Aviation Administration, Docket No. 95–ANM–29, Lind Avenue SW., Renton, Washington 98055–4056; telephone number: (206) 227–2535.

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. 95–ANM–29.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or 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 the light of comments received. All comments submitted will be available for examination at the address listed above 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 NPRM's

Any person may obtain a copy of this NPRM by submitting a request to the Federal Aviation Administration, System Management Branch, ANM–530, 1601 Lind Avenue SW., Renton, Washington 98055–4056. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's 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 amend Class D and Class E airspace at Hailey, Idaho, to accommodate a new GPS SIAP at Friedman Memorial Airport. The area would be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. Class D airspace areas extending upward from the surface of the earth, and Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 5000 and paragraph 6005, respectively, of FAA Order 7400.9C dated August 17, 1995, and effective September 16, 1995, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designations 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 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 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—[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; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 15, 1995, is amended as follows:

Paragraph 5000 Class D airspace

* * * * *

ANM ID D Hailey, ID [Revised]

Friedman Memorial Airport, Hailey, ID
(lat. 43°30′17″ N, long. 114°17′48″ W)

That airspace extending upward from the surface to, and including 7,800 feet MSL within a 4.1-mile radius of the Friedman Memorial Airport, and that airspace within 1.8 miles each side of the 159° bearing from the airport, extending from the 4.1-mile radius to 6 miles southeast of the airport. This Class D airspace area is effective during the specified dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

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

* * * * *

ANM ID E5 Hailey, ID [Revised]

Friedman Memorial Airport, Hailey, ID
(lat. 43°30′17″ N, long. 114°17′48″ W)
M–SUN MLS
(lat. 43°30′02″ N, long. 114°17′37″ W)

That airspace extending upward from 700 feet above the surface within 1.8 miles each side of the M–SUN MLS 328° azimuth, from 7.4 miles northwest to 4.3 miles southeast of the M–SUN MLS, and 1.8 miles each side of the 159° bearing from the airport, extending from the airport to 7.6 miles southeast of the airport; that airspace extending upward from 1,200 feet above the surface, within 3.5 miles each side of the M–SUN MLS 328° azimuth, from 15.7 miles northwest to the M–SUN MLS, and that airspace from lat. 43°36′00″ N, long. 114°27′03″ W, thence eastbound to lat. 43°36′00″ N, long. 114°00′03″ W, thence southbound to lat. 43°17′30″ N, long. 114°03′03″ W, thence westbound to lat. 43°17′30″ N, long. 114°27′03″ W, thence northbound to the point of beginning; excluding that airspace overlying V–231 on the east side and V–500 on the south side.

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Issued in Seattle, Washington, on January 5, 1996.

Richard E. Prang,

Acting Assistant Management, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 96–1435 Filed 1–26–96; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket Nos. RM95–8–000 and RM94–7–001]

Promoting Wholesale Competition Through Open Access Non-Discriminatory Transmission Services by Public Utilities; Recovery of Stranded Costs by Public Utilities and Transmitting Utilities

January 19, 1996.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Proposed rule; extension of time for comments on Draft Environmental Impact Statement (DEIS).

SUMMARY: On November 17, 1995, the staff of the Federal Energy Regulatory Commission issued a draft environmental impact statement for the proposed rule in this proceeding (60 FR 58304, November 27, 1995). On January 3, 1996, an extension of time for the filing of comments on the DEIS was granted because certain departments and agencies of the Federal government were closed for all but emergency matters due to a lack of appropriated funds.

DATES: Comments by all parties shall be filed on or before February 2, 1996.

ADDRESSES: Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426.

FOR FURTHER INFORMATION CONTACT: Bill Meroney, Office of Economic Policy, (202) 208–1069.

Lois D. Cashell,

Secretary.

[FR Doc. 96–1530 Filed 1–26–96; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 600 and 601

[Docket No. 95N–0411]

RIN 0910–AA68

Well-Characterized Biotechnology Products; Elimination of Establishment License Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations to eliminate the establishment license application (ELA) requirement for well-characterized biotechnology products licensed under the Public Health Service Act (PHS Act). The proposed rule would also exempt well-characterized biotechnology products licensed under the PHS Act from certain biologics regulations and harmonize the requirements applicable to these products with those applicable to similar drug products which are approved under the Federal Food, Drug, and Cosmetic Act (the act).

This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives, and it is intended to reduce unnecessary burdens for industry without diminishing public health protection.

DATES: Written comments on this proposed rule by February 28, 1996. Submit written comments on the information collection requirements by February 28, 1996, but not later than March 29, 1996. The agency proposes that any final rule that may issue based on this proposal become effective upon its date of publication in the Federal Register.

ADDRESSES: Submit written comments on this proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Tracey H. Forfa, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION

I. Background

In the Federal Register of December 8, 1995 (60 FR 63048), the agency announced its interim definition of a well-characterized therapeutic recombinant DNA-derived and monoclonal antibody biotechnology product, as follows:

A chemical entity(ies) whose identity, purity, impurities, potency, and quantity can be determined and controlled.

Identity:

a. *Recombinant DNA Biotechnology Products*

The primary structure is known (i.e., amino acid sequence), and

The secondary structure is known (e.g. disulfide linkage), and

Post-translational modifications are known (e.g., glycosylation), or

b. *Monoclonal Antibodies*

The identity can be determined by rigorous physicochemical and immunochemical characterization without fully knowing its chemical structure.

Purity and impurities:

The purity is quantifiable.

The impurities are quantifiable, and identified if feasible.

Potency and quantity:

The biological activity is measurable.

The quantity is measurable.

A well-characterized therapeutic recombinant DNA-derived and monoclonal antibody product requires proper raw material controls, process validation and controls, and sensitive and validated test methods and specifications.

As announced in the Federal Register of October 25, 1995 (60 FR 54695), FDA held a scientific workshop on December 11, 12, and 13, 1995, to discuss the definition of a well-characterized therapeutic recombinant DNA-derived and monoclonal antibody product and to identify the information necessary to characterize such products. FDA intends to consider information received at the workshop, as well as comments received in response to this proposed rule, to determine whether the definition previously given in this document should be expanded to include other categories of products that would be considered to be well-characterized, such as certain vaccines and biologic devices, e.g., test kits for screening blood.

FDA is proposing to use the phrase ''well-characterized biotechnology product,'' to describe the products that would be eligible for a single license application so that the regulatory language would accommodate such additional categories of products. FDA has not included a definition of a well-characterized biotechnology product in the proposed regulations because the agency intends to clarify the definition in a guidance document that can be more readily modified to reflect changes that may be warranted as scientific knowledge progresses. FDA specifically invites public comment on whether a definition of a well-characterized biotechnology product should be included in the regulations and, if so, what the scope of such a definition should be.

Well-characterized therapeutic recombinant DNA-derived and monoclonal antibody products that are viruses, therapeutic sera, toxins, antitoxins, vaccines, blood, blood components or derivatives, allergenic products, or analogous products applicable to the prevention, treatment, or cure of human diseases or injuries are ''biologics'' within the meaning of