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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 00–ACE–26]

Amendment to Class E Airspace; Pella, IA

AGENCY: Federal Aviation Administration, DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This document confirms the effective date of a direct final rule which revises Class E airspace at Pella, IA.

DATE: The direct final rule published at 65 FR 46240 is effective on 0901 UTC, January 25, 2001.

FOR FURTHER INFORMATION CONTACT: Kathy Randolph, Air Traffic Division, Airspace Branch, ACE–520C, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329–2525.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on September 18, 2000 (65 FR 56240). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on January 25, 2001. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Issued in Kansas City, MO, on November 30, 2000.

N.J. Lyons, Jr.,

Manager, Air Traffic Division, Central Region.

[FR Doc. 00–31645 Filed 12–11–00; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 660

[Docket No. 00N–1586]

Revision to Requirements for Licensed Anti-Human Globulin and Blood Grouping Reagents

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations applicable to microbiological controls for licensed Anti-Human Globulin (AHG) and Blood Grouping Reagents (BGR). FDA is amending the regulations to remove the requirements that the products be sterile. FDA is publishing this direct final rule because the requirement that these products be sterile is not necessary for the products to be safe, pure, and potent. FDA is issuing these amendments directly as a final rule because they are noncontroversial and there is little likelihood that FDA will receive any significant comments opposing the rule. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule under FDA's usual procedures for notice and comment in the event the agency receives any significant adverse comments. If FDA receives any significant adverse comment that warrants terminating the direct final rule, FDA will consider such comments on the proposed rule in developing the final rule.

DATES: This rule is effective June 11, 2001. Submit written comments on or before February 26, 2001. If FDA receives no significant adverse comments during the specified comment period, the agency intends to publish a confirmation document on or before the effective date of this direct final rule confirming that the direct final rule will go into effect on June 11, 2001. If the agency receives any significant adverse comment during the comment period, FDA intends to withdraw this direct final rule by publication in the **Federal Register** before the effective date of this direct final rule.

ADDRESSES: Submit written comments on the direct final rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

AHG and BGR are used primarily for testing human blood for the detection of red cell antigens and antibodies. As defined in 21 CFR 660.20, BGR is a product that comes from blood, plasma, serum, or protein-rich fluids and consists of an antibody-containing fluid containing one or more of the blood grouping antibodies listed in 21 CFR 660.28(d).

Under 21 CFR 660.50, AHG is a serum or protein-rich fluid that consists of one or more antiglobulin antibodies identified in 21 CFR 660.55(d). AHG and BGR are biological products as defined in section 351 of the Public Health Service Act (PHS ACT) (42 U.S.C 262). These products are also devices, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321), and fall within the definition of in vitro diagnostic (IVD's) products in § 809.3(a) (21 CFR 809.3(a)).

AHG and BGR must meet the licensing requirements of section 351 of the PHS Act and the regulations in parts 600 through 660 (21 CFR parts 600 through 660). Section 351 of the PHS Act, requires that a license applicant demonstrate that the biological product that is the subject of the application is safe, pure, and potent, and that the manufacturing facilities are designed to assure that the biological product continues to be safe, pure, and potent.

AHG and BGR are also medical devices and in vitro diagnostic products as defined in § 809.3(a) and therefore are subject under the act and 21 CFR 809.20(b) to the requirements in the quality system regulation (QSR) in part