

Global Positioning System (GPS) equipment. In consideration of the above, the applicable Standard Instrument Approach Procedure (SIAPs) will be altered to include "or GPS" in the title without otherwise reviewing or modifying the procedure. (Once a stand alone GPS procedure is developed, the procedure title will be altered to remove "or GPS" from these non-localizer, non-precision instrument approach procedure titles.) Because of the close and immediate relationship between these SIAPs 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 23, 1996.

Thomas C. Accardi,
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 by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 is revised to read as follows:

Authority: 49 U.S.C. 40103, 40113, 40120, 44701; 49 U.S.C. 106(g); and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§§ 97.23, 97.27, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.27 NDB, NDB/DME; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

* * * *Effective APR 25, 1996*

Stuttgart, AR, Stuttgart Muni, NDB or GPS RWY 18, Amdt 9 Cancelled
Stuttgart, AR, Stuttgart Muni, NDB RWY 18, Amdt 9
Boone, IA, Boone Muni, NDB or GPS RWY 14, Amdt 9 Cancelled
Boone, IA, Boone Muni, NDB RWY 14, Amdt 9
Clinton, IA, Clinton Muni, VOR/DME or GPS RWY 21, Amdt 8 Cancelled
Clinton, IA, Clinton Muni, VOR/DME RWY 21, Amdt 8
Clinton, IA, Clinton Muni, NDB or GPS RWY 14, Amdt 3 Cancelled
Clinton, IA, Clinton Muni, NDB or GPS RWY 14, Amdt 3
De Quincy, LA, De Quincy Industrial Airpark, VOR/DME or GPS RWY 33, Orig Cancelled
De Quincy, LA, De Quincy Industrial Airpark, VOR/DME RWY 33, Orig
De Quincy, LA, De Quincy Industrial Airpark, NDB or GPS RWY 15, Amdt 1 Cancelled
De Quincy, LA, De Quincy Industrial Airpark, NDB RWY 15, Amdt 1
Opelousas, LA, St Landry Parish-Ahart Field, VOR/DME or GPS RWY 35, Orig-A Cancelled
Opelousas, LA, St Landry Parish-Ahart Field, VOR/DME RWY 35, Orig-A
Kaiser/Lake Ozark, MO, Lee C. Fine Memorial, NDB or GPS RWY 21, Amdt 6 Cancelled
Kaiser/Lake Ozark, MO, Lee C. Fine Memorial, NDB RWY 21, Amdt 6
Albemarle, NC, Stanly County, NDB or GPS RWY 22, Orig.
Alamogordo, NM, Alamogordo-While Sands Regional, VOR or GPS RWY 3, Orig Cancelled
Alamogordo, NM, Alamogordo-While Sands Regional, VOR RWY 3, Orig
Las Vegas, NM, Las Vegas Muni, VOR or GPS RWY 2, Amdt 10A Cancelled
Las Vegas, NM, Las Vegas Muni, VOR RWY 2, Amdt 10A
Las Vegas, NM, Las Vegas Muni, VOR or GPS RWY 20, Amdt 5A Cancelled
Las Vegas, NM, Las Vegas Muni, VOR RWY 20, Amdt 5A
Taos, NM, Taos Muni, NDB or GPS RWY 4, Orig-A Cancelled
Taos, NM, Taos Muni, NDB RWY 4, Orig-A
Zuni Pueblos, NM, Black Rock, VOR/DME or GPS RWY 7, Amdt 1 Cancelled
Zuni Pueblo, NM, Black Rock, VOR/DME RWY 7, Amdt 1
Burnet, TX, Burnet Muni Kate Craddock Field, NDB or GPS RWY 1, Amdt 3 Cancelled
Burnet, TX, Burnet Muni Kate Craddock Field, NDB RWY 1, Amdt 3
Dumas, TX, Moore County, VOR/DME RNAV or GPS RWY 19, Amdt 3 Cancelled
Dumas, TX, Moore County, VOR/DME RNAV RWY 19, Amdt 3

