown toenails because of its potential for causing adverse reactions, particularly burning sensations and skin irritation.

A manufacturer subsequently conducted an additional safety study and requested the agency to find sodium sulfide 1 percent in a gel vehicle safe and effective for this OTC use (Ref. 1). The study involved four treatment groups who applied sodium sulfide nonahydrate gel: (1) One percent twice daily using a retainer ring system, (2) 2 percent twice daily using a retainer ring system, (3) 2 percent once daily using a retainer ring system, and (4) 2 percent twice daily using an absorptive bandage system. The gel was applied for 7 days or until the nail became sufficiently softened to allow for trimming, whichever occurred first. Of 64 ingrown toenail sufferers enrolled, 61 completed all aspects of the study. No adverse reactions were reported during the study, and no subjects reported any irritation. Four subjects noted some stinging and burning on day 1 and moderate discomfort on days 3 and 4, but the subjects did not discontinue treatment. The manufacturer stated that of the two systems tested the retainer ring is the preferred one because it provides ease of use and cushioning while further enhancing safety through the use of a medical grade adhesive. The design of the system allows for easy administration of sodium sulfide to the affected area by the consumer while retaining the drug in contact with the toe. The manufacturer requested approval of its revised instructions using the retainer ring system.

The agency found this study inadequate for a number of reasons. First, it was not designed as a safety study. There was no vehicle control, and safety cannot be determined without a vehicle control. The trial size was too small. The daily supervision by a podiatrist was not reflective of OTC use. Safety has to be assessed in context with the indications; the "days to trimming" in the study were outside of the prior proposed monograph description of product uses. The agency concluded that the study was not adequate to resolve the outstanding