which are required by these regulations; and (ii) a listing of each lot of reprocessed material incorporated into the lot submitted for release including the lot number, date of manufacture, and the proportion of each reprocessed lot in the final product. A reprocessed lot is all or a portion of reprocessed material rejected by the Bureau of Biologics or withdrawn from distribution or release action by the manufacturer.

(b) *Official release.* A lot of Blood Grouping Serum shall not be issued by the manufacturer until written notification of official release of the lot is received from the Director, Bureau of Biologics, Food and Drug Administration.

Effective date. These regulations shall be effective December 6, 1977, except for the labeling requirtments, which shall be effective August 7, 1978.

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

Dated: August 26, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-29206 Filed 10-6-77; 8:45 am]

[4110-03]

[Docket No. 77N-0264]

PART 650—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR DERMAL TESTS

Bulk Tuberculin, PPD

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: This rule reduces the requirement for volume of bulk tuberculin, PPD, to be submitted for testing. The current required volume exceeds the amount used in testing. This amendment will eliminate surplus material and reduce cost to the agency.

EFFECTIVE DATE: October 7, 1977.

ADDRESS: Written comments to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Al Rothschild, Bureau of Biologics (HFB-620), Food and Drug Administration, Department of Health, Education, and Welfare, 8800 Rockville Pike, Bethesda, Md. 20014 (301-443-1920).

SUPPLEMENTARY INFORMATION: The Food and Drug Administration is conducting a continuing review of the existing regulations governing biological products to ensure that the criteria of safety, purity, potency, and effectiveness established by such regulations are updated to reflect current requirements for licensed products. Consistent with the review, the Commissioner of Food and Drugs is amending the regulations to reduce the volume of bulk tuberculin, PPD, to be submitted to the Bureau of Biologics for testing—from no less than 20 milliliters to a volume of no less than 6 milliliters.

The biologics regulations in § 650.11 (c) (2) (ii) require that manufacturers of tuberculin submit for each lot manufactured a sample totaling no less than 20 milliliters of bulk tuberculin to the Bureau of Biologics for testing.

The Commissioner has reviewed the current requirement and finds that the prescribed volume of bulk tuberculin, PPD, required to be submitted significantly exceeds that actually used for testing. The Commissioner has determined that the current requirement is wasteful; unnecessarily increases the cost to the Food and Drug Administration in processing, storing, and disposing of samples; and imposes an undue hardship on manufacturers in loss of the product. Accordingly, the Commissioner is revising § 650.11(c) (2) (ii) to prescribe an appropriate smaller volume of bulk tuberculin, PPD, required to be submitted for testing.

Therefore, under the Public Health Service Act (section 351, 58 Stat. 702, as amended (42 U.S.C. 262) and the Administrative Procedure Act (sections 4, 10, 60 Stat. 238 and 243, as amended (5 U.S.C. 553, 702 et seq.)), and under authority delegated to the Commissioner (21 CFR 5.1), Part 650 is amended by revising § 650.11(c) (2) (ii) to read as follows:

§ 650.11 Potency tests.

* * * * *

(c) * * *

(2) * * *

(ii) A total of no less than 6 milliliters of bulk tuberculin.

* * * * *

Under the Administrative Procedure Act (5 U.S.C. 553 (b) and (d)), the Commissioner concludes that notice, public procedure, and delayed effective date are unnecessary for the amendment of § 650.11 because it does not impose an additional duty or burden on any person but rather relieves unnecessary requirements and clarifies the intent of the regulations.

Effective date: October 7, 1977.

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

Dated: September 28, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-29335 Filed 10-6-77;8:45 am]

[4410-01]

CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

Placement of Lorazepam in Schedule IV

AGENCY: Drug Enforcement Administration.

ACTION: Final rule.

SUMMARY: This is a rule to place the drug lorazepam into schedule IV of the Controlled Substances Act. This rule is issued in response to a letter from the Acting Assistant Secretary for Health, Department of HEW, and after the Administrator's own study of the drug. This rule requires that the manufacture, distribution, dispensing, importation, and exportation of lorazepam be subject to controls for schedule IV controlled substances.

