not impose an additional duty or burden on any person but rather promote consistency between the additional standards and the requirement of the general biologics regulations, as amended in § 610.12. Comments are nevertheless requested by February 27, 1976, and may justify further modification of this procedure.

The Commissioner has carefully considered the inflation impact of this regulation and no major inflation impact has been found, as defined in Executive Order 11821, OMB Circular A-107, and interim guidelines issued April 1, 1975, by the Department of Health, Education, and Welfare.

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 (21 CFR 2.120), Subchapter F of Chapter I of Title 21, of the Code of Federal Regulations is amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

§ 610.12 [Amended]

1. In § 610.12 *Sterility* delete paragraph (g) (5) and redesignate existing paragraphs (g) (6) through (10) as (g) (5) through (9).

PART 630—ADDITIONAL STANDARDS FOR VIRAL VACCINES

2. In § 630.74 by revise paragraphs (a) and (b) to read as follows:

§ 630.74 Tests for safety.

(a) *Clostridium tetani.* A 10 milliliter sample representative of the homogenized viral harvest or pool of several viral harvests shall be tested for the presence of *Clostridium tetani* in the following manner: Prior to the addition of preservatives other than glycerin, the test sample shall be inoculated into freshly heated Fluid Thioglycollate Medium using a ratio of inoculum to culture medium sufficient for optimal bacterial growth. The test vessels shall be incubated at 35° to 37° C and observed daily for at least 9 days of evidence of basterial growth. Within 24 to 48 hours of an indication that there may be anaerobic growth, 1.0 milliliter samples from each test vessel showing growth shall be injected subcutaneously into each of at least three mice, each weighing not more than 20 grams, or into each of at least three guinea pigs, each weighing not more than 350 grams, or into both such groups of mice and guinea pigs. The animals shall be observed daily for 6 days for signs of tetanus. If the animals show no signs of tetanus, additional groups of the same types and numbers of animals shall be injected 9 days after the original planting, with 1.0 milliliter samples from each test vessel showing growth. The animals shall be observed daily for 6 days for signs of tetanus. If any animals die within 3 days without having shown signs of tetanus, the test shall be repeated within 18 hours of the deaths with 0.1 milliliter samples of the culture from which that animal was inoculated. Samples from the culture shall be injected into each of three additional test animals of the same species and the animals observed daily for 6 days. If there is any evidence of the presence of *Clostridium tetani*, the viral harvest may not be used in the manufacture of Smallpox Vaccine.

(b) *Anaerobes.* Prior to the addition of preservatives other than glycerin, a 10 milliliter sample representative of the homogenized viral harvest or pool of viral harvests shall be inoculated into freshly heated Fluid Thioglycollate Medium using a ratio of inoculum to culture medium sufficient for optimal bacterial growth. The test vessels shall be held at 65° C for 1 hour, then incubated at 35° to 37° C and observed daily for 10 days for evidence of bacterial growth. Within 24 to 48 hours of the first appearance of anaerobic growth, 1.0 milliliter samples from each vessel showing growth shall be inoculated subcutaneously into each of at least three mice weighing not more than 20 grams and three guinea pigs weighing not more than 350 grams. Additional groups of animals shall be inoculated 9 days after the original planting if growth appears and provided the first set of test animals is negative. All test animals shall be observed daily for at least 6 days. If there is any evidence of the presence of heat resistant pathogenic anaerobes, the viral harvest may not be used in the manufacture of Smallpox Vaccine.

* * * * *

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

3. In § 640.2 revise paragraph (b) to read as follows:

§ 640.2 General requirements.