Houston, TX, Houston Intercontinental, NDB or GPS RWY 26, Amdt 1A Cancelled
Houston, TX, Houston Intercontinental, NDB RWY 26, Amdt 1A

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BILLING CODE 4910-13-M

14 CFR Part 97

[Docket No. 28476; Amdt. No. 1713]

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 (SIAPs) for operations at certain airports. These regulatory actions are needed 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 matter 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 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 SIAPs, mailed once every 2 weeks, are for sale by the

Superintendent of Documents, US 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 Standard Instrument Approach Procedures (SIAPs). The complete regulatory description on each SIAP is contained in the appropriate FAA Form 8260 and the National Flight Data Center (FDC)/Permanent (P) Notices to Airmen (NOTAM) which are incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation Regulations (FAR). Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, 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 of 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 (and FAR) 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.

The Rule

This amendment to part 97 of the Federal Aviation Regulations (14 CFR

part 97) establishes, amends, suspends, or revokes SIAPs. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained in the content of the following FDC/P NOTAM for each SIAP. The SIAP information in some previously designated FDC/Temporary (FDC/T) NOTAMs is of such duration as to be permanent. With conversion to FDC/P NOTAMs, the respective FDC/T NOTAMs have been cancelled.

The FDC/P NOTAMs for the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Approach Procedures (TERPS). In developing these chart changes to SIAPs by FDC/P NOTAMs, the TERPS criteria were applied to only these specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a National Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for all these SIAP amendments requires making them effective in less than 30 days.

Further, the SIAPs contained in this amendment are based on the criteria contained in the TERPS. Because of the close and immediate relationship between these SIAPs 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 these SIAPs effective in less than 30 days.

Conclusion

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.

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Issued in Washington, DC on February 23, 1996.

Thomas C. Accardi,
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2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

* * * *Effective Upon Publication*

FDC date	State	City	Airport	FDC No.	SIAP
02/09/96	TN	Memphis	Memphis Intl	FDC 6/0926	ILS RWY 36L AMDT 11. . .
02/09/96	TX	Fort Worth	Fort Worth Meacham Intl	FDC 6/0929	ILS RWY 16L, AMDT 5. . .
02/10/96	WV	Lewisburg	Greenbrier Valley	FDC 6/0955	ILS RWY 4 AMDT 7A. . .
02/12/96	TX	Fort Worth	Fort Worth Meacham Intl	FDC 6/0973	NDB OR GPS RWY 16L, AMDT 3. . .
02/12/96	TX	Fort Worth	Fort Worth Meacham Intl	FDC 6/0974	NDB OR GPS RWY 34R, AMDT 5. . .
02/13/96	MN	Brainerd	Brainerd-Crow Wing County Regional.	FDC 6/0999	ILS RWY 23 AMDT 4. . .
02/13/96	MN	Brainerd	Brainerd-Crow Wing County Regional.	FDC 6/1000	VOR/DME RWY 12 AMDT 8. . .
02/14/96	MN	Cambridge	Cambridge Muni	FDC 6/1009	NDB OR GPS RWY 34 AMDT 6. . .

FDC date	State	City	Airport	FDC No.	SIAP
02/14/96	NE	Falls City	Brenner Field	FDC 6/1017	NDB OR GPS-A, AMDT 3. . .
02/14/96	TX	Fort Worth	Fort Worth Meacham Intl	FDC 6/1023	LOC BC RWY 34R, AMDT 7. . .
02/15/96	CA	Lakeport	Lampson Field	FDC 6/1036	NDB OR GPS-A ORIG-A. . .
02/20/96	CA	Victorville	Southern California Intl	FDC 6/1111	ILS RWY 17 ORIG. . .

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 83G-0062]

Direct Food Substances Affirmed as Generally Recognized as Safe; Lactase Enzyme Preparation From *Candida Pseudotropicalis*

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to affirm that lactase enzyme preparation derived from *Candida pseudotropicalis* for use in milk and milk-derived products to hydrolyze lactose is generally recognized as safe (GRAS). This action is in response to a petition submitted by Pfizer, Inc.

