

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

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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.

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

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

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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.

EFFECTIVE DATE: June 23, 1997.

FOR FURTHER INFORMATION CONTACT: David LePay, Center for Drug Evaluation

and Research (HFD-340), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301-594-0020.

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 requirements.

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 investigations 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 for good cause 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:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 321, 331, 351, 352, 353, 355, 356, 357, 371); sec. 351 of the Public Health Service Act (42 U.S.C. 262).

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

§ 312.20 Requirement for an IND.

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(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]

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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