a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL MN E5 Bigforks, MN [New]

(Lat. 47°46′45″ N, long. 93°39′01″ W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of the Bigfork Municipal Airport.

* * * * *

Issued in Des Plains, Illinois on April 17, 1996.

Maureen Woods,

Acting Manager, Air Traffic Division.

[FR Doc. 96–10972 Filed 5–1–96; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 71

[Airspace Docket No. 96–AWP–7]

Amendment of Class E Airspace; Jackson, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace area at Jackson, CA. The development of a Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 1 has made this action necessary. The intended effect of this action is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Westover Field Amador County, Jackson, CA.

EFFECTIVE DATE: 0901 UTC August 15, 1996.

FOR FURTHER INFORMATION CONTACT: William Buck, Airspace Specialist, System Management Branch, AWP–530, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 725–6556.

SUPPLEMENTARY INFORMATION:

History

On March 11, 1996, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) by amending the Class E airspace area at Jackson, CA (61 FR 9657). This action will provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Westover Field Amador County, Jackson, CA.

Interested parties were invited to participate in this rulemaking proceedings by submitting written comments on the proposal to the FAA. No comments to the proposal were received. Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9C dated August 17, 1995, and effective September 16, 1995, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in this Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) amends the Class E airspace area at Jackson, CA. The development of a GPS SIAP at Westover Field Amador County has made this action necessary. The intended effect of this action is to provide adequate Class E airspace for aircraft executing the GPS RWY 1 SIAP at Westover Field Amador County, Jackson, CA.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(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 10034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 a follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AWP CA E5 Jackson, CA [Revised]

Jackson, Westover Field Amador County, CA
(Lat. 38°22′36″ N, long. 120°47′38″ W)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Westover Field Amador County.

* * * * *

Issued in Los Angeles, California, on April 18, 1996.

Harvey R. Riebel,

Acting Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 96–10971 Filed 5–1–96; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 500, 582, and 589

[Docket No. 94G–0239]

GRAS Status of Propylene Glycol; Exclusion of Use in Cat Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to exclude from generally recognized as safe (GRAS) status the use of propylene glycol (PG) in or on cat food. This final action is based on FDA's review of currently available information which has raised significant questions about the safety of this use. Semimoist pet foods containing PG were not in existence when the GRAS status of PG for use in animal feeds was established, thus the agency's prior GRAS determination does not apply to the newly intended uses of PG.

EFFECTIVE DATE: June 3, 1996.

FOR FURTHER INFORMATION CONTACT: David A. Dzanis, Center for Veterinary Medicine (HFV–222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of May 10, 1995 (60 FR 24808), FDA issued a proposed rule to amend the animal drug regulations to exclude from GRAS status the use of PG in or on cat food. In the proposed rule of May 10, 1995, the regulatory history of PG was reviewed as well as the last 13 years of scientific literature on the safety of PG in cat food. FDA concluded that there are significant questions about the safety of PG in cat food. FDA also concluded that PG is not GRAS as an ingredient of cat food, and the use is not subject to a prior sanction. When used in or on cat food, PG is deemed to be a food additive, subject to section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348), and its use in cat food must be in accordance with a published food additive regulation. Comments by the public on the proposed rule were requested to be submitted by July 24, 1995.

II. Comments on the Proposed Rule

In response to publication of the proposed rule to amend the GRAS status of PG to exclude its use in cat foods, three parties submitted comments: Two manufacturers of PG, and one pet food industry association. One party offered unconditional support of the proposed rule. The other two parties offered comments to amend the proposed rule to allow for limited use of PG.

1. One comment argued for the need for PG as a carrier for antioxidants added to cat food. Antioxidants are needed to prevent oxidation of unsaturated fats and other components of cat foods, which could adversely affect nutritional and organoleptic properties of the products. The amount of PG in the finished food stemming from such use was estimated to be 0.0009 to 0.007 percent (9 to 70 milligrams per kilogram (mg/kg).

FDA agrees that the judicious use of antioxidants serves a vital role in preserving the freshness and quality of cat foods. FDA has previously reviewed data relative to the use of PG as an antioxidant carrier and estimates the ''worst case'' inclusion level in the finished food to be less than 0.02 percent (200 mg/kg) on a dry matter basis. In such cases, PG would no longer serve any technical or functional effect in the finished food and would be present at insignificant levels. Regardless, no argument was made that PG was unique in its ability to serve as an antioxidant carrier, or that a suitable substitute for PG was unavailable or impractical.

2. Two comments argued that an establishment of an adequate safety margin below the known ''no-observed-effect-level'' (NOEL) for cats and kittens should allow for limited use of PG. The most conservative known NOEL for growing kittens is 0.135 percent (1,350 mg/kg), well below the expected levels of inclusion resulting from its use as an antioxidant carrier. Thus, establishment of an acceptable daily intake level at some level below the NOEL should allow for safe use of PG in cat foods.

