List of Subjects in 7 CFR Part 1786
Accounting, Administrative practice and procedure, Electric utilities.

For the reasons set out in the preamble, and under the authority of the Under Secretary for Rural Development, Title 7 of the Code of Federal Regulations is amended as follows:

PART 1786—PREPAYMENT OF RUS GUARANTEED AND INSURED LOANS TO ELECTRIC AND TELEPHONE BORROWERS

1. The authority citation for part 1786 continues to read as follows:


Subpart D 1786.75 through 1786.86 [Removed and Reserved]

2. Subpart D of Part 1786, consisting of sections 1786.75 through 1786.86, is removed and reserved.

Dated: June 9, 1997.
Jill Long Thompson,
Under Secretary, Rural Development.

FOR FURTHER INFORMATION CONTACT:
Eric Howard, Policy Analyst, Policy Development and Risk Control, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4498; or Jane Virga, Senior Attorney, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4020, TDD (703) 883–4444.

SUMMARY:

The final rule is 30 days from the date of publication in the Federal Register. The final rule amends the Class E airspace area at Santa Ynez, CA. The development of a GPS–A SIAP made this action necessary. The effect of this action will provide adequate airspace for aircraft executing the GPS–A SIAP at Santa Ynez Airport, Santa Ynez, 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 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:


§ 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:

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71
[Airspace Docket No. 97±AWP–19]

Amendment of Class E Airspace; Santa Ynez, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace area at Santa Ynez, CA. The development of a Global Positioning System (GPS–A) Standard Instrument Approach Procedure (SIAP) at Santa Ynez 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 Santa Ynez Airport, Santa Ynez, CA.


FOR FURTHER INFORMATION CONTACT: Larry Tonish, Airspace Specialist, Airspace Branch, AWP–520, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 725–6555.

SUPPLEMENTARY INFORMATION:

History

On April 22, 1997, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) by amending the Class E airspace area at Santa Ynez, CA (62 FR 19529). This action will provide adequate controlled airspace to accommodate a GPS–A SIAP to Santa Ynez Airport, Santa Ynez, CA. 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 6005 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) amends the Class E airspace area at Santa Ynez, CA. The development of a GPS–A SIAP made this action necessary. The effect of this action will provide adequate airspace for aircraft executing the GPS–A SIAP at Santa Ynez Airport, Santa Ynez, 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 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).
Paragraph 6005 — Class E airspace area extending upward from 700 feet or more above the surface of the earth.

* * * * *

AWP CA E5 Santa Ynez, CA [Revised]

Santa Ynez Airport, CA

(lat: 34°36'25" N, long: 120°04'32" W)

That airspace extending upward from 700 feet above the surface beginning at lat. 34°33'24" N, long. 120°00'50" W; to lat. 34°29'00" N, long. 120°06'04" W; to lat. 34°29'00" N, long. 120°12'24" W; to lat. 34°37'10" N, long. 120°22'34" W; to lat. 34°45'40" N, long. 120°18'44" W; to lat. 34°40'25" N, long. 120°02'37" W, thence clockwise along the 4.3-mile radius of the Santa Ynez Airport to the point of beginning and within 4.5 miles northeast and 2 miles southwest of the 111° bearing from the Santa Ynez Airport, extending from the 4.3-mile radius to 15 miles southeast of the Santa Ynez Airport, excluding that portion within Santa Barbara, CA, Class C and E airspace areas.

* * * * *

Issued in Los Angeles, California, on June 2, 1997.

Sabra W. Kaulia,
Assistant Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 97–15691 Filed 6–13–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 312

[Docket No. 97N–0223]

Investigational New Drug Application;
Exception from Informed Consent;
Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its investigational new drug application (IND) regulations to clarify that, within 30 days after the receipt of an IND for any clinical investigation involving an exception from informed consent, FDA will provide a written determination as to whether the investigation may begin. This action is intended to clarify a recent amendment to the IND regulations for clinical investigations involving an exception from informed consent that states that FDA will provide a written authorization within 30 days of receipt of the IND.


SUPPLEMENTARY INFORMATION: In the Federal Register of October 2, 1996 (61 FR 51498), FDA amended its regulations by adding §50.24 (21 CFR 50.24) to provide a narrow exception from informed consent requirements for a limited class of emergency research. Under the amendments, certain research activities involving human subjects who are in need of emergency medical intervention, but who cannot give informed consent because of their life-threatening medical condition, and who do not have a legally authorized person to represent them, may be exempt from the informed consent requirement.

The October 2, 1996, final rule also amended the IND regulations at §312.20(c) by adding paragraph (c) (21 CFR 312.20(c)), which requires a sponsor to submit a separate IND for any clinical investigation involving an exception from informed consent under §50.24. This requirement is to ensure that FDA has an opportunity to review the protocol and supporting information before the investigation begins. Section 312.20(c) also provides that the clinical investigation may not proceed without the prior written authorization from FDA. The requirement for written authorization is to document that the agency has reviewed the protocol and supporting information and has agreed that the investigation may proceed. To enable sponsors to begin these investigations as expeditiously as possible, current §312.20(c) also states that “FDA shall provide such written authorization 30 days after FDA receives the IND or earlier.”

Current IND regulations at §312.40(b) (21 CFR 312.40(b)) state that an IND goes into effect 30 days after FDA receives the IND or upon earlier notification by FDA that the investigation may begin, unless FDA notifies the sponsor that the investigations are subject to a clinical hold. Thus, under current IND regulations, FDA may grant or deny permission for the investigations to begin, within 30 days after it receives an IND. The statement in §312.20(c) that “FDA shall provide such written authorization 30 days after FDA receives the IND or earlier” suggests that the agency may only grant permission for the investigations to begin. To correct this unintended meaning, FDA is amending the last sentence in §312.20(c) to state that “FDA shall provide a written determination 30 days after FDA receives the IND or earlier.”

Because this amendment is nonsubstantive and is intended only to provide consistency with current IND regulations, FDA finds that notice and public procedure and delayed effective date are unnecessary (5 U.S.C. 553(b)(B) and (d)).

List of Subjects in 21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 312 is amended as follows:

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

1. The authority citation for 21 CFR part 312 continues to read as follows:


Section 312.20 is amended by revising the last sentence of paragraph (c) to read as follows:

§312.20 Requirement for an IND.

(c) * * * * * FDA shall provide a written determination 30 days after FDA receives the IND or earlier.

Dated: June 10, 1997.

William K. Hubbard,
Associate Commissioner for Policy Coordination.

[FR Doc. 97–15759 Filed 6–13–97; 8:45 am]

BILLING CODE 4160–01–F

CENTRAL INTELLIGENCE AGENCY

32 CFR Parts 1900, 1901, 1907, 1908, and 1909

Freedom of Information Act; Privacy Act; and Executive Order 12958; Implementation

AGENCY: Central Intelligence Agency.

ACTION: Interim Rule.

SUMMARY: The Central Intelligence Agency is hereby promulgating interim rules and soliciting comments prior to adoption of final rules to implement its obligations under the Freedom of Information Act, the Privacy Act, and Executive Order 12958 (or successor Orders) provisions relating to classification challenges by authorized holders, requests for mandatory