Medicine (21 CFR 5.83), Part 558 is amended in § 558.325 by revising paragraph (b)(3) to read as follows:

§ 558.325 Lincomycin.

* * * * *

(b) * * *

(3) Premix level of 50 grams per pound has been granted to No. 000009 in § 510.600(c) of this chapter for use as provided in paragraph (f)(1) and (2) of this section.

* * * * *

Effective date. This regulation is effective *August 10, 1982.*

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: August 4, 1982.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

[FR Doc. 82-21635 Filed 8-9-82; 8:45 am]

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21 CFR Parts 610 and 660

[Docket No. 80N-0049]

Leukocyte Typing Serum; Revocation of Additional Standards

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking the additional standards for Leukocyte Typing Serum. The agency has determined that Leukocyte Typing Serum should be delicensed and regulated under the 1976 Medical Device amendments to the Federal Food, Drug, and Cosmetic Act. Accordingly, the agency is revoking the additional standards for Leukocyte Typing Serum that were codified under §§ 660.10 through 660.15 (21 CFR 660.10 through 660.15) of the biologic regulations.

EFFECTIVE DATES: Effective September 9, 1982. Labeling requirements for currently licensed Leukocyte Typing Serum products shall become effective September 12, 1983.

FOR FURTHER INFORMATION CONTACT: Joseph Wilczek, National Center for Drugs and Biologics (HFB-620), 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: In the Federal Register of August 1, 1980 (45 FR 51226), FDA proposed to revoke the additional standards for Leukocyte Typing Serum. Leukocyte Typing Serum, prepared from blood or plasma of human donors or lower animals and containing antibodies for identification of human leukocyte antigens, is an in vitro diagnostic product as defined under § 809.3(a) (21 CFR 809.3(a)) of the medical device regulations. The agency proposed to revoke the additional standards for Leukocyte Typing Serum, described under §§ 660.10 through 660.15, on the basis that the product is appropriately regulated under the Federal Food, Drug, and Cosmetic Act as amended by the Medical Device Amendments of 1976 (21 U.S.C. 301 et seq.) and that the product should no longer be subject to the biologics licensing requirements of the Public Health Service Act (42 U.S.C. 262).

Interested persons were given until September 30, 1980, to submit written comments regarding the proposed rule. Three letters were received, each of which supported the proposed rule change.

Accordingly, the agency is removing Leukocyte Typing Serum (Dried) from the dating period requirements under § 610.53 (21 CFR 610.53), revoking the additional standards regulations for Leukocyte Typing Serum under §§ 660.10 through 660.15, and revoking the establishment and product licenses for Leukocyte Typing Serum. The 1977 FDA guideline for the production, testing, and lot release of Leukocyte Typing Sera is no longer in effect. Manufacturers of Leukocyte Typing Serum will be subject to the labeling requirements for in vitro diagnostic reagents under § 809.10 (21 CFR 809.10) and the applicable good manufacturing practice regulations under Part 820 (21 CFR Part 820).

FDA has reconsidered its intention stated in the preamble to the August 1, 1980 proposal that the Bureau of Medical Devices be the lead bureau for regulating these products. In a Federal Register notice of April 9, 1982 (47 FR 15412), FDA announced the availability of a new working agreement among the FDA's Bureaus of Medical Devices, Radiological Health, and Biologics. The agreement outlines the division among these Bureaus of certain regulatory responsibilities for medical devices. The Bureau of Biologics is designated as the lead Bureau in FDA for regulating certain medical devices, including Leukocyte Typing Serum. In a subsequent Federal Register notice of June 22, 1982 (47 FR 26913), FDA announced the merger of the Bureaus of Drugs and Biologics into the National Center for Drugs and Biologics (NCDB). Under this merger the former Bureau of Biologics is now the Office of Biologics within NCDB.

Because the expertise on Leukocyte Typing Serum is in the Office of Biologics, the agency believes that the Office of Biologics should continue the lead in regulating these products. Therefore, although manufacturers will be required to register with the Bureau of Medical Devices, all questions on regulatory matters should continue to be addressed to the Office of Biologics.

Manufacturers should register and list Leukocyte Typing Sera under Part 807 (21 CFR Part 807) rather than Part 607 (21 CFR Part 607). Manufacturers have 30 days from the effective date of this regulation in which to register under Part 807. See 21 CFR 807.20. Premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) is not required for the continued distribution of Leukocyte Typing Sera that is currently marketed under licensure. Distribution of currently licensed products bearing labeling required under §§ 660.14 and 610.60 through 610.62 (21 CFR 660.14 and 610.60 through 610.62) may continue for up to 12 months after the effective revocation date of the product licenses. In addition, submission of samples and protocols for lot release is no longer required.

The economic impact of this rule has been assessed in accordance with Executive Order 12291. The rule will relieve manufacturers of all current licensing restrictions for Leukoycte Typing Serum. Two manufacturers will need to make minor labeling changes, but will have 1 year after the effective date of the rule to make these revisions. The rule is not expected to increase the cost of the products. Marketing of these products, and perhaps introduction of these products by additional manufacturers, will be facilitated because current licensing restrictions are being revoked. Therefore, the agency concludes that the rule does not warrant designation as a major rule under any of the criteria specified under section 1(b) of Executive Order 12291.

The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because the proposed rule was issued prior to January 1, 1981, and is therefore exempt.