FDA agrees that the estimated level of PG in cat foods resulting from its use as an antioxidant carrier appears to offer an adequate margin of safety relative to the known NOEL. Thus, FDA's primary regulatory concern at this time is limited to cat foods containing PG at levels exceeding 0.02 percent. However, FDA does not believe that a specific level of PG for inclusion in cat food can be based solely on the existing NOEL. This is because the NOEL was determined on the basis of the presence or absence of Heinz bodies in a study performed in 1979, and it has not been subject to reassessment using the more sensitive methods available today to evaluate possible adverse effects. The more current studies using more specific indicators of red blood cell damage did not look at effects near the existing NOEL, nor did they establish an NOEL in and of themselves. Also, although data are known on the effects of PG on adult cats and growing kittens, there are no data on the potential effects of PG on other life stages of cats. For example, the possible congenital effects stemming from the feeding of PG to pregnant cats has not been adequately assessed.

III. Conclusion

The proposed rule has not been changed as a result of received comments. Therefore, the final rule provides that PG for use in cat food is not GRAS and is a food additive subject to section 409 of the act.

IV. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 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, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, this final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

This assessment analyzes the economic effects of this rule to exclude from GRAS status the use of PG in or on cat food. PG is used as a humectant, plasticizer, and microbiological preservative in semimoist cat food. Semimoist cat foods containing PG did not exist when the GRAS status for its use in animal feeds was established, and this GRAS determination does not apply to the newly intended use of PG. Currently available information on the effects of PG demonstrates serious concerns about its safety in cats.

FDA requested that pet food manufacturers discontinue the use of PG as an ingredient in semimoist cat foods in 1992. The majority of manufacturers in the industry have complied with this request. Agency experts estimate that

PG is currently used in at most 5 percent of semimoist cat foods and at most 10 percent of cat snacks, which are similar in texture and content to semimoist foods. These usage rates continue to decline.

FDA estimates of 1993 sales of semimoist cat foods and snacks to U.S. households are $85 million and $53 million, respectively (Neilsen Marketing Research data). Those sales representing semimoist cat foods and cat snacks which contain PG are approximately $9,550 million (5 percent of $85 million plus 10 percent of $53 million). The effect of this rule would be to replace these sales with other cat foods and cat snacks not containing PG. Most of the industry has already substituted glycerin for PG in semimoist foods and snacks. It is likely that the remaining portion of the industry would make the substitution of glycerin for PG rather than surrender their share of the semimoist cat food and cat snack market. The cost of this substitution to the production process is expected to be small.

Purchases of PG by semimoist cat food and cat snack manufacturers represent a very small percentage of total PG sales, estimated at less than 1 percent. Demand for semimoist cat foods has declined considerably since 1987. Although demand for cat snacks continues to grow, its sales are still a small part of the total pet food industry. Thus, the effect of this final rule on PG manufacturers would also be small. The effects of this final rule on small businesses would not be substantial. Although more small sized companies are involved in manufacturing cat snack foods than in semimoist foods, their costs of compliance would not be significant.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. For the above reasons, the agency certifies that this rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. Federalism

FDA has analyzed this rule in accordance with the principles and criteria set forth in Executive Order 12612 and has determined that this rule does not warrant the preparation of a Federalism Assessment.

List of Subjects

21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Polychlorinated biphenyls (PCB's).

21 CFR Parts 582 and 589

Animal feeds, Animal foods, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 500, 582, and 589 are amended as follows:

PART 500—GENERAL

1. The authority citation for 21 CFR part 500 continues to read as follows:

Authority: Secs. 201, 301, 402, 403, 409, 501, 502, 503, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371).

2. New § 500.50 is added to subpart B to read as follows:

§ 500.50 Propylene glycol in or on cat food.

The Food and Drug Administration has determined that propylene glycol in or on cat food is not generally recognized as safe and is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act (the act). The Food and Drug Administration also has determined that this use of propylene glycol is not prior sanctioned.

PART 582—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

3. The authority citation for 21 CFR part 582 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

4. Section 582.1666 is amended by revising paragraph (b) to read as follows:

§ 582.1666 Propylene glycol.

* * * * *

(b) *Conditions of use.* This substance is generally recognized as safe (except in cat food) when used in accordance with good manufacturing or feeding practice.

PART 589—SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED

5. The authority citation for 21 CFR part 589 continues to read as follows:

Authority: Secs. 201, 402, 409, 701, of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

6. New § 589.1001 is added to subpart B to read as follows:

§ 589.1001 Propylene glycol in or on cat food.

The Food and Drug Administration has determined that propylene glycol in or on cat food has not been shown by adequate scientific data to be safe for use. Use of propylene glycol in or on cat food causes the feed to be adulterated and in violation of the Federal Food, Drug, and Cosmetic Act (the act), in the absence of a regulation providing for its safe use as a food additive under section 409 of the act, unless it is subject to an effective notice of claimed investigational exemption for a food additive under § 570.17 of this chapter, or unless the substance is intended for use as a new animal drug and is subject to an approved application under section 512 of the act or an effective notice of claimed investigational exemption for a new animal drug under part 511 of this chapter.

Dated: April 23, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–10893 Filed 5–1–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8663]

RIN 1545–AT43

Transfers to Investment Companies

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations amending regulations under section 351(e) of the Internal Revenue Code relating to transfers to investment companies. The final regulations concern the treatment of certain transfers to a controlled corporation. Generally, the final regulations amend the regulations to provide when certain transfers will not cause a diversification of the transferors' interests.

EFFEFCITVE DATE: These regulations are effective May 2, 1996.

FOR FURTHER INFORMATION CONTACT: Andrew M. Eisenberg, (202) 622–7790 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

1. Background

This document contains final regulations under section 351. The final regulations provide for the treatment of