

FDC date	State	City	Airport	FDC No.	SIAP
02/09/98 ...	FL.	MELBOURNE	MELBOURNE INTL	FDC 8/0934	VOR OR GPS RWY 27L, AMDT 11B...
02/09/98 ...	FL.	MELBOURNE	MELBOURNE INTL	FDC 8/0935	NDB OR GPS RWY 9R, AMDT 14...
02/09/98 ...	MO.	AVA	AVA/BILL MARTIN MEMORIAL	FDC 8/0928	NDB RWY 31, ORIG...
02/09/98 ...	MO.	AVA	AVA/BILL MARTIN MEMORIAL	FDC 8/0933	REPLACES NOTAM IN TL98-05. VOR/DME RNAV OR GPS RWY 31, AMDT 1...
02/10/98 ...	NC.	NORTH WILKESBORO	WILKES COUNTY	FDC 8/0969	REPLACES NOTAM IN TL98-05. NDB RWY 1, AMDT 1B...
02/10/98 ...	NC.	NORTH WILKESBORO	WILKES COUNTY	FDC 8/0970	GPS RWY 1, ORIG...
02/10/98 ...	NE.	BEATRICE	BEATRICE MUNI	FDC 8/0972	NDB RWY 13, AMDT 8...
02/10/98 ...	NE.	BEATRICE	BEATRICE MUNI	FDC 8/0973	NDB OR GPS-A, AMDT 3...
02/10/98 ...	NE.	BEATRICE	BEATRICE MUNI	FDC 8/0974	VOR OR GPS RWY 13, AMDT 16...
02/10/98 ...	NE.	BEATRICE	BEATRICE MUNI	FDC 8/0975	GPS RWY 35, ORIG...
02/10/98 ...	NE.	BEATRICE	BEATRICE MUNI	FDC 8/0978	VOR RWY 35, AMDT 6...
02/10/98 ...	WI.	NEW RICHMOND	NEW RICHMOND MUNI	FDC 8/0961	NDB OR GPS RWY 14, AMDT 1...
02/11/98 ...	IL.	CHICAGO/PROSPECT HEIGHTS/WHEELING.	PALWAUKEE MUNI	FDC 8/1004	VOR RWY 16, ORIG...
02/11/98 ...	MA.	BOSTON	GENERAL EDWARD LAWRENCE LOGAN INTL.	FDC 8/0977	ILS RWY 33L, AMDT 1...
02/11/98 ...	NE.	AINSWORTH	AINSWORTH MUNI	FDC 8/0989	VOR OR GPS RWY 17, AMDT 2...
02/11/98 ...	NE.	BEATRICE	BEATRICE MUNI	FDC 8/0995	GPS RWY 35, ORIG-A...
02/12/98 ...	KS.	SALINA	SALINA MUNI	FDC 8/1010	ILS RWY 35, AMDT 18A...
02/12/98 ...	MS.	STARKVILLE	OKTIBBEHA	FDC 8/1014	VOR OR GPS RWY 6, AMDT 6...
02/12/98 ...	TN.	COLUMBIA/MOUNT PLEASANT	MAURY COUNTY	FDC 8/1020	SDF RWY 23, AMDT 4B...
02/12/98 ...	TN.	COLUMBIA/MOUNT PLEASANT	MAURY COUNTY	FDC 8/1021	NDB OR GPS RWY 23, AMDT 3B...
02/17/98 ...	MO.	SEDALIA	SEDALIA MEMORIAL	FDC 8/1027	GPS RWY 36, ORIG...
02/17/98 ...	MO.	SEDALIA	SEDALIA MEMORIAL	FDC 8/1028	NDB RWY 36, AMDT 8A...
02/17/98 ...	MO.	SEDALIA	SEDALIA MEMORIAL	FDC 8/1029	NDB RWY 18, AMDT 7B...
02/17/98 ...	MO.	SEDALIA	SEDALIA MEMORIAL	FDC 8/1030	GPS RWY 18, ORIG...
02/17/98 ...	NY.	ONEONTA	ONEONTA MUNI	FDC 8/1070	VOR OR TPS RWY 6 AMDT 4...
02/17/98 ...	NY.	UTICA	ONEIDA COUNTY	FDC 8/1067	ILS RWY 15 AMDT 3...
02/17/98 ...	NY.	UTICA	ONEIDA COUNTY	FDC 8/1069	ILS RWY 33 AMDT...
02/17/98 ...	NY.	UTICA	ONEIDA COUNTY	FDC 8/1072	NDB RWY 33 AMDT 12...
02/17/98 ...	TN.	CAMDEN	BENTON COUNTY	FDC 8/1084	VOR/DME OR GPS RWY 3, AMDT 3...
02/17/98 ...	TX.	McKINNEY	McKINNEY MUNI	FDC 8/1058	VOR/DME OR GPS-A, ORIG...
02/17/98 ...	TX.	McKINNEY	McKINNEY MUNI	FDC 8/1062	ILS RWY 17, AMDT 1...
02/18/98 ...	NY.	ONEONTA	ONEONTA MUNI	FDC 8/1101	LOC RWY 24 AMDT 1...
02/18/98 ...	NY.	UTICA	ONEIDA COUNTY	FDC 8/1095	NDB OR GPS RWY 15 AMDT 9...
02/18/98 ...	NY.	UTICA	ONEIDA COUNTY	FDC 8/1097	VOR/DME OR GPS RWY 33 AMDT 4...
12/11/97 ...	IA.	DES MOINES	DES MOINES INTL	FDC 7/8102	NDB OR GPS RWY 31R, AMDT 18A...

