(1) Loosen the screws (19) and the stop (15).

(2) Open and push the cabin sliding door aft until the roller goes past the locking pin (13) while keeping the roller (21) inside the rail (12).

(3) Move the cabin sliding door forward to bring the roller (21) into contact with the locking pin (13).

(4) Move the stop (15) as far forward as possible toward the nose of the aircraft.

(5) Mark the location of the stop (15) with respect to the rail (14).

(6) Unlock the cabin sliding door and move it forward to gain access to the screws (19).

(7) Hold the stop (15) aligned with the rail (14), and secure the stop (15) and the screws (19) at the location previously marked.

(8) Ensure that the pin (13) locking mechanism (pin) locks the cabin sliding door in the open position. If the pin does not lock the door in the open position, before further flight, repair or replace the pin with an airworthy pin.

(9) Bring the roller (22) into contact with the stop (15) of the rail (14).

(10) If the roller (21) is completely inside the rail (12) with a minimum clearance of 3 mm from the aft end of the rail (12), the cabin door is properly adjusted and no further action is required by this AD.

(11) If the roller (21) is less than 3 mm from the aft end of the rail (12), before further flight, repeat steps (1) through (10) until a minimum clearance of 3 mm is obtained.

(b) 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, Regulations Group, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Regulations Group.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Regulations Group.

(c) Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the helicopter with the sliding cabin door closed or removed to a location where the requirements of this AD can be accomplished.

(d) This amendment becomes effective on September 12, 2000.

Note 3: The subject of this AD is addressed in Direction Generale De L'Aviation Civile (France) AD T2000–285–005(A), dated June 30, 2000.

Issued in Fort Worth, Texas, on August 21, 2000.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 00–21870 Filed 8–25–00; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 00–AGL–17]

Modification of Class E Airspace; Dickinson, ND

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E airspace at Dickinson, ND. An examination of the Class E airspace for Dickinson, ND, has revealed a discrepancy in the airport reference point used for the controlled airspace legal descriptions. This action corrects that discrepancy by incorporating the current airport reference point in the Class E airspace for Dickinson Municipal Airport.

EFFECTIVE DATE: 0901 UTC, November 30, 2000.

FOR FURTHER INFORMATION CONTACT: Denis C. Burke, Air Traffic Division, Airspace Branch, AGL–520, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294-7568.

SUPPLEMENTARY INFORMATION:

History

On Friday, June 16, 2000, the FAA proposed to amend 14 CFR part 71 to modify Class E airspace at Dickinson, ND (65 FR 37725). The proposal was to modify controlled airspace extending upward from the surface to contain Instrument Flight Rules (IFR) operations in controlled airspace during portions of the terminal operation and while transiting between the enroute and terminal environments.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. Class E airspace areas designated as surface areas are published in paragraph 6002, and Class E 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 designations listed in this document will be published subsequently in the Order.

The Rule

This amendment to 14 CFR part 71 modifies Class E airspace at Dickinson, ND, to accommodate aircraft executing instrument flight procedures into and out Dickinson Municipal Airport. The area will be depicted on appropriate aeronautical charts.

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. Therefore, this 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 will only affect air traffic procedures and air navigation, it is certified that this rule 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).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 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 95665, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the 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 6002 Class E airspace designated as a surface area.

* * * * *

AGL ND E2 Dickinson, ND [Revised]

Dickinson Municipal Airport, ND
(Lat 46°47′51″ N., long 102°48′ 07″ W.)

Within an 4.4-mile radius of the Dickinson Municipal Airport, and within 1.4 miles each side of the 150° bearing from the airport,

extending from the 4.4-mile radius to 7.0 miles southeast of the airport.

* * * * *

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

* * * * *

AGL ND E5 Dickinson, ND [Reviseds]

Dickinson Municipal Airport, ND
(Lat 46°47′51″ N., long 102°48′07″ W.)
Dickinson VORTAC
(Lat 46°51′36″ N., long 102°46′25″ W.)

That airspace extending upward from 700 feet above the surface within an 8.3-mile radius of the Dickinson Municipal Airport, and within 4.0 mileseach side of the 150° bearing from the airport, extending from the 8.3-mile radius to 14.0 miles southeast of the airport, and that airspace extending upward from 1,200 feet above the surface within a 225.2-mile radius of the Dickinson VORTAC extending clockwise from the Dickinson VORTAC 214° radial to the Dickinson VORTAC 093° radial.

