

(iv) to the best of the applicant's knowledge and belief, the estimates required by paragraph (g)(4) of this section are reasonable; and

(v) the applicant has no knowledge of any other information not described in the application which is inconsistent with these conclusions and estimates;

(8) A statement by the purchaser, under oath, to the best of the purchaser's knowledge or belief, that:

(i) the price prescribed in § 271.702(c)(1) is necessary to provide a reasonable incentive for the performance of the production enhancement work; and

(ii) but for the availability of the price prescribed in § 271.702(c)(1), the production enhancement work would not have been performed or will not be performed; and

(9) If the jurisdictional agency so requires, certified copies of records upon which the applicant relied, including copies of the jurisdictional agency's official files.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 610, 660

[Docket No. 80N-0049]

Leukocyte Typing Serum; Revocation of Additional Standards; Transfer of Responsibility From the Bureau of Biologics to the Bureau of Medical Devices

AGENCY: Food and Drug Administration.
ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) has determined that Leukocyte Typing Serum, a licensed biological product and also a medical device, is appropriately and efficiently regulated under the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act. The agency concludes that, in light of the regulatory controls of the Amendments, the product should no longer be subject to the biologics licensing requirements of the Public Health Service Act. Consistent with this determination the agency believes that compliance with the additional standards for Leukocyte Typing Serum prescribed in FDA's regulations should no longer be required for the manufacture of the product, and proposes that these standards be revoked.

DATES: Comments by September 30, 1980. The proposed effective date of the final rule is 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Rm. 4-62, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Richard E. Fisher, Bureau of Biologics (HFB-820), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306; or William C. Dierksheide, Bureau of Medical Devices (HFK-440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7114.

SUPPLEMENTARY INFORMATION: Leukocyte Typing Serum is an in vitro diagnostic product prepared from blood or plasma of human donors or lower animals. It contains antibodies directed against tissue antigens on the surface of human peripheral leukocytes and is a valuable reagent for identifying suitable donors for platelet and leukocyte transfusion and organ transplants.

Since December 1974, Leukocyte Typing Serum has been licensed as a biological product under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262). The current biologics regulations in §§ 660.10 through 660.15 (21 CFR 660.10-660.15) prescribe additional standards for the manufacture of Leukocyte Typing Serum.

The Medical Device Amendments (Pub. L. 94-295) to the Federal Food, Drug, and Cosmetic Act (act) (21 U.S.C. 301-392) provide the agency with significant new and expanded authority to ensure the safety and effectiveness of medical devices intended for human use. Fundamental to this authority are the control provisions relating to adulteration (section 501), misbranding (section 502), registration (section 510), classification (section 513), good manufacturing practice (section 520(f)), and other general controls referred to below. These control provisions will enable the agency to regulate adequately the safety and effectiveness of Leukocyte Typing Serum as an in vitro diagnostic product. The agency concludes that Leukocyte Typing Serum, which is both a biological product and a medical device, is more appropriately and efficiently regulated simply as a medical device under the act than under the biologics licensure requirements of section 351 of the PHS Act, and that the product no longer need be subject to the PHS Act or to the additional standards for the manufacture of Leukocyte Typing

Serum specified in §§ 660.10 through 660.15 (21 CFR 660.10-660.15).

If this proposal is published in final form, Leukocyte Typing Serum shall be subject to the general control provisions of the act, including, but not limited to, provisions relating to adulteration (section 501), misbranding (section 502), registration (section 510), classification (section 513), banned devices (section 516), notification and other remedies (section 518), records and reports (section 519), possible restrictions on sale, distribution, or use (section 520(e)), and good manufacturing practice (section 520(f)).

Section 513 of the act (21 U.S.C. 360c) requires the classification of all medical devices into one of three regulatory classes, namely: Class I (general controls), class II (performance standards), or class III (premarket approval). Leukocyte Typing Serum has not yet been classified. The agency has requested the Immunology Device Section of the Immunology and Microbiology Devices Panel to make a recommendation to FDA on the classification of this device. After receipt of the Panel's recommendation, FDA will publish for comment a proposed classification regulation and, after considering comments, a final classification regulation. If Leukocyte Typing Serum is classified into class I, it will be subject only to the general controls mentioned earlier. If it is classified into class II, the product will be subject in the future to a performance standard as well as general controls. If it is classified into class III, the product will be subject in the future to premarket approval as well as general controls.

If a final regulation based on this proposal is made effective, manufacturers of Leukocyte Typing Serum will be required to register with the Bureau of Medical Devices, Food and Drug Administration, pursuant to § 807.20 (21 CFR 807.20) and section 510 of the act (21 U.S.C. 360). Manufacturers of the product shall continue to be subject to the labeling requirements for in vitro diagnostic reagents prescribed in § 809.10 (21 CFR 809.10) and the good manufacturing practice regulation in Part 820 (21 CFR Part 820). The agency believes that these and other general controls applicable to medical devices are sufficient to ensure the safety and effectiveness of the product. The appropriate regulatory status of the product will, of course, again be considered in the course of the rulemaking classifying the device.

