final rule to delete the requirement to inspect the subject area.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the change previously described. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

The FAA estimates that 20 airplanes of U.S. registry will be affected by this AD, that it will take approximately 120 work hours per airplane to accomplish the required actions, and that the average labor rate is $55 per work hour. Required parts will cost approximately $2,390 per airplane. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $179,800, or $8,990 per airplane.

The total cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. However, the FAA has been advised that all 20 affected U.S.-registered airplanes have been modified in accordance with the requirements of the AD as of December 1993. Therefore, there currently is no economic cost impact of this rule on U.S. operators.

The regulations adopted herein will not have substantial direct effects 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, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this 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) 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 final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

94–07–13 Fokker: Amendment 39–8871. Docket 93–NM–148–AD.

Applicability: Model F–28 Mark 0100 series airplanes; having serial numbers 11244 to 11308 inclusive, 11310, 11312, 11313, 11314, 11316, 11321, 11328, and 11329; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent fatigue cracking and other damage to the engine mount shear shelf web, which subsequently could lead to loss of the engine mounting structure, accomplish the following:

(a) Prior to the accumulation of 12,000 total flight hours or within 90 days after the effective date of this AD, whichever occurs later, modify (reinforce) the engine mount shear shelf webs in accordance with Part 1 or Part 2, as applicable, of the Accomplishment Instructions of Fokker Service Bulletin SBF100–71–012, dated February 7, 1992.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, FAA, Transport Airplane Directorate, ANM–113. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(c) Special flight permits may be issued in accordance with Federal Aviation Regulations (FAR) 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) The modification shall be done in accordance with Fokker Service Bulletin SBF100–71–012, dated February 7, 1992. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies may be obtained from Fokker Aircraft USA, Inc., 1199 North Fairfax Street, Alexandria, Virginia 22314. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(e) This amendment becomes effective on May 16, 1994.

Issued in Renton, Washington, on March 30, 1994.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94–8056 Filed 4–13–94; 8:45 am]

BILLING CODE 4910–13–U

---

14 CFR Part 39

[Docket No. 94–NM–34–AD; Amendment 39–8880; AD 94–08–08]

Airworthiness Directives; Jetstream Aircraft Limited Model 4101 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to certain Jetstream Model 4101 airplanes. This action requires installation of fusible trunnion pins in the shock struts and drag braces of the main landing gear (MLG). This amendment is prompted by a report of incorrectly manufactured trunnion pins that may cause the MLG to compromise the structural integrity of the wing fuel tanks. The actions specified in this AD are intended to prevent damage to the wing fuel tanks and the resultant fuel spillage and fire hazard when the maximum intended design load limits are exceeded during landing.

DATES: Effective April 29, 1994.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of April 29, 1994.

Comments for inclusion in the Rules Docket must be received on or before June 13, 1994.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 94–NM–34–AD, 1601 Lind Avenue SW., Renton, Washington 98055–4056.

The service information referenced in this AD may be obtained from Jetstream Aircraft, Incorporated, P.O. Box 16029, Dulles International Airport, Washington, DC 20041–6029. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: William Schroeder, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington; telephone (206) 227–2148; fax (206) 227–1320.

SUPPLEMENTARY INFORMATION: The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom, recently notified the FAA that an unsafe condition may exist on certain Jetstream Model 4101 airplanes. The CAA advises that certain trunnion pins in the shock struts and drag braces of the main landing gear (MLG) were manufactured incorrectly. The trunnion pins in these airplanes were designed to be fusible so that the MLG would break away from the airplane when landing loads exceed the intended design limits, such as those that may be encountered during emergency landing. However, the defective trunnion pins were not manufactured with this fusible characteristic. Therefore, these defective trunnion pins may cause the MLG to fail to break away from the airplane and, consequently, may compromise the structural integrity of the wing fuel tank. This condition, if not corrected, could result in damage to the wing fuel tanks and the resultant fuel spillage and fire hazard when the maximum intended design load limits are exceeded during landing.

Jetstream has issued Service Bulletin J41–32–017, dated February 7, 1994, that describes procedures for installation of new fusible trunnion pins in the shock struts and drag braces of the MLG. The CAA classified this service bulletin as mandatory in order to assure the continued airworthiness of these airplanes in the United Kingdom.

