to adequately protect the public health and safety by providing reasonable assurance that appropriate measures can be taken offsite in the event of a radiological emergency.'' The petitioners add that society as a whole has a moral obligation to make sure that every possible measure is in place to insure the safety and well-being of young children.

The petitioners contend that, if the NRC refuses to require the basic protections for preschoolers laid out in the petition, the agency will be perpetuating an improper implementation of FEMA regulations as they pertain to properly protecting the public in the event of a radiological emergency. The petitioners stress that the NRC's principal duty is to safeguard the public, and maintain that, barring the adoption of the provisions requested by the petitioners, the NRC will be guilty of negligence in the fulfillment of its duty.

Dated at Rockville, Maryland, this 28th day of October, 2002.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 02–27861 Filed 10–31–02; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 02–AEA–18]

Establishment of Class E Airspace; Crisfield, MD

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

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

DATES: Comments must be received on or before December 2, 2002.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Airspace Branch, AEA–520, Docket No. 02–AEA–18, 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 action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 02–AEA–18''. 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 action 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 docket 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 area at Crisfield, MD. The development of a SIAP to serve flights operating IFR into the airport makes 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 of the earth are published in Paragraph 6005 of FAA Order 7400.9K, dated August 30, 2002, and effective September 16, 2002, 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 procedures 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 7400.9K, Airspace Designations and Reporting Points, dated August 30, 2002 and effective September 16, 2002, 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, Crisfield [NEW]

Crisfield Municipal Airport
(Lat. 38°01′01″ N., long. 75°49′44″ W.)

That airspace extending upward from 700 feet above the surface within a 6.0-mile radius of Crisfield Municipal Airport, Crisfield, MD.

Issued in Jamaica, New York on October 23, 2002.

John G. McCartney,

Acting Assistant Manager, Air Traffic Division, Eastern Region.

[FR Doc. 02–27844 Filed 10–31–02; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. 85N–0214]

180–Day Generic Drug Exclusivity for Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a proposed rule published in the **Federal Register** of August 6, 1999 (64 FR 42873) (the August 1999 proposed rule). FDA proposed to amend its regulations governing 180-day exclusivity and the timing of certain abbreviated new drug application (ANDA) approvals under the Federal Food, Drug, and Cosmetic Act (the act). The proposed amendments to the regulations were made in response to court decisions that affected the agency's previous interpretation of relevant provisions of the act. Since the proposed rule was published, there have been additional court decisions that address FDA's interpretation of the act, including the interpretation described in portions of the proposed rule. In light of these decisions, FDA is withdrawing the August 1999 proposed rule and will reevaluate its interpretation of the act. FDA will continue to regulate directly from the statute and applicable regulations and make regulatory decisions on an issue-by-issue basis.

DATES: The proposed rule is withdrawn November 1, 2002.

FOR FURTHER INFORMATION CONTACT: J. Kenneth Borgerding, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 6, 1999 (64 FR 42873), FDA proposed to amend its regulations governing 180-day generic drug exclusivity under the act. The August 1999 proposed rule was an effort to clarify existing eligibility requirements for 180-day generic drug exclusivity and to describe new eligibility requirements for ANDA sponsors. The August 1999 proposed rule described a number of challenges to FDA's previous interpretations of relevant statutory provisions and proposed a new approach to implementing 180-day generic drug exclusivity. The publication of the proposed amendments was FDA's response to then-recent court decisions affecting portions of its regulations. (See *Mova Pharmaceutical Corp.* v. *Shalala*, 140 F.3d 1060 (D.C. Cir. 1998), and *Granutec, Inc.* v. *Shalala*, 139 F.3d 889, 1998 WL 153410 (4th Cir. Apr. 3, 1998)).

The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the Hatch-Waxman Amendments) created section 505(j) of the act (21 U.S.C. 355(j)). The ANDA approval program established by section 505(j) of the act permits a generic version of a previously approved innovator drug to be approved without submission of a full new drug application (NDA). An ANDA references a previously approved drug product (the ''listed drug'') and relies on the agency's prior finding of safety and effectiveness for that drug product.

Applicants seeking approval for an NDA must include in their NDA information about patents for the drug that is the subject of the NDA. FDA publishes this patent information as part of the agency's publication ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (the Orange Book).

Under section 505(j)(2)(A)(vii) of the act, generic drug applicants must include in an ANDA a patent certification for each patent listed in the Orange Book for the listed drug. The applicant must certify to one of the following for each listed patent: (1) That no patent information on the listed drug has been submitted to FDA; (2) that such patent has expired; (3) the date on which such patent will expire; or (4) that such patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the drug product for which the ANDA is submitted. These certifications are referred to as ''paragraph I,'' ''paragraph II,'' ''paragraph III,'' and ''paragraph IV'' certifications, respectively. The ANDA applicant must also provide notice of a paragraph IV certification to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA refers.

Section 505(j)(5)(B)(iv) of the act provides an incentive for ANDA applicants to file paragraph IV certifications challenging patents that may be invalid, unenforceable, or not infringed by the drug product that is the subject of the ANDA. In certain circumstances, the first ANDA applicant with a paragraph IV certification is granted 180-day exclusivity. The 180-day exclusivity gives the first ANDA applicant protection from market competition by subsequent generic versions of the same drug product for a 180-day period from either the date the first ANDA applicant begins commercially marketing its drug product or from the date of a court decision holding the patent that is the subject of the paragraph IV certification invalid, unenforceable, or not infringed.

In 1994, FDA issued its final rule implementing the patent and marketing exclusivity provisions of the Hatch-Waxman Amendments. The requirements for 180-day exclusivity are contained in § 314.107(c)(1) (21 CFR 314.107(c)(1)).

In 1998, two appellate courts found that FDA's interpretation of section 505(j)(5)(B)(iv) of the act as expressed in § 314.107(c)(1) was not supported by the act (*Mova*, 140 F.3d at 1077; *Granutec*, 139 F.3d at 889). The *Mova* and *Granutec* courts concluded that the ''successful defense'' requirement imposed by § 314.107(c)(1) which required an ANDA applicant to be sued for patent infringement and to win before it could qualify for 180-day exclusivity was invalid. They held that 180 days of marketing exclusivity should be granted to the first ANDA applicant that files a paragraph IV certification, regardless of whether the applicant is subsequently sued for patent infringement.

Shortly after these decisions, the agency published a guidance for industry entitled ''180–Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal