§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

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

* * * * *

AWP CA E5 Groveland, CA [New]

Pine Mountain Lake Airport, CA
(lat. 37°51′42″N, long. 120°10′43″W)

That airspace extending upward from 700 feet above the surface within a 5.7-mile radius of the Pine Mountain Lake Airport and within 2 miles southwest and 3 miles northeast of the 135° bearing from the Pine Mountain Lake Airport extending from the 5.7-mile radius to 11 miles southeast of the airport.

* * * * *

Issued in Los Angeles, California, on September 25, 1996.

James H. Snow,

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

[FR Doc. 96–25608 Filed 10–4–96; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 71

[Airspace Docket No. 96–AWP–16]

Establishment of Class E Airspace; Phoenix, Deer Valley Municipal Airport, AZ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes a Class E airspace area at Phoenix, Deer Valley Municipal Airport, AZ. The development of a Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 07R to Phoenix-Deer Valley Municipal Airport has made this action necessary. The intended effect of this action is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Phoenix-Deer Valley Municipal Airport. AZ.

EFFECTIVE DATE: 0901 UTC December 5, 1996.

FOR FURTHER INFORMATION CONTACT: William Buck, Airspace Specialist, Operations 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 September 5, 1996, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) by establishing a Class E airspace area at Phoenix-Deer Valley Municipal Airport, AZ (61 FR 46744). This action will provide adequate controlled airspace to accommodate at GPS SIAP to RWY 07R at Phoenix-Deer Valley Municipal Airport, AZ.

Interested parties were invited to participate in this rulemaking proceeding 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 6002 of FAA Order 7400.9D dated September 4, 1996, and effective September 16, 1996, 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) establishes a Class E airspace area at Phoenix-Deer Valley Municipal Airport, AZ. The development of a GPS SIAP to RWY 07R has made this action necessary. The effect of this action will provide adequate airspace for aircraft executing the GPS RWY 07R SIAP at Phoenix-Deer Valley Municipal Airport, AZ.

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 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 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9665, 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 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

Paragraph 6002 Class E airspace areas designated as a surface area for an airport.

* * * * *

AWP AZ E2 Phoenix, Deer Valley Municipal, AZ [New]

Phoenix, Deer Valley Municipal Airport, AZ
(lat. 33°41′18″N, long. 112°04′56″W)

* * * * *

Within 3 miles south and 2 miles north of the 287° bearing from the Deer Valley Municipal Airport extending from the 4.4-mile radius of the Deer Valley Municipal Airport to 9.2 miles west of the airport.

Issued in Los Angeles, California, on September 25, 1996.

James H. Snow,

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

[FR Doc. 96–25607 Filed 10–4–96; 8:45 am]

BILLING CODE 4910–13–M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 232

[Release Nos. 33–7351; 34–37774; 35–26585; 39–2343; IC–22257]

RIN 3235–AG96

Adoption of Updated EDGAR Filer Manual

AGENCY: Securities and Exchange Commission.

ACTION: Final rules.

SUMMARY: The Securities and Exchange Commission (''Commission'') is adopting an updated edition of the EDGAR Filer Manual and is providing for its incorporation by reference into the Code of Federal Regulations.

EFFECTIVE DATE: The amendment to 17 CFR part 232 (Regulation S–T) will be effective on October 7, 1996. The new edition of the EDGAR Filer Manual (Release 5.10) will be effective on October 7, 1996. The incorporation by reference of the EDGAR Filer Manual is approved by the Director of the Federal Register as of October 7, 1996.

FOR FURTHER INFORMATION CONTACT: In the Office of Information Technology, David T. Copenhafer at (202) 942–8800; for questions concerning investment company filings, Ruth Armfield Sanders, Senior Counsel, Division of Investment Management, at (202) 942–0591.