This airplane model is manufactured in the United Kingdom and is type certificated for operation in the United States under the provisions of Section 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the CAA has kept the FAA informed of the situation described above. The FAA has examined the findings of the CAA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, this AD is being issued to prevent damage to the wing fuel tanks and the resultant fuel spillage and fire hazard. This AD requires installation of new trunnion pins in the shock struts and drag braces of the MLG. The actions are required to be accomplished in accordance with the service bulletin described previously.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 94–NM–34–AD." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects 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, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

94–08–08 Jetstream Aircraft Limited: Amendment 39–8880. Docket 94–NM–34–AD.

Applicability: Model 4101 airplanes having constructors numbers 41004 through 41027 inclusive; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent damage to the wing fuel tanks and the resultant fuel spillage and fire hazard

when the maximum intended design load limits are exceeded during landing, accomplish the following:

(a) Within 300 hours time-in-service after the effective date of this AD, install new trunnion pins in the shock struts and drag braces of the main landing gear in accordance with Jetstream Service Bulletin J41–32–017, dated February 7, 1994.

(b) As of the effective date of this AD, no person shall install any shock strut assembly having part number AIR83072–8, or drag brace assembly having part number AIR84352–2, on any airplane.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM–113. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(d) Special flight permits may be issued in accordance with Federal Aviation Regulations (FAR) 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

(e) The installation shall be done in accordance with Jetstream Service Bulletin J41–32–017, dated February 7, 1994. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies may be obtained from Jetstream Aircraft, Incorporated, P.O. Box 16029, Dulles International Airport, Washington, DC 20041–6029. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(f) This amendment becomes effective on April 29, 1994.

Issued in Renton, Washington, on April 6, 1994.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 94–8684 Filed 4–13–94; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 131

[Docket No. 91P–0090]

Evaporated Milk; Amendment of the Standard of Identity

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the standard of identity for evaporated milk by revising the minimum milkfat and total milk solids content requirements and establishing a minimum milk solids-not-fat content requirement. This action is in response to a petition filed by the American Dairy Products Institute (ADPI) and will promote honesty and fair dealing in the interest of consumers.

DATES: Effective June 13, 1994, written objections and requests for a hearing by May 16, 1994.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION: Nannie H. Rainey, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION:

I. The Proposal

In the **Federal Register** of July 22, 1992 (57 FR 32470), FDA published a proposal, based on a petition from ADPI, 130 North Franklin St., Chicago, IL 60606, to amend the standard of identity for evaporated milk (21 CFR 131.130) to: (1) Reduce the minimum milkfat content requirement from 7.5 percent to 6.5 percent by weight; (2) reduce the minimum total milk solids content requirement from 25 percent to 23 percent by weight; and (3) add a minimum milk solids-not-fat content requirement of 16.5 percent by weight. Interested persons were given until September 21, 1992, to submit comments.

II. Comments

The agency received seven responses, each containing one or more comments, from a consumer, a trade association, and several manufacturers. Six letters supported, and one opposed, the proposal. A summary of the opposing comments and the agency's responses follow.

1. The comment contended that the solids content of fluid milk (producers' milk) has probably increased over the last 20 years, and that the proposed reduction in the minimum required milkfat and total milk solids content of evaporated milk is inconsistent with the intent of the standard of identity for evaporated milk, as well as the intent of the subsequent amendments, that the milkfat and milk solids-not-fat contents be reasonably related to those of the milk used in the manufacture of evaporated milk.

The agency disagrees with the comment. According to data supplied by the U.S. Department of Agriculture (USDA) (Ref. 1), the composition of producers' milk has remained fairly constant through the 1970's and the 1980's. These data show that the yearly average milkfat content for all producers' milk, before standardization for beverage purposes, during the period 1970 to 1991 (Ref. 1) ranged between 3.64 percent and 3.68 percent, with an overall average of 3.66 percent.

The agency does not agree that the change in compositional requirements is inconsistent with the intent of the evaporated milk standard. Throughout the history of the evaporated milk standard, the labeling of evaporated milk products and the instructional materials pertaining to the use of the food supplied to consumers by food manufacturers, trade associations, and USDA (Ref. 2), as well as policy statements by FDA, have described the food as a 2 to 1 concentrate of milk. Instructions on the label or in labeling of evaporated milk frequently show that the food is to be diluted with an equivalent portion of water for use in preparation of beverages made using the food. In addition, recipes for other foods often state that a can of evaporated milk may be diluted with a can of water for use in recipes calling for the addition of milk (Ref. 2).