[FR Doc. 98-5695 Filed 3-4-98; 8:45 am]

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DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 97****[Docket No. 29154; Amdt. No. 1854]****RIN 2120-AA65****Standard Instrument Approach Procedures; Miscellaneous Amendments****AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Final rule.**SUMMARY:** This amendment establishes, amends, suspends, or revokes Standard

Instrument Approach Procedures (SIAP's) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: An effective date for each SIAP is specified in the amendatory provisions.

Incorporation by reference—approved by the Director of the Federal Register

on December 31, 1980, and reapproved as of January 1, 1982.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located; or

3. The Flight Inspection Area Office which originated the SIAP.

*For Purchase—*Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA-200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription—Copies of all SIAP's mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Paul J. Best, Flight Procedures Standards Branch (AFS-420), Technical Programs Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-8277.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes SIAP's. The complete regulatory description of each SIAP is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 14 CFR 97.20 of the Federal Aviation Regulations (FAR). The applicable FAA Forms are identified as FAA Form 8260-5. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAP's, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

This amendment or part 97 is effective upon publication of each separate SIAP as contained in the transmittal. The SIAP's contained in this amendment are based on the criteria contained in the United States Standard for Terminal Instrument Approach Procedures (TERPS). In developing these SIAPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports.

The FAA has determined through testing that current non-localizer type, non-precision instrument approaches developed using the TERPS criteria can

be flown by aircraft equipped with a Global Positioning System (GPS) and or Flight Management System (FMS) equipment. In consideration of the above, the applicable SIAP's will be altered to include "or GPS or FMS" in the title without otherwise reviewing or modifying the procedure. (Once a stand alone GPS or FMS procedure is developed, the procedure title will be altered to remove "or GPS or FMS" from these non-localizer, non-precision instrument approach procedure titles.)

The FAA has determined through extensive analysis that current SIAP's intended for use by Area Navigation (RNAV) equipped aircraft can be flown by aircraft utilizing various other types of navigational equipment. In consideration of the above, those SIAP's currently designated as "RNAV" will be redesignated as "VOR/DME RNAV" without otherwise reviewing or modifying the SIAP's.

Because of the close and immediate relationship between these SIAP's and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are, impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

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. It, therefore—(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. For the same reason, the FAA certifies that this amendment 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 97

Air Traffic Control, Airports, Navigation (Air).

Issued in Washington, DC on February 20, 1998.

Tom E. Stuckey,

Acting Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 continues to read:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113-40114, 40120, 44502, 44514, 44701, 44719, 44721-44722.