EFFECTIVE DATE: October 3, 1977.

FOR FURTHER INFORMATION CONTACT:

Howard McClain, Chief, Regulatory Control Division, telephone 202-382-5676.

SUPPLEMENTARY INFORMATION: A Notice was published in the FEDERAL REGISTER on Tuesday, June 28, 1977 (42 FR 32805-06) proposing that schedule IV of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 812(c)) be amended to include lorazepam. All interested persons were given until July 28, 1977 to submit their comments or objections in writing regarding this proposal.

One comment was received in response to the proposal, from the American Society of Hospital Pharmacists, which supported the proposed schedule IV placement of lorazepam.

No further comments or objections were received, nor were there any requests for a hearing, and in view thereof, and based upon the investigations and review of the Drug Enforcement Administration and upon the scientific and medical evaluation and recommendation of the Acting Assistant Secretary in behalf of the Secretary of Health, Education, and Welfare, received pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), the Administrator of the Drug Enforcement Administration finds that:

1. Based on information now available, lorazepam has a low potential for abuse relative to the drugs or other substances currently listed in schedule III;

2. Lorazepam will, upon the issuance of a New Drug Application by the FDA, have a currently accepted medical use in treatment in the United States;

3. Abuse of lorazepam may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

Therefore, under the authority vested in him by the Act and by regulations of the Department of Justice, the Administrator of the Drug Enforcement Administration hereby orders that § 1308.14(b) of Title 21 of the Code of Federal Regulations (CFR) be amended to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(b) *Depressants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is

possible within the specific chemical designation:

* * * * *

(11)	Lorazepam	2885
(12)	Mebutamate	2800
(13)	Meprobamate	2820
(14)	Methohexital	2264
(15)	Methylphenobarbital (mephobarbital)	2250
(16)	Oxazepam	2835
(17)	Paraldehyde	2585
(18)	Petrichoral	2591
(19)	Phenobarbital	2285
(20)	Prazepam	2764

* * * * *

The Food and Drug Administration issued a letter approving the New Drug Application on September 30, 1977.

Dated: October 3, 1977.

PETER B. BENSINGER,
Administrator, Drug Enforcement Administration.

[FR Doc.77-29575 Filed 10-6-77;8:45 am]

[1505-01]

Title 29—Labor

CHAPTER V—EMPLOYMENT AND TRAINING ADMINISTRATION

TEMPORARY EMPLOYMENT OF ALIENS ON GUAM

Labor Certification Process

Correction

In FR Doc. 77-26599 appearing at page 45898 in the issue for Tuesday, September 13, 1977, the following correction should be made.

On page 48900, first column, line 7, now reading, "process for occupation of Guam other", should read, "process for occupations on Guam other".

[3810-70]

Title 32—National Defense

CHAPTER I—OFFICE OF THE SECRETARY OF DEFENSE

[DoD Instruction 7730.54]

PART 114—DEPARTMENT OF DEFENSE RESERVE COMPONENTS

Common Personnel Data System

AGENCY: Office of the Secretary of Defense.

ACTION: Final rule.

SUMMARY: This rule establishes Department of Defense (DoD) policies and procedures for the Reserve Components Common Personnel Data System (RCCPDS) to meet statutory requirements. The requirements provide that adequate and current personnel records be maintained to ensure proper management and mobilization readiness of Reserve Components. This rule outlines the processes and assigns responsibilities to comply with those requirements.

EFFECTIVE DATE: September 21, 1977.

FOR FURTHER INFORMATION CONTACT:

Major Donald L. McCabe, USAF, telephone: 697-4334 or 697-0624, Office of the Deputy Assistant Secretary of Defense (Reserve Affairs), The Pentagon, Room 3C980, Washington, D.C. 20301.

SUPPLEMENTARY INFORMATION: In FR Doc. 77-22299 published in the FEDERAL REGISTER on August 3, 1977 (42 FR 39234), the Office of the Secretary of Defense published a proposed rule establishing DoD policies and procedures for the Reserve Components Common Personnel Data System (RCCPDS) to meet statutory requirements. The requirements provided that adequate and current personnel records be maintained to ensure proper management and mobilization readiness of Reserve Components. The proposed rule outlined the processes and assigned responsibilities to comply with those requirements. No substantive comments were received. Accordingly, 32 CFR Part 114 as proposed at 42 FR 39234, August 3, 1977 is formally adopted to read as set forth below.

