Manager, International Branch, ANM–116; or the DGAC (or its delegated agent).

Alternative Methods of Compliance

(m)(1) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

(2) Alternate methods of compliance approved previously in accordance with AD 96–11–05, Amendment 39–9630, for paragraphs (a) through (h) of that AD, are approved as alternative methods of compliance with paragraphs (a) through (h) of this AD.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(n) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 3: The subject of this AD is addressed in French airworthiness directive 1999–239–287(B), dated June 2, 1999.

Issued in Renton, Washington, on February 8, 2000.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–3397 Filed 2–11–00; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 00–ASO–4]

Proposed Establishment of Class E Airspace; Andrews—Murphy, NC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to establish Class E airspace at Andrews—Murphy, NC. A Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP), helicopter point in space approach, has been developed for Andrews—Murphy, NC. As a result, controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to accommodate the SIAP.

DATES: Comments must be received on or before March 15, 2000.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Docket No. 00–ASO–4, Manager, Airspace Branch, ASO–520, P.O. Box 20636, Atlanta, Georgia 30320.

The official docket may be examined in the Office of the Regional Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337, telephone (404) 305–5627.

FOR FURTHER INFORMATION CONTACT: Nancy B. Shelton, Manager, Airspace Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5627.

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 those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 00–ASO–4.'' The postcard will be date/time stamped and returned to the commenter. All communications received 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 the comments received. All comments submitted will be available for examination in the Office of the Regional Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337, 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 NPRMs

Any person may obtain a copy of this Notice of Proposed rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Manager, Airspace Branch, ASO–520, Air Traffic Division, P.O. Box 20636, Atlanta, Georgia 30320. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR Part 71) to establish Class E airspace at Andrews—Murphy, NC. A GPS SIAP, helicopter point in space approach, has been developed for Andrews—Murphy, NC. Controlled airspace extending upward from 700 feet AGL is needed to accommodate the SIAP. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface are published in Paragraph 6005 of FAA Order 7400.9G, dated September 1, 1999, and effective September 16, 1999, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the 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. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not ''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 rule, when promulgated, 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).

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; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 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 Federal Aviation Administration Order 7400.9G, Airspace Designations and Reporting Points, dated September 1, 1999, and effective September 16, 1999, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth

* * * * *

ASO NC E5 Andrews—Murphy, NC [New]

Andrews—Murphy, NC

Point In Space Coordinates

(Lat. 35°11′10″ N, long. 83°52′57″ W)

That airspace extending upward from 700 feet or more above the surface within a 6-mile radius of the point in space (lat. 35°11′10″ N, long 83°52′57″ W) serving Andrews—Murphy NC; excluding that airspace within the Knoxville. TN, Class E airspace.

* * * * *

Issued in College Park, Georgia, on January 31, 2000.

Nancy B. Shelton,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 00–3302 Filed 2–11–00; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10, 14, 19, and 25

[Docket No. 99N–4783]

Administrative Practices and Procedures; Good Guidance Practices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its administrative regulations to codify its policies and procedures for the development, issuance, and use of guidance documents. This action is necessary in order to comply with requirements of the Food and Drug Administration Modernization Act of 1997 (FDAMA). FDAMA codifies certain parts of the agency's current ''Good Guidance Practices'' (GGP's) and directs the agency to issue a regulation that is consistent with the Federal Food, Drug, and Cosmetic Act (the act) and that specifies FDA's policies and procedures for the development, issuance, and use of guidance documents. The intended effect of this regulation is to make the agency's procedures for development, issuance, and use of guidance documents clear to the public.

DATES: Submit written comments and recommendations by May 1, 2000.

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: Lisa L. Barclay, Office of Policy (HF–22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3370.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Presidential Memorandum on Plain Language issued on June 1, 1998, directs FDA to ensure that all of its documents are clear and easy-to-read. Part of achieving that goal involves having readers of a regulation feel that it is speaking directly to them. The agency has attempted to incorporate plain language concepts through the use of pronouns and other plain language in this regulation as much as possible. For example, the agency will be using the term ''you'' to refer to all affected parties outside of the agency. For purposes of this regulation, ''you'' and ''public'' are used interchangeably. The agency would like your comments on how effectively it has used plain language in this regulation, and whether this has made the document more clear and easy to understand.

II. History

In May 1995, the Indiana Medical Device Manufacturer's Council filed a citizen's petition with the agency, which requested, among other things, that FDA establish greater controls over the initiation, development, and issuance of guidance documents to assure the appropriate level of meaningful public participation. In response to this petition, the agency issued a proposed guidance document that set forth the agency's position on how it would proceed in the future with respect to guidance document development, issuance, and use (61 FR 9181, March 7, 1996).

The agency invited public comment on its proposal, and on April 26, 1996, the agency held a public meeting to discuss it. After reviewing and considering all of the comments received during the meeting and the public comment period, the agency finalized its procedures. In the **Federal Register** of February 27, 1997 (62 FR 8961), FDA published a notice announcing the agency's GGP's guidance document (the 1997 GGP document).

The 1997 GGP document provided a definition of guidance; established a standard way of naming guidance documents; described the legal effect of guidance documents; established practices for developing guidance documents and receiving public input; established ways for making guidance documents available to the public; and provided information concerning the agency's existing appeals processes for disputes regarding guidance documents.

On November 21, 1997, the President signed FDAMA into law (Public Law No. 105–115). Section 405 of FDAMA, which added section 701(h) to the act (21 U.S.C. 371(h)), establishes certain aspects of the 1997 GGP document as the law. It also directs the agency to evaluate the effectiveness of the 1997 GGP document and then develop and issue regulations specifying its policies and procedures for the development, issuance, and use of guidance documents. The agency conducted an internal evaluation of the effectiveness of the 1997 GGP document and now is proposing changes to its existing part 10 (21 CFR part 10) regulations to clarify its procedures for development, issuance, and use of guidance documents. The proposal, in large part, tracks the 1997 GGP document. As discussed below in part V.A of this document, any changes from the 1997 GGP document that FDA is proposing are based on the language in FDAMA, or FDA's internal evaluation of GGP's. Your comments on the proposal will help FDA further evaluate the effectiveness of its 1997 GGP document.

III. 1997 GGP Document

The 1997 GGP document issued by the agency in February 1997 provided a great deal of information regarding the agency's procedures for the development, issuance, and use of guidance documents. Below is a brief overview of the key parts of the 1997 GGP document.

First, the 1997 GGP document explained its purpose. The purpose of GGP's is to ensure that agency guidance