The standard of identity for milk in § 131.110 (21 CFR 131.110) defines minimum compositional requirements for the food of not less than 3.25 percent of milkfat and not less than 8.25 percent of milk solids not fat. The minimum compositional requirements for evaporated milk that FDA is adopting in this final rule (i.e., not less than 6.5 percent of milkfat, 16.5 percent of milk solids not fat, and 23 percent total milk solids) correspond to a twofold concentration of standardized milk and, thus, are directly related to those of milk. Because the change in compositional requirements accurately reflects the general understanding that evaporated milk is a twofold concentrate of milk, the agency finds that the change in the evaporated milk standard is consistent with the intent of the standard and, therefore, is revising the standard as proposed.

2. The comment disagreed that the test results that ADPI submitted from a monadic (i.e., single-product evaluation) in-home use test were a reliable indication of real consumer preferences. The comment stated that monadic ratings are not accepted by

organizations such as the National Advertising Division of the Better Business Bureau to support product comparative claims.

FDA acknowledges the comment's concern that ADPI's in-home use test was not a conclusive demonstration that consumers preferred the lower fat, lower solids evaporated milk over the traditional standardized evaporated milk. However, ADPI submitted information in its petition on a total of three industry research tests on consumer perceptions of traditional standardized evaporated milk compared to evaporated milk manufactured to conform to the parameters for which ADPI had petitioned. The monadic in-home use test was only one of these tests. In the other two tests, each participant was able to evaluate both products.

FDA has reviewed the studies that ADPI submitted (Ref. 3). The agency concludes that there was sufficient evidence to support ADPI's claim that consumers were unable to distinguish between the standardized evaporated milk and evaporated milk manufactured to conform to the petitioned parameters. Taken individually, the studies did not provide overwhelming data, but the combined weight of the three studies has convinced the agency that consumers' perceptions of the two products were not significantly different. Each test was performed under different circumstances (i.e., employing different evaluation techniques) and used a different representative sample of consumers. The studies examined a wide variety of possible consumer uses of evaporated milk in realistic, everyday situations. Additionally, these were separate studies employing within-subjects and between-subjects designs that came to identical conclusions. Based on all of the evidence in the petition, the agency finds that it can conclude that consumers are unable to discriminate between standardized evaporated milk and the evaporated milk manufactured to conform to the suggested parameters.

3. The comment stated that the overwhelming use of evaporated milk is in recipes, and that it was not aware of anyone reconstituting evaporated milk for beverage use in the United States. The comment questioned whether consumers consider evaporated milk to be a 2:1 concentrate of fluid milk, and whether the amendment would make reconstitution for beverage use more convenient.

The agency agrees that evaporated milk is used primarily as an ingredient of other foods. FDA notes that evaporated milk may be used in recipes, as manufactured, or in reconstituted form as a direct replacement for milk. Another significant use of evaporated milk is in coffee and tea (Ref. 4). Although the common consumption of reconstituted evaporated milk as a beverage is decreasing (Refs. 5 and 6), evaporated milk does replace fluid milk for beverage purposes in individual households as a result of commercial purchases, as well as through the USDA commodity distribution program; in institutions; and by participants in the USDA Supplemental Food Program for Women, Infants, and Children (Ref. 4). In fact, one comment from a consumer stated that he and his family have used evaporated milk regularly in food recipes, in coffee, and in the preparation of beverage milk.

Evaporated milk has been touted as a 2:1 concentration of milk for many years (Ref. 7). A 2:1 concentrate is easier for consumers to reconstitute than a 2.3:1 concentrate because it is in whole units. In addition, as noted above, a 2:1 concentrate, when diluted, results in a product whose composition is the same as that for beverage milk. Therefore, FDA concludes that providing for a 2:1 concentrate of milk under the standard of identity for evaporated milk is in the best interest of consumers, and that the concerns raised by the comment are without merit.

4. The comment argued that a change in the standard of identity for evaporated milk is unnecessary because consumers that want a lower fat, lower cholesterol evaporated milk can purchase evaporated lowfat milk or evaporated skimmed milk.