SUPPLEMENTARY INFORMATION: The Commission today announces the adoption of an updated EDGAR Filer Manual (''Filer Manual''), which sets forth the technical formatting requirements governing the preparation and submission of electronic filings through the Electronic Data Gathering, Analysis, and Retrieval (''EDGAR'') system.[1] Compliance with the provisions of the Filer Manual is required in order to assure the timely acceptance and processing of filings made in electronic format.[2] Filers should consult the Filer Manual in conjunction with the Commission's rules governing mandated electronic filing when preparing documents for electronic submission.[3] In this update, notice is provided to filers concerning the change in electronic filing requirements resulting from the elimination of fees previously adopted by the Commission under the Independent Offices Appropriations Act of 1952 (''IOAA'').[4]

In addition, several submission types have been added to accommodate existing rules. Specifically, new EDGAR submission type ''POS 8C'' has been added to accommodate filings of post-effective amendments under the Securities Act of 1933 (the ''Securities Act'')[5] by certain investment companies. This submission type is to be used by investment companies whose registration statements are filed on Forms N–2 and N–5 for the submission of post-effective amendments under the Securities Act, or for post-effective amendments under both the Securities Act and the Investment Company Act of 1940.[6] Also added for investment companies are submission types ''485BXT,'' ''485BXTE,'' and ''485BXTF.'' These three submission types are to be used by open-end investment companies submitting filings under Securities Act rule 485(b)(1)(v) to designate new effective dates for filings previously made under Securities Act rule 485(a).[7]

Rule 301 of Regulation S–T also is being amended to provide for the incorporation by reference of the Filer Manual into the Code of Federal Regulations, which 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. The revised Filer Manual and the amendment to Rule 301 will be effective on October 7, 1996.

Paper copies of the updated Filer Manual may be obtained at the following address: Public Reference Room, U.S. Securities and Exchange Commission, Mail Stop 1–2, 450 Fifth Street, N.W., Washington D.C. 20549. Electronic format copies will be available on the EDGAR electronic bulletin board. Copies also may be obtained from Disclosure Incorporated, the paper and microfiche contractor for the Commission, at (800) 638–8241.

Since the Filer Manual relates solely to agency procedure or practice, publication for notice and comment is not required under the Administrative Procedure Act.[8] It follows that the requirements of the Regulatory Flexibility Act[9] do not apply.

The effective date for the updated Filer Manual and the rule amendments is October 7, 1996. In accordance with the Administrative Procedure Act, 5 U.S.C. 553(d)(3), the Commission finds that there is good cause to establish an effective date less than 30 days after publication of these rules. The EDGAR system was upgraded to Release 5.10 on September 14, 1996, to add the new submission types and implement technical system enhancements, and upgraded again on Saturday, October 5, 1996, to implement system adjustments to accommodate the elimination of IOAA fees, in anticipation of an effective date of Monday, October 7, 1996. The Commission believes that it is necessary to coordinate the effectiveness of the updated Filer Manual with the effective date for the elimination of IOAA fees to avoid confusion for EDGAR filers.

Statutory Basis

The amendment to Regulation S–T is being adopted under Sections 6, 7, 8, 10, and 19(a) of the Securities Act,[10] Sections 3, 12, 13, 14, 15, 23, and 35A of the Securities Exchange Act of 1934,[11] Section 20 of the Public Utility Holding Company Act of 1935,[12] Section 319 of the Trust Indenture Act of 1939,[13] and Sections 8, 30, 31, and 38 of the Investment Company Act of 1940.[14]

List of Subjects in 17 CFR Part 232

Incorporation by reference; Investment companies; Registration requirements; Reporting and recordkeeping requirements; Securities.

Text of the Amendment

In accordance with the foregoing, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

1. The authority citation for Part 232 continues to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77sss(a), 78c(b), 78*l*, 78m, 78n, 78o(d), 78w(a), 78*ll*(d), 79t(a), 80a–8, 80a–29, 80a–30 and 80a–37.