* * * * *

Issued in Des Plaines, Illinois on August 7, 2000.

Christopher R. Blum,

Manager, Air Traffic Division, Great Lakes Region.

[FR Doc. 00–21815 Filed 8–25–00; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 640

[Docket No. 98N–0608]

Revision of Requirements Applicable to Albumin (Human), Plasma Protein Fraction (Human), and Immune Globulin (Human)

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations by removing, revising, or updating specific regulations applicable to blood derivative products to be more consistent with current practices and to remove unnecessary or outdated requirements. FDA is taking this action as part of the agency's ''Blood Initiative'' in which FDA is reviewing and revising, when appropriate, its regulations, policies, guidance, and procedures related to blood products, including blood derivatives.

DATES: This rule is effective September 27, 2000.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 14, 1999 (64 FR 26282), FDA published a direct final rule to amend the biologics regulations in part 640 (21 CFR part 640) by removing, revising, or updating specific regulations applicable to blood derivative products to be more consistent with current practices and to remove unnecessary or outdated requirements. FDA issued these amendments directly as a final rule because the agency believed they were noncontroversial and that there was little likelihood that there would be comments opposing the rule. In the **Federal Register** of May 14, 1999 (64 FR 26344), FDA published a companion proposed rule under FDA's usual procedures for notice and comment in the event the agency received any significant adverse comments to the direct final rule. FDA received three significant adverse comments during the comment period, and the agency has considered these comments in developing the final rule.

In the **Federal Register** of March 14, 2000 (65 FR 13678), FDA published a direct final rule with a confirmation in part and technical amendment. The document confirmed those provisions for which there were no adverse comments. This final rulemaking responds to those proposed provisions for which there were significant adverse comments.

II. Responses to Comments on the Proposed Rule

A. Proposed § 640.81(e)

The proposed changes to § 640.81(e) were: (1) The insertion of the word ''continuously,'' to clarify that the heating process shall be continuous for the time and at the temperature specified in the regulations and (2) the removal of an extraneous degree sign.

One comment did not object to the proposed changes to § 640.81(e), but it recommended deletion of the sentence that currently precedes the sentence for which the changes are proposed. That sentence reads: ''Heating of the final containers of Albumin (Human) shall begin within 24 hours after completion of filling.'' The comment also stated that the proposed rule should be broadened to allow for heat treatment to occur in bulk during the manufacturing process.

FDA disagrees with the comment. Even though the comment did not address the proposed rule, but rather the regulation as it currently exists, the agency has considered the comment and the arguments listed in support of the recommended deletion and/or broadening. The comment listed several potential advantages of heating in bulk over heating in the final containers. These included better control and monitoring, obviation of the need for a water bath and the attendant potential microbial contamination of the product, and diminished leaching of contaminants from the containers. The comment noted that heating in bulk would allow the product to be filled in a post-viral-inactivation filling suite.

Despite these theoretical advantages, the agency does not find that they provide sufficient assurance of safety equal to or greater than that provided by the current process to warrant deleting this portion of the regulation. Furthermore, the agency is not aware that any of the disadvantages of the current process implied by the comment cannot be overcome by appropriate process validation and adherence to current good manufacturing practice.

Nothing in the current regulation or the proposed rule precludes heat treatment in bulk during the manufacturing process for Albumin (Human), provided that it is conducted according to current good manufacturing practice and described in an approved Biologics License Application (BLA). An applicant who wishes to include such a step in the manufacture of Albumin (Human) should describe it in a BLA or Biologics License Supplement that addresses such matters as validation of the process and demonstration that the treatment does not affect adversely the characteristics of the product, including its purity, safety, and stability.

However, the agency has concluded that heat treatment in bulk, even for 10 to 11 hours at 60±0.5 °C, does not permit the manufacturer to forgo heating Albumin (Human) in the final containers, as prescribed in § 640.81(e). This requirement is intended to minimize the occurrence of viral transmission by albumin-containing products (Ref. 1).

B. Proposed § 640.81(f)

The proposed changes to § 640.81(f) would clarify the acceptable amounts of stabilizers that must be present in Albumin (Human) and Plasma Protein Fraction (Human) to reflect the amounts of those stabilizers that are currently used in these products.

One comment objected to the proposed quantity of sodium caprylate per gram (/g) of protein and