FDA notes that consumers may continue to purchase evaporated lowfat milk or evaporated skimmed milk. However, comments from a manufacturer of evaporated milk that were submitted in support of the proposal stated that many of its customers have expressed an interest in lower fat and lower calorie foods, and that the amendment would afford it (the commenting manufacturer) the opportunity to meet the demands of this segment of the public. Furthermore, the fat reduction, although modest, is consistent with "The Surgeon General's Report on Nutrition and Health" (Ref. 8) and the National Academy of Sciences' report on "Diet and Health, Implications for Reducing Chronic Disease Risk" (Ref. 9), which recommend that consumers reduce their consumption of fats and cholesterol. Therefore, FDA finds that the amended standard will benefit consumers.

FDA also notes that the nutritional benefit is only one of several bases that support the amended standard. Therefore, FDA concludes that the argument raised by the comment is without merit.

5. The comment noted that the proposed reduction in the minimum required milkfat content and milk solids content in evaporated milk would make the U.S. standard of identity for evaporated milk inconsistent with the International Codex standard for evaporated milk.

FDA acknowledges that the amended standard is not identical to the International Codex standard for evaporated milk. The Codex standard requires that evaporated milk contain not less than 7.5 percent of milkfat and not less than 25 percent of total milk solids. Because the new requirements in the standard that FDA is adopting will establish lower values for minimum milkfat and minimum total milk solids content than those of the Codex standard for evaporated milk, products complying with the Codex standard will meet FDA's standard of identity. U.S. exporters of evaporated milk may need to reformulate their products if they are to be shipped to countries that require that the food comply with the minimum requirements of the Codex standard, but this fact provides no basis for not making the proposed change in the standard.

Accordingly, after consideration of all comments, the agency is amending the standard of identity for evaporated milk in § 131.130(a) by reducing the minimum milkfat content requirement from 7.5 percent to 6.5 percent by weight, reducing the minimum total milk solids content requirement from 25 percent to 23 percent by weight, and establishing a minimum milk solids-not-fat content requirement of 16.5 percent by weight. FDA concludes that the amendments will promote honesty and fair dealing in the interest of consumers.

III. Economic Impact

FDA has examined the economic implications of this final rule to amend the standard of identity for evaporated milk in 21 CFR part 131 as required by Executive Order (E.O.) 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). The Regulatory Flexibility Act requires that the agency analyze options for regulatory relief for small businesses.

On July 22, 1992, FDA analyzed the economic impact of the requirements that the agency is adopting under the previous E.O. 12291 and found that they would not have a significant impact on small business. The agency noted in the proposed rule that manufacturers may continue to process evaporated milks using current formulations. Thus, no changes are required in formulations unless manufacturers wish to reformulate their products. In the proposal, the agency tentatively concluded that the regulation would have zero costs associated with it. FDA has received no information or comments that would alter the tentative finding that it set out in the proposed rule that there is no substantive economic issue in this rulemaking.

Thus, the agency finds that this final rule is not a significant regulatory action as defined in E.O. 12866. In compliance with the Regulatory Flexibility Act, the agency certifies that the final rule will not have a significant impact on a substantial number of small businesses.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(b)(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.

V. Objections

Any person who will be adversely affected by this regulation may at any time on or before May 16, 1994, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Rourke, J., Dairy Division , U.S. Department of Agriculture, facsimile of Summary Data on Milkfat Content of Producers' Milk, 1970 through 1991, to Shellee A. Davis, February 17, 1993.

2. Leighton, R. J., and R. F. Mann, letter to Fred R. Shank, FDA, May 4, 1993.

3. Heaton, A. W., FDA Division of Consumer Studies, memorandum to Shellee A. Davis, November 6, 1992.

4. Clark, W. S., letter to Dockets Management Branch, February, 25, 1992.

5. USDA Summary Data from the Nationwide Food Consumption Survey/ Individual, 1977–1978.

6. USDA Summary Data from the Nationwide Food Consumption Survey/ Individual, 1987–1988.

7. Jenness, R., and S. Patton, "Principles of Dairy Chemistry," p. 325, John Wiley & Sons, Inc., New York, NY, 1959.

8. U.S. Department of Health and Human Services, Public Health Service, "The Surgeon General's Report on Nutrition and Health," DHHS (PHS) Publication No. 88–50210 (GPO Stock No. 017–001–00465–1), pp. 9–11, U.S. Government Printing Office, Washington, DC, 1988.

9. Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, National Research Council, National Academy of Sciences; Executive Summary from "Diet and Health, Implications for Reducing Chronic Disease Risk," National Academy Press, Washington, DC, 1989.

List of Subjects in 21 CFR Part 131

Cream, Food grades and standards, Milk, Yogurt.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 131 is amended as follows:

PART 131—MILK AND CREAM

1. The authority citation for 21 CFR part 131 is revised to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 379e).

2. Section 131.130 is amended by revising paragraph (a) to read as follows:

§ 131.130 Evaporated milk.

(a) *Description.* Evaporated milk is the liquid food obtained by partial removal of water only from milk. It contains not less than 6.5 percent by weight of milkfat, not less than 16.5 percent by weight of milk solids not fat, and not less than 23 percent by weight of total milk solids. Evaporated milk contains added vitamin D as prescribed by paragraph (b) of this section. It is homogenized. It is sealed in a container and so processed by heat, either before or after sealing, as to prevent spoilage.

* * * * *

Dated: April 8, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–8979 Filed 4–11–94; 12:13 pm]

BILLING CODE 4160–01–F

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Tetracycline Hydrochloride Soluble Powder

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 two supplemental new animal drug applications (NADA's) for safe and effective use of tetracycline hydrochloride soluble powder. One supplemental NADA was filed by Wade Jones Co., Inc., and covers the use of the drug product in the drinking water of calves and swine for the control and treatment of certain bacterial diseases and in the drinking water of poultry for the control of certain bacterial diseases susceptible to the drug. The other supplemental NADA was filed by Pfizer, Inc., and also covers use of the drug in the drinking water of poultry for the control of certain susceptible bacterial diseases. Both approvals reflect compliance with the results of the National Academy of Sciences/National Research Council (NAS/NRC), Drug Efficacy Study Group's (DESI) evaluation of the drug's effectiveness and FDA's conclusions concerning that evaluation. Additionally, the agency is technically amending the regulations to make other needed corrections.

EFFECTIVE DATE: April 14, 1994.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1623.

SUPPLEMENTARY INFORMATION:

I. Background

Wade Jones Co., Inc., 409 North Bloomington, Lowell, AR 72745 (Wade Jones), filed a supplement to approved NADA 65–140 for a soluble powder containing 324 grams (g) of tetracycline hydrochloride (TC HCl) activity per pound (lb). The drug is available in several product container sizes, 2 and 5 lb tubs and 2.53, 5, and 10 ounce (oz) packets. The drug is indicated for use in chickens at 200 to 400 milligrams per gallon (mg/gal) for control of infectious synovitis caused by *Mycoplasma synoviae* and at 400 to 800 mg/gal for control of chronic respiratory disease caused by *M. gallisepticum* and E. coli. The drug is indicated for use in turkeys at 400 mg/gal for control of infectious synovitis caused by *M. synoviae* and at 25 mg/lb of body weight for control of complicating bacterial organisms associated with bluecomb. It is also indicated for use in swine and calves at 10 mg/lb of body weight for control and treatment of bacterial enteritis (scours) and bacterial pneumonia. The NADA was originally approved July 5, 1966.

Pfizer, Inc., 235 East 42d St., New York, NY 10017 (Pfizer), filed supplemental NADA 65–123 for TC HCl soluble powder (6.4 ounce (oz) packet) to provide for use in chickens and turkeys under the same conditions of use expressed above for the Wade Jones application. The NADA was originally approved April 27, 1955.

II. The NAS/NRC DESI Evaluation

The drug products were subject to a NAS/NRC DESI evaluation of effectiveness (DESI 0012NV). The findings were published in the **Federal Register** of July 8, 1970 (35 FR 10966). NAS/NRC evaluated the products as "probably effective" for oral treatment of animal diseases when such diseases are caused by pathogenic microorganisms sensitive to tetracycline hydrochloride, diseases such as: (1) Enteric and respiratory diseases in poultry; (2) gastrointestinal and respiratory diseases in swine; (3) infected wounds, gastrointestinal and respiratory diseases in calves, sheep, and goats; (4) digestive system and respiratory diseases, pyelonephritis, peritonitis, infected wounds, abscesses, ulcers, and secondary bacterial invaders in dogs and cats; (5) coccidiosis in dogs; and (6) hexamitiasis in turkeys.

