§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998, and effective September 16, 1998, 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 Imperial County Airport, CA [NEW]

Imperial County, CA
(Lat. 32°50′03″N, long, 115°34′43″W)
El Centro NAF, CA
(Lat. 32°49′45″N long. 115°40′18″W)
Brawley Municipal Airport, CA
(Lat. 32°59′35″W long. 115°31′01″W)

That airspace extending upward from 700 feet above the surface within a 6-mile radius of Imperial County Airport; excluding that portion within the El Centro NAF, CA, Class D airspace area and excluding that airspace within the Brawly Municipal Airport, CA Class E airspace area.

* * * * *

Issued in Los Angeles, California, on March 31, 1999.

Dawna J. Vicars,

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

[FR Doc. 99–9135 Filed 4–12–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AWP–2]

Proposed Establishment of Class E Airspace; Taylor, AZ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to establish a Class E airspace area at Taylor, AZ. The establishment of a Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 21 at Taylor Municipal Airport has made this proposal necessary. Additional controlled airspace extending upward from 700 feet or more above the surface of the earth is needed to contain aircraft executing the GPS RWY 21 SIAP to Taylor Municipal Airport. The intended effect of this proposal is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Taylor Municipal Airport, Taylor, AZ.

DATES: Comments must be received on or before May 31, 1999.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Attn: Manager, Airspace Branch, AWP–520, Docket No. 97–AWP–2, Air Traffic Division, 15000 Aviation Boulevard, Lawndale, California, 90261.

The official docket may be examined in the Office of the Regional Counsel, Western Pacific Region, Federal Aviation Administration, Room 6007, 15000 Aviation Boulevard, Lawndale, California, 90261.

An informal docket may also be examined during normal business hours at the Office of the Manager, Airspace Branch, Air Traffic Division at the above address.

FOR FURTHER INFORMATION CONTACT: Larry Tonish, Air Traffic Airspace Specialist, Airspace Branch, AWP–520, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California, 90261, telephone (310) 725–6539.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with the comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–AWP–2.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Airspace Branch, Air Traffic Division, 15000 Aviation Boulevard, Lawndale, California 90261, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Airspace Branch, 15000 Aviation Boulevard, Lawndale, California 90261. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedures.

The Proposal

The FAA is considering an amendment to 14 CFR part 71 by establishing a Class E airspace area at Taylor, AZ. The establishment of a GPS RWY 21 SIAP at Taylor Municipal Airport has made this proposal necessary. Additional controlled airspace extending upward from 700 feet above the surface is needed to contain aircraft executing the new approach procedure at Taylor Municipal Airport. The intended effect of this proposal is to provide adequate controlled airspace for aircraft executing the GPS RWY 21 SIAP at Taylor Municipal Airport, Taylor, AZ. Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9F dated September 10, 1998, and effective September 16, 1998, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in this Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed 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 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 proposed 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).

The Proposed Amendment

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

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; ROUTES; AND REPORTING POINTS

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

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998, and effective September 16, 1998, is amended as follows:

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

* * * * *

AWP AZ E5 Taylor, AZ [NEW]

Taylor Municipal Airport, AZ
(Lat. 34°27′17″N, long. 110°06′89″W)
Show Low Municipal Airport, AZ
(Lat. 34°15′56″N, long. 110°00′17″W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Taylor Municipal Airport, excluding the portion within the Show Low, AZ, Class E airspace area. That airspace extending upward from 1,200 feet above the surface within 5 miles southeast and 8 miles northwest of the 041° bearing from the Taylor Municipal Airport, extending from the Taylor Municipal Airport to the southern boundary of V–264.

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Issued in Los Angeles, California, on March 31, 1999.

Leonard A. Mobley,

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

[FR Doc. 99–9134 Filed 4–12–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 99N–0188]

Progestational Drug Products for Human Use; Requirements for Labeling Directed to the Patient

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revoke its regulation requiring patient labeling for progestational drug products. This patient labeling is required to inform patients of an increased risk of birth defects reported to be associated with the use of these drugs during the first 4 months of pregnancy. FDA has concluded that, based on a review of the scientific data, such labeling for all progestogens is not warranted. In addition, the diversity of drugs that can be described as progestational, and the diversity of conditions these drugs may be used to treat, make it inappropriate to consider these drugs a single class for labeling purposes. This action is intended to provide consumers with more appropriate labeling for certain drug products.

DATES: Written comments by July 12, 1999. See section VI of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Diane V. Moore, Center for Drug Evaluation and Research (HFD–580), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4260.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 22, 1977 (42 FR 37646), FDA published a notice setting forth professional labeling for progestational drug products, other than progestogen-containing products for contraception, and included a box warning recommending against use during the first 4 months of pregnancy. The category ''progestational drug products'' includes natural progesterone and all synthetic progestins. The basis for the warning, as stated in the notice, was:

Reports during the past several years have indicated that the use of sex hormones during early pregnancy may seriously damage the offspring. Several reports suggest an association between intrauterine exposure to sex hormone treatment and congenital anomalies, including congenital heart defects and limb reduction defects.

Based on these reports, FDA also published in the **Federal Register** of July 22, 1977 (42 FR 37643), a proposed rule to require patient labeling for progestational drug products. The final regulation was published in the **Federal Register** of October 13, 1978 (43 FR 47178), and it is codified at § 310.516 (21 CFR 310.516). It requires that progestational drug products be dispensed with a patient package insert containing a ''brief discussion of the nature of the risks of birth defects resulting from the use of these drugs during the first 4 months of pregnancy'' (§ 310.516(b)(4)). The regulation applies to any drug product that contains a progestogen, with the exceptions of contraceptives and oral dosage forms labeled solely for the treatment of advanced cancer[1] (§ 310.516(e)(4)). Texts for patient and professional labeling were published at the same time and contained essentially the same warning concerning heart and limb defects (see 42 FR 37646 at 37647 and 37648, July 22, 1977).

In the late 1980's, FDA evaluated the scientific literature concerning the possible teratogenicity of progestational drugs and concluded that the labeling for progestational drug products should be revised. Available evidence indicated the warning about congenital heart defects and limb reduction defects should be deleted. At that time, several reports suggested an association between exposure to progestational drugs during pregnancy and an increased risk of hypospadias in male fetuses and mild virilization of the external genitalia in female fetuses.

Because FDA continued to believe that there was some risk of birth defects associated with progestogens, the patient labeling and box warning statements were revised. In the **Federal Register** of January 12, 1989 (54 FR 1243), FDA published revised guideline texts for patient and professional labeling for progestational drug products that deleted the warning about possible congenital heart defects and limb reduction defects and added a warning about an increased risk of certain genital abnormalities. The

[1] The original regulation exempted contraceptives, which were required to comply with the labeling requirements of 21 CFR 310.501. In 1981 the regulation was amended to exempt advanced cancer drugs (46 FR 53656, October 30, 1981).