DATES: Effective February 29, 1996. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications listed in new § 184.1387, effective February 29, 1996.

FOR FURTHER INFORMATION CONTACT: Nega Beru, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3097.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the procedures described in § 170.35 (21 CFR 170.35), Pfizer, Inc., 235 East 42d St., New York, NY 10017, submitted a petition (GRASP 2G0282) proposing that lactase enzyme preparation from *C. pseudotropicalis* be affirmed as GRAS for use as a direct human food ingredient. (Lactase, the enzyme, is to be distinguished from lactase enzyme preparation, which contains lactase as the principal active component but also contains other components derived from the production organism and fermentation media. This document will refer to the

former as "lactase" and to the latter as "lactase enzyme preparation.") Lactase enzyme preparation is used to hydrolyze lactose in milk and milk products.

FDA published a notice of filing of this petition in the Federal Register of March 29, 1983 (48 FR 13098), and gave interested persons an opportunity to submit comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. FDA received no comments in response to that notice.

II. Standards for GRAS Affirmation

Under § 170.30 (21 CFR 170.30), general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances added to food. The basis of such views may be either: (1) Scientific procedures, or (2) in the case of a substance used in food prior to January 1, 1958, experience based on common use in food (§ 170.30(a)). General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive and ordinarily is to be based upon published studies, which may be corroborated by unpublished studies and other data and information (§ 170.30(b)). General recognition of safety through experience based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive, and ordinarily is to be based upon generally available data and information concerning the pre-1958 history of use of the food ingredient (§ 170.30(c)).

The petition states that *C. pseudotropicalis* was isolated from dairy products prior to 1958 (Refs. 1 and 2). Therefore, the petition argues, lactase produced by the organism has been part of the human diet for many years and may be presumed to have been in common use in food prior to January 1, 1958. The petition also states that Pfizer, Inc., first began commercial production of lactase enzyme preparation derived from *C. pseudotropicalis* in 1982 for use in certain dairy products.

The agency recognizes that *C. pseudotropicalis* was isolated from dairy products prior to 1958. However, lactase enzyme preparation derived from *C. pseudotropicalis* does not itself have a history of common use as an ingredient in food before 1958. Therefore, the enzyme preparation does not qualify for GRAS status based on a history of common use in food (§ 170.30(c)). Accordingly, FDA has evaluated the enzyme preparation on the basis of scientific procedures under § 170.30(b).

In evaluating this petition, the agency reviewed information concerning: (1) The identity and function of the enzyme, (2) the production and purification of the lactase enzyme preparation, and (3) the safety of the production organism and the finished lactase enzyme preparation.

III. Identity and Technical Effect

Lactase is the accepted name for the enzyme β -D-galactoside galactohydrolase (EC 3.2.1.23), which catalyzes the hydrolysis of the disaccharide lactose to its component monosaccharides, glucose and galactose. Lactase enzyme preparations may be produced by fermentation utilizing any of a large number of microorganisms. A typical example is the enzyme produced by the yeast *Kluyveromyces lactis* (Ref. 3).

The lactase preparation that is the subject of this petition is a soluble enzyme preparation derived from the yeast *C. pseudotropicalis* and is composed of the enzyme lactase as the principal active ingredient, other components derived from the production organism and the fermentation media, residual amounts of processing aids, and substances added as stabilizers or diluents. The petitioned enzyme preparation meets the general and additional requirements for enzyme preparations found in the Food Chemicals Codex, 3d ed. (1981), which are incorporated by reference in § 184.1387 (Ref. 4).

Lactase enzyme preparation is intended for use in hydrolyzing lactose to reduce the lactose content of food products. The petitioner provided published information to demonstrate that lactase enzyme preparation from *C. pseudotropicalis* hydrolyzes lactose in milk and milk products.