§ 97.23, 97.27, 97.33, 97.35 [Amended]

2. Amend 97.23, 97.27, 97.33 and 97.35, as appropriate, by adding, revising, or removing the following SIAP's, effective at 0901 UTC on the dates specified:

* * * *Effective April 23, 1998*

Little Rock, AR, Adams Field, NDB or GPS RWY 4L, Amdt 18 CANCELLED
 Little Rock, AR, Adams Field, NDB RWY 4L, Amdt 18
 West Memphis, AR, West Memphis Muni, NDB or GPS RWY 17, Amdt 9 CANCELLED
 West Memphis, AR, West Memphis Muni, NDB RWY 17, Amdt 10
 Phoenix, AZ, Williams Gateway, VOR or TACAN or GPS RWY 30C, Orig-C CANCELLED
 Phoenix, AZ, Williams Gateway, VOR or TACAN RWY 30C, Orig-C
 Yuma, AZ, Yuma MCAS/Yuma Intl, VOR/DME or GPS RWY 17, Orig CANCELLED
 Yuma, AZ, Yuma MCAS/Yuma Intl, VOR/DME RWY 17, Orig
 Yuma, AZ, Yuma MCAS/Yuma Intl, VOR/DME RNAV or GPS RWY 21R, Amdt 3 CANCELLED
 Yuma, AZ, Yuma MCAS/Yuma Intl, VOR/DME RNAV RWY 21R, Amdt 3
 Petaluma, CA, Petaluma Muni, VOR or GPS RWY 29, Orig CANCELLED
 Petaluma, CA, Petaluma Muni, VOR RWY 29, Orig
 Wilmington, DE, New Castle County, VOR/DME RNAV or GPS RWY 9, Orig CANCELLED
 Wilmington, DE, New Castle County, VOR/DME RNAV RWY 9, Orig
 Ocala, FL, Ocala Regional/Jim Taylor Field, NDB or GPS RWY 36, Amdt 3 CANCELLED
 Ocala, FL, Ocala Regional/Jim Taylor Field, NDB RWY 36, Amdt 3
 Orlando, FL, Orlando Intl, VOR/DME or GPS RWY 36L, Amdt 4A CANCELLED
 Orlando, FL, Orlando Intl, VOR/DME RWY 36L, Amdt 4A
 Ortonville, MN, Ortonville Muni-Martinson Field, NDB or GPS RWY 34, Amdt 1A CANCELLED
 Ortonville, MN, Ortonville Muni-Martinson Field, NDB RWY 34, Amdt 2
 Poplar Bluff, MO, Poplar Bluff Muni, NDB or GPS RWY 36, Amdt 1A CANCELLED
 Poplar Bluff, MO, Poplar Bluff Muni, NDB RWY 36, Amdt 1A
 Greenwood, MS, Greenwood-Leflore, VOR/DME RNAV or GPS RWY 36, Amdt 3A CANCELLED
 Greenwood, MS, Greenwood-Leflore, VOR/DME RNAV RWY 36, Amdt 3A
 Greenwood, MS, Greenwood-Leflore, VOR or GPS RWY 5, Amdt 10A CANCELLED
 Greenwood, MS, Greenwood-Leflore, VOR RWY 5, Amdt 10A
 Greenwood, MS, Greenwood-Leflore, NDB or GPS RWY 18, Amdt 1A CANCELLED

Greenwood, MS, Greenwood-Leflore, NDB or GPS RWY 18, Amdt 1A
 Minden, NE, Pioneer Village Field, VOR or GPS RWY 34, Amdt 1A CANCELLED
 Minden, NE, Pioneer Village Field, VOR RWY 34, Amdt 1A
 Ocean City, NJ, Ocean City Muni, VOR or GPS RWY 6, Amdt 1 CANCELLED
 Ocean City, NJ, Ocean City Muni, VOR RWY 6, Amdt 1
 Teterboro, NJ, Teterboro, VOR/DME RNAV or GPS RWY 24, Orig-B CANCELLED
 Teterboro, NJ, Teterboro, VOR/DME RNAV RWY 24, Orig-B
 Shirley, NY, Brookhaven, VOR or GPS RWY 6, Amdt 2 CANCELLED
 Shirley, NY, Brookhaven, VOR RWY 6, Amdt 2
 Clemson, SC, Clemson-Oconee County, VOR/DME or GPS RWY 25, Orig-A CANCELLED
 Clemson, SC, Clemson-Oconee County, VOR/DME RWY 25, Orig-A
 Cedar City, UT, Cedar City Muni, NDB or GPS RWY 20, Orig CANCELLED
 Cedar City, UT, Cedar City Muni, NDB RWY 20, Orig
 Fredericksburg, VA, Shannon, VOR or GPS RWY 24, Amdt 7 CANCELLED
 Fredericksburg, VA, Shannon, VOR RWY 24, Amdt 7
 Spokane, WA, Spokane Intl, VOR or GPS RWY 3, Amdt 12 CANCELLED
 Spokane, WA, Spokane Intl, VOR RWY 3, Amdt 12
 Ravenswood, WV, Jackson County, VOR/DME or GPS RWY 3, Amdt 2A CANCELLED
 Ravenswood, WV, Jackson County, VOR/DME RWY 4, Amdt 2A