NAS/NRC reached the following conclusions applicable to the subject TC HCl drug products:

(1) Most of the dosage directions provide for a less than effective dose, and the recommended minimum oral dose for large animals is 10 mg/lb of body weight daily in divided doses and for small animals 25 mg/lb body weight daily in divided doses;

(2) claims for the treatment of viral diseases must be limited to microorganisms belonging to the psittacosis-lymphogranuloma group;

(3) each disease claim should be properly qualified as "appropriate for use in (name of disease) caused by pathogens sensitive to (name of drug)," and if the disease cannot be so qualified the claim must be dropped;

(4) claims made "for prevention of" or "to prevent" should be replaced with "as an aid in the control of" or "to aid in the control of";

(5) as applicable, the manufacturer's label should warn that treated animals must consume enough medicated water or medicated feed to provide a therapeutic dose under the conditions that prevail—as a precaution, the label should state the desired oral dose per unit of animal weight per day for each species as a guide to effective use of the preparation in drinking water or feed.

FDA concurred with the NAS/NRC findings, interpreting the phrase "cannot be so qualified" in item (3) of the paragraph immediately above to mean "is not supported by adequate data." FDA proceeded to review all available data relating to the effectiveness of similar products to determine which label claims were supported by the requisite proof of effectiveness. The review resulted in the agency concluding that the data supported effectiveness only for the control and treatment of certain bacterial diseases susceptible to TC HCl in calves, swine, chickens, and turkeys.

Subsequently, Wade Jones and Pfizer complied with the NAS/NRC evaluation and FDA's conclusions by filing supplemental NADA's which revised the drug products' labeling as follows: (1) Adopting the dosage recommended by NAS/NRC; (2) dropping all claims for viral diseases; (3) properly qualifying disease claims; (4) revising prevention claims to read "Control of"; and (5) adding to the manufacturer's label the warning statement concerning factors influencing adequate consumption of medicated water.

The NAS/NRC evaluation is concerned only with the drugs' effectiveness and safety to the treated animal. It does not take into account the safety for human food use of food derived from drug-treated animals.

Wade Jones' supplemental NADA is approved as of September 15, 1993, and Pfizer's supplemental NADA is approved as of March 18, 1994. The regulations are amended by revising § 520.2345d (21 CFR 520.2345d) to reflect the approvals.

FDA's approval of the supplemental NADA's does not involve a reevaluation or reaffirmation of the human food safety data in the parent applications. Tolerances for residues of the drug and its metabolites in chickens, turkeys, swine, and calves of 0.25 part per million are currently codified in 21 CFR 556.720.

III. Environmental Impact

The agency has carefully considered the potential environmental effects of approving the Wade Jones Supplement. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

With regard to approving the Pfizer supplement, the agency has determined under 21 CFR 25.24(d)(1)(i) 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), these approvals do not qualify for exclusivity periods because their applications do not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) and, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) essential to approval of the supplements and conducted or sponsored by the applicants.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), summaries of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

IV. The Technical Amendments

In conjunction with amending § 520.2345d to codify the NAS/NRC DESI finalization of Wade Jones' and

Pfizer's NADA's the agency is using this occasion to rewrite § 520.2345d to clarify the regulations. Section 520.2345d is the recodified version of section 546.180d(c). This latter section was one of many antibiotic drug sections affected by the final rule that published in the Federal Register of August 18, 1992 (57 FR 37318) for the purpose of: (1) Removing the technical regulations that included the requirements for certification and tests and methods of assay and (2) recodifying, based on route of administration, the remaining provisions concerning conditions of marketing. However, when § 546.180d was recodified, the agency did not include other technical changes to update changes in the approved conditions of marketing. Accordingly, FDA is revising § 520.2345d to codify the currently approved conditions of marketing and to make the following needed corrections: (1) The section heading is revised to fully identify the drug as the hydrochloride; (2) the "*Specifications*" paragraph is removed and information concerning drug concentrations is incorporated into the "*Sponsors*" paragraph; (3) the second sentence of the NAS/NRC status paragraph is removed because it has been superseded by enactment of the Generic Animal Drug and Patent Term Restoration Act of 1988; (4) the drug labeler code for Upjohn Co. (000009) is removed because the firm was incorrectly listed as the sponsor of approvals for the use of TC HCl soluble powder in the drinking water of calves, swine, chickens, and turkeys; (5) the drug labeler code for Vetri-Tech, Inc. (058752), has been changed to that for Arkansas Micro Specialties, Inc. (047863), since Vetri-Tech, Inc., has transferred ownership of its NADA (use of drug in chickens) to Arkansas Micro Specialties, Inc., (57 FR 12711, April 13, 1992), and (6) in the calf and swine claims, the name of the causative agent, *Hemophilus* is changed to *Actinobacillus pleuropneumoniae*, the current scientific name.