* * * * *

(b) *Periodic check on sterile technique.* Were blood is collected in an open system, that is, where the blood container is entered, at least one container of such blood that upon visual examination appears normal shall be tested each month between the 18th and 24th day after collection, as a continuing check on technique of blood collection, as follows: The test shall be performed with a total sample of no less than 10 milliliters of blood and a total volume of Fluid Thioglycollate Medium 10 times the volume of the sample of blood. The test sample shall be inoculated into one or more test vessels in a ratio of blood to medium of 1 to 10 for each vessel, mixed thoroughly, incubated for 7 to 9 days at a temperature of 30° to 32°C, and examined for evidence of growth of microorganisms every workday throughout the test period. On the third, fourth, or fifth day, at least a milliliter of material from each test vessel shall be subcultured in additional test vessels containing the same culture medium and in such proportion as will permit significant visual inspection, mixed thoroughly, incubated for 7 to 9 days at a temperature of 30° to 32° C, and examined for evidence of growth of microorganisms every workday throughout the test period. If growth is observed in any test vessel, the test shall be repeated to rule out faulty test procedure, using another sample of blood from either, (1) the container from which the initial test sample was taken; (2) the residual cells or plasma from that blood; or (3) two different containers of blood, each 18 to 24 days old and each tested separately. The formula for Fluid Thioglycolate Medium shall be as prescribed in § 610.12(e) (1) of this chapter. Media and design of container shall meet the requirements prescribed in § 610.12(e) (2) (i) and (ii) of this chapter. In lieu of performing one test using an incubation temperature of 30° to 32° C, two tests may be performed: Each in all respects as prescribed in this paragraph, one at an incubation temperature of 18° to 22° C and one at an incubation temperature of 35° to 37° C. A different test may be performed provided that prior to the performance of such a test, a manufacturer submits data that the Commissioner of Food and Drugs finds adequate to establish that the different test is equal or superior to the test herein prescribed as a check on sterile technique, and makes the finding a matter of official record.

PART 680—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

4. In § 680.3 revise paragraph (c) (2) to read as follows:

§ 680.3 Tests.

* * * * *

(c) * * *

(2) For lots consisting of no more than 5 final containers, the final container test shall be performed in accordance with § 610.12(g) (6) of this chapter using the sample therein prescribed or using a sample of no less than 0.25 ml. of product from each final container, divided in approximately equal proportions for testing in Fluid Thioglycollate and Soybean-Casein Digest Media. The test sample in the later alternative method may be an overfill in the final container.

Effective date. This regulation shall be effective on January 28, 1976.

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

Dated: January 21, 1976.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.76-2429 Filed 1-27-76;8:45 am]

CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

Peyote

On April 22, 1975, the Administrator of the Drug Enforcement Administration

issued a statement of policy and interpretation regarding peyote, a Schedule I controlled substance, and an order which provided as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(12) Peyote ---------- 7415

Meaning all parts of the plant presently classified botantically as Lophophora Williamsii Lemaire, whether growing or not; the seeds thereof; any extract from any part of such plant; and every compound, manufacture, salt, derivative, mixture or preparation of such plant, its seeds or extracts.

(Interprets 21 USC 812(c), Schedule I(c)(12))

* * * * *

This was published in the FEDERAL REGISTER on April 28, 1975 (40 FR 18426).

Subsequently, on July 3, 1975, the Acting Administrator of the Drug Enforcement Administration issued an order further amending 21 CFR § 1308.11(d) by including therein the thiophene analog of phencyclidine (40 FR 28611; July 8, 1975). In that order Section 1308.11(d) was republished to accommodate the thiophene analog of phencyclidine, and peyote, previously listed as item (12) in such section, was redesignated therein as item (15). However, upon its redesignation the above-referenced language of the April 28, 1975 order defining peyote was inadvertently omitted.

Therefore, under the authority vested in the Attorney General by section 201 (a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a)), and delegated to the Administrator of the Drug Enforcement Administration by § 0.100 of Title 28 of the Code of Federal Regulations, and further, having been duly designated as Acting Administrator by Order No. 607-75 of the Attorney General, dated May 30, 1975, in accordance with the authority stated therein, and pursuant to the authority delegated to the Acting Administrator by § 0.132(d) of Title 28 of the Code of Federal Regulations, the Acting Administrator hereby orders that § 1308.11 of Title 21 of the Code of Federal Regulations be amended to read:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(15) Peyote ---------- 7415

Meaning all parts of the plant presently classified botanically as Lophophora Williamsii Lemaire, whether growing or not; the seeds thereof; any extract from any part of such plant; and every compound, manufacture, salt, derivative, mixture or preparation of such plant, its seeds or extracts.

(Interprets 21 USC 812(c), Schedule I(c)(12))

This order is effective on the date of its issuance.

Dated: January 21, 1976.

HENRY S. DOGIN,
Acting Administrator,
Drug Enforcement Administration.