[FR Doc. 98-5696 Filed 3-4-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. 97N-0141]

Adequate and Well-Controlled Studies for Investigational Use and Approval of New Animal Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA), as directed by the Animal Drug Availability Act of 1996 (ADAA), is amending its regulations governing new animal drug applications to further define the term "adequate and well-controlled studies." The purpose of this final rule is to further define "adequate and well-controlled" to require that field investigations be designed and conducted in a scientifically sound manner, taking into account practical

conditions in the field and differences between field conditions and laboratory conditions.

DATES: The regulations are effective on April 6, 1998.

FOR FURTHER INFORMATION CONTACT: Herman M. Schoenemann, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1638.

SUPPLEMENTARY INFORMATION:

I. Background

Congress enacted the ADAA (Pub. L. 104-250) on October 9, 1996. Section 2(e) of the ADAA directs FDA to issue, within 18 months of its enactment, final regulations to further define the term "adequate and well-controlled" to require that field investigations be designed and conducted in a scientifically sound manner, taking into account practical conditions in the field and differences between field conditions and laboratory conditions. In an advance notice of proposed rulemaking that published in the **Federal Register** of November 21, 1996 (61 FR 59209), FDA solicited comments from interested parties on how to further define "adequate and well-controlled as it relates to field studies."¹ Docket No. 96N-0411 was created for comments responding to this notice.

In the **Federal Register** of May 8, 1997 (62 FR 25153), FDA proposed to amend its regulations in part 514 (21 CFR part 514) to further define the term "adequate and well-controlled studies." FDA provided 75 days for public comment on the proposed rule. Docket No. 97N-0141 was created for comments regarding this proposed rule. As proposed, one of the characteristics of an adequate and well-controlled study is that such a study, when conducted in target animals, be conducted in compliance with "good study practices" (GSP's). Elsewhere in the **Federal Register** of May 8, 1997 (62 FR 25152), FDA reopened Docket No. 96N-0411 and gave interested parties 30 days to comment on GSP's.

The primary purpose of conducting adequate and well-controlled studies is, and has always been, to distinguish the effect of the drug from other influences, such as spontaneous change in the course of disease and biased observation, so that it can be determined whether the drug is effective. This final rule defines the essential characteristics of adequate and well-controlled studies

¹ The terms field investigation and field study are used interchangeably in this final rule.

and explicitly addresses differences between field and laboratory studies.

II. Comments on the Proposed Rule

FDA received two letters, one from the Animal Health Institute (AHI) and one from the Coalition for Animal Health (the Coalition), commenting on the proposed definition of "adequate and well-controlled studies." FDA also received three letters in response to its reopening Docket No. 96N-0411 for comments specifically on GSP's. Comments relating to GSP's can be found in that docket. FDA met with representatives of the Coalition on June 11, 1997, and July 11, 1997, to discuss the proposed rule and GSP's. Those discussions were recorded in memoranda of meeting that have been placed in the docket for the proposed rule, Docket No. 97N-0141, and in Docket No. 96N-0411.

In general, the comments agreed that the characteristics of an adequate and well-controlled study set forth in the proposed regulation represent sound scientific principles essential for adequate and well-controlled studies. However, the comments criticized FDA's failure to address more explicitly in the proposed regulation the differences between field and laboratory studies and objected to FDA's reference to GSP's.

A. Section 514.117(a)

1. AHI recommended that FDA clarify in proposed § 514.117(a) that reports of adequate and well-controlled studies refer to reports of adequate and well-controlled "effectiveness" studies. Based on the following discussion, FDA does not find it necessary to make such a clarification.

Under section 512(d)(1)(E) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(d)(1)(E)), FDA must refuse to approve a new animal drug application if there is a lack of substantial evidence that the drug will have the effect it is purported or represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling. By definition, substantial evidence consists of one or more adequate and well-controlled studies on the basis of which experts qualified by scientific training and experience to evaluate the effectiveness of the drug could fairly and reasonably conclude that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its proposed labeling (section 512(d)(3) of the act). Thus, it is clear and well established that adequate and well-