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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 520.2345d is revised to read as follows:

§ 520.2345d Tetracycline hydrochloride soluble powder.

(a) *Sponsors.* The following sponsors listed in § 510.600(c) of this chapter hold approvals for the drug concentrations (i.e., grams of tetracycline hydrochloride per pound) and conditions of use indicated:

(1) 047864 and 054273, 102.4 and 324 grams per pound as in paragraph (d) of this section.

(2) 000069, 25 grams per pound as in paragraphs (d)(3) and (d)(4) of this section.

(3) 010042, 102.4 and 324 grams per pound as in paragraphs (d)(1) and (d)(2) of this section.

(4) 047863, 102.4 and 324 grams per pound as in paragraph (d)(3) of this section.

(b) *Related tolerances.* See § 556.720 of this chapter.

(c) *National Academy of Sciences/National Research Council (NAS/NRC) status.* The conditions of use specified in paragraph (d) of this section were NAS/NRC reviewed and found effective.

(d) *Conditions of use in drinking water*—(1) *Calves*—(i) *Amount.* 10 milligrams per pound of body weight per day in divided doses.

(ii) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp., susceptible to tetracycline.

(iii) *Limitations.* Administer for 3 to 5 days; do not slaughter animals for food within 4 days of treatment for sponsor 010042 and within 5 days of treatment for sponsors 047864 and 054273; prepare a fresh solution daily; use as the sole source of tetracycline.

(2) *Swine*—(i) *Amount.* 10 milligrams per pound of body weight per day in divided doses.

(ii) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *E. coli* and bacterial pneumonia associated with *Pasteurella* spp., *A. pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp., susceptible to tetracycline.

(iii) *Limitations.* Administer for 3 to 5 days; do not slaughter animals for food within 7 days of treatment for sponsor 010042 and within 4 days of treatment for sponsors 047864 and 054273; prepare a fresh solution daily; use as the sole source of tetracycline.

(3) *Chickens*—(i) *Amount.* Chronic respiratory disease: 400 to 800 milligrams per gallon. Infectious synovitis: 200 to 400 milligrams per gallon.

(ii) *Indications for use.* Control of chronic respiratory disease (CRD or air-sac disease) caused by *Mycoplasma gallisepticum* and *E. coli*; control of infectious synovitis caused by *M. synoviae* susceptible to tetracycline.

(iii) *Limitations.* Administer for 7 to 14 days; do not slaughter for food within 4 days of treatment; not for use in chickens producing eggs for human consumption; prepare a fresh solution daily; use as the sole source of tetracycline.

(4) *Turkeys*—(i) *Amount.* For infectious synovitis: 400 milligrams per gallon. For complicating bacterial organisms associated with bluecomb (transmissible enteritis or coronaviral enteritis): 25 milligrams per pound of body weight per day.

(ii) *Indications for use.* Control of infectious synovitis caused by *M. synoviae*; control of bluecomb complicated by organisms sensitive to tetracycline.

(iii) *Limitations.* Administer for 7 to 14 days; do not slaughter for food within 4 days of treatment; not for use in turkeys producing eggs for human consumption; prepare a fresh solution daily; use as the sole source of tetracycline.

Dated: April 7, 1994.

Robert C. Livingston,

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

[FR Doc. 94–9044 Filed 4–13–94; 8:45 am]

BILLING CODE 4160–01–F

---

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Enalapril Maleate Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the approval of a new animal drug application (NADA) filed by Merck Research Laboratories, Division of Merck & Co., Inc. The NADA provides for the oral use of ENACARD™ (enalapril maleate) tablets for the treatment of heart failure in dogs.

EFFECTIVE DATE: April 14, 1994.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0614.