2. Section 232.301 is revised to read as follows:

§ 232.301 EDGAR Filer Manual.

Electronic filings shall be prepared in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets out the technical formatting requirements for electronic submissions. The September 1996 edition of the *EDGAR Filer Manual: Guide for Electronic Filing with the U.S. Securities and Exchange Commission (Release 5.10*) is incorporated into the Code of Federal Regulations by reference, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Compliance with the requirements found therein is essential to the timely receipt and acceptance of documents

[1] The Filer Manual originally was adopted on April 1, 1993, and became effective on April 26, 1993. Release No. 33–6986 (April 1, 1993) [58 FR 18638]. The most recent update to the Filer Manual was adopted in Release No. 33–7241 (November 13, 1995) [60 FR 57682].

[2] *See* Rule 301 of Regulation S–T (17 CFR 232.301).

[3] *See* Release Nos. 33–6977 (February 23, 1993) [58 FR 14628], IC–19284 (February 23, 1993) [58 FR 14848], 35–25746 (February 23, 1993) [58 FR 14999], and 33–6980 (February 23, 1993) [58 FR 15009] for a comprehensive treatment of the rules adopted by the Commission governing mandated electronic filing. *See also* Release No. 33–7122 (December 19, 1994) [59 FR 67752], in which the Commission made the EDGAR rules final and applicable to all domestic registrants and adopted minor amendments to the EDGAR rules, and Release No. 33–7241, in which the Commission adopted the most recent update to the Filer Manual and additional minor technical amendments to the EDGAR rules.

[4] 31 U.S.C. 9701. *See* Release No. 33–7331 (September 17, 1996) [61 FR 49957], adopting, and Release No. 33–7293 (May 16, 1996) [61 FR 25601], proposing, the fee elimination.

[5] 15 U.S.C. 77a *et seq.*

[6] 15 U.S.C. 80a–8, 80a–29, 80a–30 and 80a–37.

[7] *See* Release Nos. IC–20486 (August 17, 1994) [59 FR 43460] and IC–20486A (September 19, 1994) [59 FR 48798].

[8] 5 U.S.C. 601–612.

[9] 5 U.S.C. 553(b).

[10] 15 U.S.C. 77f, 77g, 77h, 77j and 77s(a).

[11] 15 U.S.C. 78c, 78*l*, 78m, 78n, 78o, 78w and 78*ll*.

[12] 15 U.S.C. 79t.

[13] 15 U.S.C. 77sss.

[14] 15 U.S.C. 80a–8, 80a–29, 80a–30 and 80a–37.

filed with or otherwise submitted to the Commission in electronic format. Paper copies of the EDGAR Filer Manual may be obtained at the following address: Public Reference Room, U.S. Securities and Exchange Commission, Mail Stop 1–2, 450 5th Street, N.W., Washington, D.C. 20549. They also may be obtained from Disclosure Incorporated by calling (800) 638–8241. Electronic format copies are available through the EDGAR electronic bulletin board. Information on becoming an EDGAR E-mail/electronic bulletin board subscriber is available by contacting CompuServe Inc. at (800) 848–8199.

By the Commission.

Dated: October 2, 1996.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 96–25815 Filed 10–4–96; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 355

[Docket No. 80N–0042]

RIN 0910–AA01

Anticaries Drug Products for Over-the-Counter Human Use; Final Monograph; Technical Amendment; Partial Delay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment; partial delay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulation that established conditions under which over-the-counter (OTC) anticaries drug products (products that aid in the prevention of dental cavities) are generally recognized as safe and effective and not misbranded (60 FR 52478, October 6, 1995). This final rule makes a nonsubstantive change in the definition of a dentifrice, clarifies how OTC dentifrice gels are included in certain labeling aspects of the final monograph, and clarifies that the second general warning regarding ''accidental ingestion'' is the statement to be used for OTC fluoride-containing dentifrice, treatment rinse, and preventive treatment gel drug products. This amendment also revises the second general warning statement to indicate to consumers that ''accidental ingestion'' of these products means swallowing more than is used during normal brushing or rinsing. Because of the need to revise labeling for this minor revision, the agency is delaying the effective date of the regulation to provide manufacturers with an additional 6 months to comply with the labeling requirements of the monograph. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