Accordingly, the agency proposes to revoke the additional standards for the manufacture of Leukocyte Typing Serum specified in §§ 660.10 through 660.15 on

the ground that the licensure requirements of section 351 of the PHS Act are no longer necessary to ensure a safe and effective product.

Until the effective date of a final regulation based on this proposal, Leukocyte Typing Serum remains subject to the licensure requirements of section 351 of the PHS Act. If the proposal is adopted, the product will no longer require a product license; proceedings will be promptly initiated to revoke all existing licenses; and manufacturers then distributing Leukocyte Typing Serum may continue to do so without notification to the Bureau of Medical Devices. All manufacturers not distributing the product at the time of the effective date of the final regulation will be required, before beginning commercial distribution of the product, to submit to the Bureau of Medical Devices a premarket notification as described in §§ 807.81, 807.87, and 807.90 (21 CFR 807.81, 807.87, and 807.90).

On the effective date of the final regulation based on this proposal the Bureau of Medical Devices will regulate these products solely as medical devices. All questions on regulatory matters should be addressed to the Bureau of Medical Devices. The Bureau of Medical Devices will consult, as necessary, with the Bureau of Biologics on such questions. Decisions will be issued by the Bureau of Medical Devices.

The agency has determined pursuant to 21 CFR 25.24(d)(10) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or collectively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Therefore, under the Public Health Service Act (sec. 351, 58 Stat. 702, as amended (42 U.S.C. 262)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Title 21 of Chapter 21 of the Code of Federal Regulations be amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

§ 610.53 [Amended]

1. Part 610 is amended in § 610.53 *Dating periods for specific products*, in paragraph (a), by deleting the listing for "Leukocyte Typing Serum (Dried)."

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

§§ 660.10—660.15 [Revoked]

2. Part 660 is amended by revoking Subpart B—Leukocyte Typing Serum, consisting of §§ 660.10 *Leukocyte typing serum*, 660.11 *Potency tests*, 660.12 *Specificity test*, 660.13 *Processing*, 660.14 *Labeling*, and 660.15 *Samples, protocols, official release*, and reserving it for future use.

Interested persons may, on or before September 30, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20957, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rule making does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: July 21, 1980.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-22939 Filed 7-31-80; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

24 CFR Part 570

[Docket No. R-80-852]

Community Development Block Grants and Urban Development Action Grants; Conforming Amendments

AGENCY: Department of Housing and Urban Development.

ACTION: Notice of transmittal of interim rule to Congress under section 7(o) of the Department of HUD Act.

SUMMARY: Recently enacted legislation authorizes Congress to review certain HUD rules for fifteen (15) calendar days of continuous session of Congress prior

to each such rule's publication in the Federal Register. This Notice lists and summarizes for public information an interim rule which the Secretary is submitting to Congress for such review. This interim rule makes technical changes to 24 CFR Part 570 (Community Development Block Grant regulations) to conform the regulations to the Housing and Community Development Amendments of 1979.

FOR FURTHER INFORMATION CONTACT: Burton Bloomberg, Director, Office of Regulations, Office of General Counsel, 451 7th Street SW., Washington, D.C. 20410, (202) 755-6207.

SUPPLEMENTARY INFORMATION: Concurrently with issuance of this Notice, the Secretary is forwarding to the Chairman and Ranking Minority Members of both the Senate Banking, Housing and Urban Affairs Committee and the House Banking, Finance and Urban Affairs Committee the following interim rulemaking document:

24 CFR Part 570—Community Development Block Grants and Urban Development Action Grants—Conforming Amendments

(Sec. 7(o) of the Department of HUD Act, 42 U.S.C. 3535(o), Section 324 of the Housing and Community Development Amendments of 1978)

Issued at Washington, D.C., July 25, 1980.

Moon Landrieu,
Secretary, Department of Housing and Urban Development.

[FR Doc. 80-23170 Filed 7-31-80; 8:45 am]

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24 CFR Part 570

[Docket No. R-80-849]

Community Development Block Grants; Innovative Grants Program; Transmittal of Interim Rule to Congress

AGENCY: Department of Housing and Urban Development.

ACTION: Notice of transmittal of interim rule to Congress under section 7(o) of the Department of HUD Act.

SUMMARY: Recently enacted legislation authorizes Congress to review certain HUD rules for fifteen (15) calendar days of continuous session of Congress prior to each such rule's publication in the Federal Register. This Notice lists and summarizes for public information an interim rule which the Secretary is submitting to Congress for such review. This interim rule sets forth complete and explicit guidelines for prospective applicants in the Innovative Grants