MAURICE W. ROCHE,
Director, Correspondence and Directives, Office of the Assistant Secretary of Defense (Comptroller).

OCTOBER 4, 1977.

Sec.
114.1 Applicability and scope.
114.2 Statutory requirement.
114.3 Preservation of privacy.
114.4 Responsibilities.
114.5 Furnishing Selective Service with Information.
114.6 Effective date and implementation.

AUTHORITY: Title 10, U.S.C. section 275.

§ 114.1 Applicability and scope.

(a) The provisions of this part apply to the Office of the Secretary of Defense, the Military Departments, the Organization of the Joint Chiefs of Staff and the Defense Agencies. Additionally, the Coast Guard of the Department of Transportation has agreed to provide information in conformance with this Part.

(b) Its provisions govern all male and female officers, warrant officers, and enlisted personnel assigned to the Ready Reserve, the Standby Reserve, and the Retired Reserve. Included are reservists on active duty for training who continue their assignment with a Reserve Component.

(c) Individuals who are enlisted members of a Regular component and also have a Reserve commission should not be reported in the Reserve Components Common Personnel Data System (RCCPDS).

(d) Individuals on extended active duty who are part of the active force should not be reported.

§ 114.2 Statutory requirement.

(a) Title 10, United States Code, section 275 requires the Armed Force to maintain adequate and current personnel records of Reserve Components, which shall include each member's:

(1) Physical condition.
(2) Dependence status.
(3) Military qualifications.
(4) Civilian occupation skills.
(5) Availability for service, and such other information as the Secretary of the Military Department concerned may prescribe.

(b) *Common DoD Data Base.* A computerized common data base has been established to meet the above statutory requirement and to provide statistical tabulations of Reserve Components strengths and related data for use throughout the Department of Defense, by other Government Agencies and by the Congress, and for appropriate public release by the Assistant Secretary of Defense (Public Affairs).

(c) *Minimum data requirements.* The items of personnel data included in this reporting system partially satisfy the minimum essential data items needed to meet the statutory requirements of 10 U.S.C. Additionally, data falling within the following categories will be maintained in individual records (either in a manual or automated mode) to satisfy fully statutory requirements:

(1) Retirement Points Earnings (all point earning reservists).

(2) Retirement Authority (all retired reservists).

(3) Professional Military Education for Enlisted Members (all point earning enlisted members).

(4) Servicemen's Group Life Insurance Option Selected (all point earning reservists).

(d) *Data Maintenance Policy.* The Military Departments shall maintain only such additional items of data on an individual as necessary to (1) manage adequately their Guard and Reserve Forces, and (2) ensure mobilization readiness.

§ 114.3 Preservation of Privacy.

The requirements and procedures prescribed by the Privacy Act, 5 U.S.C. 552a, and 32 CFR Part 286a must be followed in order to safeguard the personnel data maintained in this reporting system. Individuals having access to identifiable personnel information may be held personally responsible and punishable under the law for making unauthorized disclosures.

§ 114.4 Responsibilities.

(a) The Assistant Secretary of Defense (Manpower, Reserve Affairs, and Logistics) or his designee, the Deputy Assistant Secretary of Defense (Reserve Affairs), shall be responsible for:

(1) Collecting, summarizing and publishing, on a periodic basis, the "Official Manpower Strengths and Statistics" report for the Reserve Components of the Department of Defense and, through the Office of the Assistant Secretary of Defense (Public Affairs), for public release.

(2) Providing access to the DoD Data Base to each of the Military Departments through an on-line time sharing terminal system. The Guard and Reserve Components will have access only to their portion of the data base by means of assigned passwords controlled by the Deputy Assistant Secretary of Defense (Reserve Affairs).

(b) The Secretaries of the Military Departments shall be responsible for:

(1) Implementing Directives.