List of Subjects in 21 CFR Parts 610 and 660

Biologics, Labeling.

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

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 5.10), Parts 610 and 660 are amended as follows:

§ 610.53 [Amended]

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

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

§§ 660.10–660.15 [Removed]

2. Part 660 is amended by removing 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.

Effective dates. This regulation is effective September 9, 1982. Labeling requirements for currently licensed Leukocyte Typing Serum products shall become effective September 12, 1982.

(Sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262))

Dated: July 22, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-21634 Filed 8-9-82; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 261

[DOD Directive 1015.3]

Armed Services Military Clubs and Package Stores

AGENCY: Office of the Secretary, DOD.

ACTION: Final rule.

SUMMARY: The Department of Defense (DOD) has revised its regulations on alcoholic beverage control to provide policy and assign responsibilities to heads of DOD Components and DOD commanders for the operation of military clubs and package stores of the Army, Navy, Air Force, and Marine Corps. This rule incorporates regulatory requirements mandated by Congress and provides uniformity with related rules.

EFFECTIVE DATE: This rule [DOD Directive 1015.3] was approved and signed by the Deputy Secretary of Defense on May 14, 1982, and is effective as of that date.

FOR FURTHER INFORMATION CONTACT: Major Arpad A. Spurgyi, Office of the Deputy Assistant Secretary of Defense (Military Personnel and Force Management), Washington, D.C. 20301, telephone 202-697-9525.

SUPPLEMENTARY INFORMATION: In FR Doc. 73-10682, appearing in the Federal Register (38 FR 14167) on May 30, 1973, this Office of the Secretary of Defense (OSD) published Part 261 of this title, under "Alcoholic Beverage Control." OSD has revised this Part and is reissuing it under the new subject title indicated above. Incorporated in § 261.4, below, is an excerpt from DOD 1015.3-R[1] that deals specifically with DOD cooperation with local, state, and federal officials.

List of Subjects in 32 CFR Part 261

Alcohol and alcoholic beverages, Armed Forces.

Accordingly, Chapter 1, 32 CFR Part 261, is revised to read as follows:

PART 261—ARMED SERVICES MILITARY CLUB AND PACKAGE STORES

Authority: 50 U.S.C. Appendix, Section 473, section 6.

§ 261.1 Purpose.

This Part incorporates DOD Directive 1330.15, "Alcoholic Beverage Control," May 4, 1964, (which is hereby cancelled), provides policy and assigns responsibilities for the operation of military clubs and package stores of the Army, Navy, Air Force, and the Marine Corps; and authorizes the development, publication, and maintenance of DOD 1015.3-R, "Armed Services and Military Club and Package Store Regulations."

§ 261.2 Applicability.

The provisions of this P A R T apply to the Office of the Secretary of Defense and the Military Departments, including DOD activities with clubs and package stores designated as a service (executive agent) responsibility, and Defense Agencies (hereinafter referred to as "DOD Components"). The term "Military Services," as used herein, refers to the Army, Navy, Air Force, and Marine Corps.

§ 261.3 Policy.

It is the policy of the Department of Defense that Armed Services military clubs and package stores be established as an essential part of the DOD Morale, Welfare and Recreation (MWR) program. In addition, the Department of Defense shall establish controls and procedures governing the sale of alcoholic beverages in these clubs and package stores. Affirmative measures shall be taken to provide character guidance, emphasizing the harmful effects of the immoderate use of alcohol. Chaplains and local community and national organizations shall assist in this effort. Military clubs shall provide dining, essential feeding (where required), and social programs, services, and facilities to eligible patrons. Package stores shall provide the sale of alcoholic beverages purchased for off-premise consumption by authorized patrons, and also provide a resale source of alcoholic beverages for all other authorized activities under 50 U.S.C., Appendix, Section 473. The establishment, management, and control of club and package store nonappropriated fund instrumentalities (NAFIs) shall be in accordance with DOD Directive 1015.1, "Establishment, Management, and Control of Nonappropriated Fund Instrumentalities (NAFIs)," August 19, 1981.

§ 261.4 Procedures.

Procedures and guidance are prescribed in DOD 1015.3-R, "Armed Services Military Club and Package Store Regulations." Chapter 4, section C., of this guidance reads as follows:

"C. *COOPERATION.* The Department of Defense shall cooperate with local, state, and federal officials to the degree that their duties relate to the provisions of this chapter. However, the purchase of all alcoholic beverages for resale at any camp, post, station, base, or other DOD installation within the United States shall be in such a manner and under such conditions as shall obtain for the government the most advantageous contract, price and other considered factors. These other factors shall not be construed as meaning any submission to state control, nor shall cooperation be construed or represented as an admission of any legal obligation to submit to state control, pay state or local taxes, or purchase alcoholic beverages within geographical boundaries or at prices or from suppliers prescribed by any state."

§ 261.5 Responsibilities.

(a) The *Assistant Secretary of Defense (Manpower, Reserve Affairs,* and Logistics) (ASD(MRA&AL)) shall:

(1) Provide guidance and direction in carrying out the provisions of this Part; and shall establish, maintain, and disestablish clubs and package stores in accordance with DOD Directive 1015.1.

(2) Delegate executive agent responsibilities consistent with DOD Directive 1015.1.

[1] Copies may be obtained from the U.S. Naval Publications and Forms Center, 5801 Tabor Avenue, Philadelphia, PA 19120.