approximately 6 to 6½ inches in width. The NTSB did not submit any comments concerning the changes proposed in Notice No. 95–1 and has not made any formal recommendations concerning the width of passageways leading to Type III exits.

The issues raised by the last late commenter were all addressed in response to other commenters; however, that commenter questioned the use of the term ''clear path'' in the graph of pathway widths versus egress time contained in the preamble to Notice No. 95–1. ''Clear path'' was used in the preliminary graph of the results of the second test series to denote a configuration in which the forward-most edge of the unobstructed passageway was no farther forward than the forward-most edge of the emergency exit. It was recognized that the term could cause confusion, so the test configurations were described in terms of centerline offset or seat encroachment in the final reports.

Reason for Withdrawal

CAMI is presently doing further studies on access to Type III exits. The withdrawal of Notice No. 95–1 enables future rulemaking action that will be able to benefit from this ongoing research and produce a more accurate, fresh perspective on the issues.

In addition, the FAA is involved in eliminating unnecessary differences between the Federal Aviation Regulations and the Joint Aviation Requirements used in European countries. This is an ongoing process of aligning its regulations with those of the Joint Aviation Authorities (JAA) known as harmonization. Our desire to harmonize the two codes has dictated our efforts in many areas of current regulatory activity. ARAC's Occupant Safety Issues Area, formerly known as the Emergency Evacuation Issues Area, is working on a recommendation for a harmonized proposal on the issues addressed by Notice No. 95–1. ARAC will make its recommendation after completion of a FAA research program to study access to Type III exits. Continuing industry input through the ARAC process will contribute to a more complete analysis of the issues. Therefore, we have determined that it would be better to wait and see if some future regulatory action including the broader scope of this harmonized proposal would better serve the public interest.

Withdrawal of Proposed Rule

Withdrawal of Notice No. 95–1 does not preclude the FAA from issuing another NPRM on the subject matter in the future or committing the agency to any future course of action. To achieve harmonization goals, we will make any necessary changes to the Code of Federal Regulations through a future NPRM with opportunity for public comment. Therefore, the FAA withdraws Notice No. 95–1, published on January 30, 1995 (60 FR 5794).

Issued in Washington, DC, on April 26, 2002.

John Hickey,

Director, Aircraft Certification Service (AIR–1).

[FR Doc. 02–10947 Filed 5–2–02; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 02–AEA–01]

Establishment of Class E Airspace; Lee Airport, Annapolis, MD

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to establish Class E airspace at Lee Airport (ANP), Annapolis, MD. The development of a Standard Instrument Approach Procedure (SIAP) to serve flights operating into the Lee Airport during Instrument Flight Rules (IFR) conditions make this action necessary. Controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to contain aircraft executing an approach. The area would be depicted on aeronautical charts for pilot reference.

DATES: Comments must be received on or before June 3, 2002.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Airspace Branch, AEA–520, Docket No. 02–AEA–01 FAA Eastern Region, 1 Aviation Plaza, Jamaica, NY, 11434–4809.

The official docket may be examined in the Office of the Regional Counsel, AEA–7, FAA Eastern Region, 1 Aviation Plaza, Jamaica, NY, 11434–4809.

An informal docket may also be examined during normal business hours in the Airspace Branch, AEA–520, FAA Eastern Region, 1 Aviation Plaza, Jamaica, NY, 11434–4809.

FOR FURTHER INFORMATION CONTACT: Mr. Francis T. Jordan, Jr., Airspace Specialist, Airspace Branch, AEA–520 FAA Eastern Region, 1 Aviation Plaza, Jamaica, NY, 11434–4809: telephone: (718) 553–4521.

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, 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. 02–AEA–01''. The postcard will be date/time stamped and returned to the commenter. All communications received on or before the 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 comments received. All comments submitted will be available for examination in the Rules Docket closing both before and after the closing date for comments. A report summarizing each substantive public contact with the 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 Office of the Regional Counsel, AEA–7, FAA Eastern Region, 1 Aviation Plaza, Jamaica, NY, 11434–4809. Communications must identify the notice number of this NRPM. 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 area at Annapolis, MD. The development of a SIAP to serve flights operating into the airport under Instrument Flight Rules (IFR) make this action necessary. 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 7400.9J, dated August 31, 2001, and effective September 16, 2001, 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. Therefore, this proposed 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 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 would only affect air traffic procedure and air navigation, it is certified that this proposed rule would not have 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—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; EO 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 7400.9J, dated August 31, 2001, and effective September 16, 2001, is proposed to be amended as follows:

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

AEA MD E5, Annapolis [New]

Lee Airport

(Lat. 38°56′34″ N., long. 76°34′06″ W.)

That airspace extending upward from 700 feet above the surface within a 6.2 mile radius of the Lee Airport, Annapolis, MD.

Issued in Jamaica, New York, on March 28, 2002.

Richard J. Ducharme,

Assistant Manager, Air Traffic Division, Eastern Region.

[FR Doc. 02–11055 Filed 5–2–02; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 601

[Docket No. 00N–1652]

RIN 0910–AB91

Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing the format in which certain labeling is required to be submitted for review with new drug applications (NDAs), certain biological license applications (BLAs), abbreviated new drug applications (ANDAs), supplements, and annual reports. The proposal would require that certain labeling content be submitted electronically in a form that FDA can process, review, and archive. Submitting the content of labeling in electronic format would simplify the drug labeling review process and speed up the approval of labeling changes.

DATES: Submit written or electronic comments by August 1, 2002. Submit written comments on the information collection requirements by June 3, 2002. See section X of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT:

Randy Levin, Center for Drug Evaluation and Research (HFD–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5411, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

A. Current Labeling Submission Requirements

Section § 314.50 (21 CFR 314.50) of our (FDA's) current regulations describes the content and format requirements for NDAs. Under § 314.50(e)(2)(ii), an applicant is required to submit, in the archival copy of an application, copies of the label and all labeling for the drug product. Under § 314.50(l)(1), information in the archival copy required under § 314.50(a) (i.e., the application form, including the signature of the applicant) and § 314.50(e) (i.e., samples and labeling) must be submitted to the agency on paper, while other required information may be submitted either on paper or on microfiche (or another suitable microform system, if FDA and the applicant agree). Under § 314.71(b) (21 CFR 314.71(b)), supplements to approved applications submitted to the agency under § 314.70 (21 CFR 314.70) must follow the procedures described in § 314.50. In addition, § 314.81(b)(2)(iii) (21 CFR 314.81(b)(2)(iii)) requires that ''currently used professional labeling, patient brochures, or package inserts'' be submitted with annual reports.

Section § 314.94 (21 CFR 314.94) sets forth requirements for the content and format of ANDAs. Under § 314.94(a)(8)(ii), the archival copy of an ANDA must include copies of the label and all labeling for the drug product. Under § 314.94(d), an applicant may submit all or portions of the archival copy of an ANDA in any form that FDA and the applicant agree is acceptable. Under § 314.97 (21 CFR 314.97), supplements and other changes to approved ANDAs must be submitted to the agency under the requirements of §§ 314.70 and 314.71. As noted previously, under § 314.71(b), supplements to approved applications submitted to the agency under 314.70 must follow the procedures described in § 314.50. Finally, under § 314.98(c) (21 CFR 314.98(c)), ANDA applicants must submit annual reports as required in § 314.81(b)(2)(iii).

Section § 601.2 (21 CFR 601.2) describes the requirements for submission of a BLA, which include the