DATES: The effective date for § 355.50 added at 60 FR 52508, October 6, 1995, is delayed until April 7, 1997. This final rule is effective April 7, 1997.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–105), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2304.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of October 6, 1995 (60 FR 52478), FDA issued a final monograph for OTC anticaries drug products (21 CFR part 355) establishing conditions under which the drug products that are subject to that monograph will be generally recognized as safe and effective and not misbranded. The effective date of the monograph is October 7, 1996.

On April 17, 1996, the Joint Oral Care Task Group of the Nonprescription Drug Manufacturers Association (NDMA) and the Cosmetic, Toiletry and Fragrance Association (CTFA) (the Task Group) submitted three citizen petitions (Refs. 1, 2, and 3) to amend the final monograph for OTC anticaries drug products. The first petition requested a technical amendment to the final monograph to clarify the use of the term ''gel'' in the context of dentifrice gels and preventive treatment gels in § 355.50(c) and (d). The petition indicated that this technical amendment would be helpful in avoiding unnecessary discussion and/or confusion about how OTC dentifrice gels are included in certain labeling aspects of the final monograph.

The two other petitions requested an exemption from the requirements of the general warnings under § 330.1(g) (21 CFR 330.1(g)) for OTC fluoride-containing dentifrice, treatment rinse, and preventive treatment gel drug products based on these products' long history of safe use, the package size limitations to limit potential toxicity, and the potential for consumer confusion and alarm that the general warnings would cause.

The Task Group added that the second general warning for these drug products is confusing with regard to the terms ''accidental overdose'' and ''accidental ingestion.'' Because these products are not intended for oral administration in the context of an orally administered medicine and because no dosage amounts are specified in the labeling, there is no ''overdose'' per se. The Task Group contended that consumers may mistakenly consider any accidental ingestion (even the swallowing of some product during normal usage) as dangerous and thus needlessly call health professionals in poison control centers, emergency rooms, and doctors' offices for assistance.

II. The Agency's Response to the Petitions

Based on these petitions, the agency has determined that in order to avoid possible confusion about how OTC dentifrice gels and powders are included in certain labeling aspects of the final monograph for OTC anticaries drug products, the definition of ''Dentifrice'' in § 355.3(e) should be revised to read: ''An abrasive-containing dosage form (gel, paste, or powder) for delivering an anticaries drug to the teeth.''

To clarify how OTC dentifrice gels are included in the labeling aspects in § 355.10(a)(1), (b)(1), (b)(2), and (c)(1) and § 355.50(d)(1)(i) and (d)(1)(ii) of the final monograph, this technical amendment revises the heading in each of these sections by adding the words ''gel or'' before the word ''paste.'' To better clarify how OTC dentifrice gels and preventive treatment gels are included in the labeling aspects in § 355.50(c)(1) and (c)(2), respectively, this technical amendment includes the following revisions: (1) The heading in § 355.50(c)(1) is revised to read: *''For all fluoride dentifrice (gel, paste, and powder) products,''* and (2) the heading in § 355.50(c)(2) is revised to read: *''For all fluoride rinse and preventive treatment gel products.''*

With regard to the second general warning in § 330.1(g), the agency points out that the correct second general warning to be used for fluoride-containing gel, paste, powder, treatment rinse, and preventive treatment gel drug products included in the final monograph is the statement for accidental ingestion and not for accidental overdose. That statement reads: ''In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.'' The agency considers this information important to provide consumers guidance if an accidental ingestion occurs, particularly if a young child accidentally swallows or ingests an