[FR Doc.76-2496 Filed 1-27-76;8:45 am]

Title 41—Public Contracts and Property Management

CHAPTER 8—VETERANS ADMINISTRATION

PART 8-14—INSPECTION AND ACCEPTANCE

Inspection at Destination

Part 8-14, Inspection and Acceptance, Chapter 8, Title 41, Code of Federal Regulations, is amended as set forth below.

The supply depots are authorized to correct packaging, packing, or marking not in accordance with contract requirements when the cost of correcting a partial receipt or projected cost of correcting total receipt does not exceed $50. Section 8-14.105-3 is amended to raise depot authorization of packaging, packing, or marking corrections to $100. In addition organizational titles have been updated and minor editorial change made to reflect agency policy of using precise terms denoting gender.

It is the general policy of the Veterans Administration to allow time for interested parties to participate in the rule making process (§ 1.12, Title 38, Code of Federal Regulations). However, the amendments herein concern agency procedure and practices. Therefore, the public rule making process is deemed unnecessary in this instance.

1. In § 8-14.105-3, paragraph (b) is revised to read as follows:

§ 8-14.105-3 Inspection at destination.

* * * * *

(b) VA supply depots will report all instances of noncompliance to the contracting officer on VA Form 10-2055, Sample Transmittal Sheet and Inspection Report. The supply depots are authorized to correct packaging, packing, or marking not in accordance with contract requirements when the cost of correcting a partial receipt or projected cost of correcting total receipt does not exceed $100. When projected costs exceed $100, authorization will be obtained from the contracting officer prior to taking corrective action. The corrections made and the actual amount to be charged to the vendor will be shown on the reverse of VA Form 10-2055.

2. In § 8-14.105-51, paragraph (b)(4) is revised to read as follows:

§ 8-14.105-51 Inspection of subsistence.

* * * * *

(b) When either the Department of Agriculture or the Department of Commerce is indicated as the inspection activity, the solicitation will also provide that the contractor is responsible for:

* * * * *

(4) Furnishing samples for inspection at his/her expense.

* * * * *

3. In § 8-14.105-53, paragraph (b) introduction and paragraph (b)(3) are revised to read as follows:

§ 8-14.105-53 Supply depot selection of samples for test.

* * * * *

(b) On items bearing lot numbers, one unit will be selected from each lot to be tested, unless otherwise specified. Contracts will require that the contractor's shipping document or packing list indicate the lot numbers of items shipped to each depot on the contract. To reduce handling and transportation costs, samples of lots received at more than one location will be submitted as follows:

* * * * *

(3) The VA Supply Depot, Bell, Calif., will submit samples from lots not received at Hines or Somerville.

* * * * *

(72 Stat. 1114, sec. 205(c), 63 Stat. 390; 38 U.S.C. 210, 40 U.S.C. 486(c))

These regulations are effective January 28, 1976.

Approved: January 22, 1976.

By direction of the Administrator.

[SEAL] ODELL W. VAUGHN,
Deputy Administrator.

[FR Doc.76-2437 Filed 1-27-76;8:45 am]

Title 49—Transportation

CHAPTER V—NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION

[Docket No. 73-3; Notice 05]

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

School Bus Passenger Seating and Crash Protection

This notice establishes a new motor vehicle safety Standard No. 222, *School Bus Seating and Crash Protection*, that specifies seating, restraining barrier, and impact zone requirements for school buses.

The Motor Vehicle and Schoolbus Safety Amendments of 1974, Pub. L. 93-492, directed the issuance of a school bus seating systems performance standard (and other standards in seven areas of vehicle performance). The NHTSA had already issued two proposals for school bus seating systems prior to enactment of the 1974 Safety Amendments (the Act) (38 FR 4776, February 22, 1973) (39 FR 27585, July 30, 1974) and subsequently published two additional proposals (40 FR 17855, April 23, 1975) (40 FR 47141, October 8, 1975). Each aspect of the requirements was fully considered in the course of this rulemaking activity. Comments received in response to the most recent proposal were limited to a few aspects of the standard.

The largest number of comments were received on the requirement that school bus passenger seats be equipped with seat belt anchorages at each seating position. The standard relies on compartmentalization between well-padded and well-constructed seats to provide occupant protection on school buses (other than van-type buses). At the same time, seat belt anchorages were proposed so that a greater measure of protection could be gained if a particular user chose to use the anchorages by installation of