likely to be read and understood by ordinary individuals under customary conditions of purchase.

Any person who will be adversely affected by the foregoing order may at any time within 30 days following the date of its publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C., 20201, written objections thereto, preferably in quintuplicate. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing, and such objections must be supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof.

Effective date. This order shall become effective 60 days from the date of its publication in the FEDERAL REGISTER, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced by publication in the FEDERAL REGISTER.

(Secs. 401, 701, 52 Stat. 1046, 1055, as amended 70 Stat. 948; 21 U.S.C. 341, 371)

Dated: March 11, 1966.

JAMES L. GODDARD,
Commissioner of Food and Drugs.

[F.R. Doc. 66-2919; Filed Mar. 18, 1966, 8:47 a.m.]

SUBCHAPTER C—DRUGS

PART 166—DEPRESSANT AND STIMULANT DRUGS; DEFINITIONS, PROCEDURAL AND INTERPRETATIVE REGULATIONS

Listing of Additional Drugs Subject to Control; Temporary Exemption From Record-Keeping Requirements

By publication in the FEDERAL REGISTER of January 18, 1966 (31 F.R. 565), the Commissioner of Food and Drugs proposed the control, under the Drug Abuse Control Amendments of 1965, of seventeen drugs having a potential for abuse because of their stimulant or depressant effect on the central nervous system or because of their hallucinogenic effect. Interested persons were invited to present their views on the proposal, on additional trade or other names which should be listed, and on combinations of controlled drugs with other drugs which, because of their lack of significant potentiality for abuse, should be considered for exemption.

Having considered the comments and suggestions filed in response to the proposal, the definitions contained in § 166.2 (21 CFR 166.2), the reasons stated in the proposal, and other pertinent information, the Commissioner has concluded that all the listed drugs in the proposal, except phenmetrazine and its salts (Preludin), should be controlled at this time. For the present phenmetrazine and its salts are not included in the list, because it has been determined that the voluminous information and data submitted, in reply to the proposal with reference to this drug and competitive anorexiants, should be given study and consideration by the Commissioner's Advisory Committee. Final determination on listing of phenmetrazine will be announced later.

On the basis of study of Food and Drug Administration files, the Commissioner exempts, by amending § 166.8(b), combinations which include the drugs listed below under § 166.3 (b) and (c) (1) from the recordkeeping requirements of section 511(d) (1) of the Federal Food, Drug, and Cosmetic Act on an interim basis until August 1, 1966, since it is found that such action would present no significant hazard to the public health. In addition, the Commissioner proposes to give prompt attention to the recommendations for exemptions submitted pursuant to the proposal of January 18, 1966.

No exemption from section 511(d) (1) of the act is necessary for hallucinogenic drugs in combination with other drugs, since combinations of the drugs in this group, listed below under § 166.3(c) (3), are legally available only as investigational drugs to be used only by qualified investigators under plans of investigations reported to the Food and Drug Administration under the act.

On the basis of comments received from various branches of the Native American Church, the Commissioner exempts the Church from the registration and recordkeeping requirements of the act for the possession of peyote for bona fide religious ceremonies. However, registration and recordkeeping are required for peyote until such time as it comes into possession of the Church.

Section 166.16(a) is changed to provide for initial inventory of drugs brought under control after February 1, 1966. Such control is necessary to maintain the continuity of records from production to dispensing to the individual drug user.

Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(v), 511, 701, 52 Stat. 1055, as amended, 79 Stat. 227 et seq.; 21 U.S.C. 321(v), 360a, 371) and under the authority delegated to the Commissioner by the Secretary of Health, Education, and Welfare (21 CFR 2.120; 31 F.R. 3008), Part 166 is amended by adding to § 166.3 new paragraphs (b) and (c) and by revising § 166.8(b) and § 166.16(a) The affected portions read as follows:

§ 166.3 Listing of drugs defined in section 201(v) of the act.

* * * * *

(b) The Commissioner has investigated and designates all drugs, unless exempted by regulations in this part, containing any amount of the following substances as having potential for abuse and habit forming because of their stimulant effect on the central nervous system:

Established name	*Some trade and other names*
d-, dl-Methamphetamine and their salts	*d-, dl*-Desoxyephedrine and their salts.

(c) The Commissioner has investigated and designates all drugs, unless exempted by regulations in this part, containing any amount of the following substances as having a potential for abuse because of their:

(1) Depressant effect on the central nervous system:

Established name	*Some trade and other names*
Chloral hydrate	Chloral.
Chlordiazepoxide and its salts.	Librium.
Diazepam	Valium.
Ethchlorvynol	Placidyl.
Ethinamate	Valmid.
Glutethimide	Doriden.
Meprobamate	Apascil, Atraxin, Biobamat, Calmiren, Cirpon, Cyrpon, Ecuanil, Equanil, Equanil LA, Harmonin, Mepantin, Mepavlon, Meproleaf, Meprosin, Meprospan, Meprotabs, Miltown, Nervonus, Neuramate, Oasil, Pameco, Panediol, Perequil, Perquietil, Pertranquil, Placidon, Probamyl, Quanil, Quilate, Sedabamate, Sedazil, Urbil, Viobamate.
Methyprylon	Noludar.
Paraldehyde	

(2) Stimulant effect on the central nervous system: [Reserved]

(3) Hallucinogenic effect:

Established name	*Some trade and other names*
DMT	Dimethyltryptamine.
LSD-25; LSD	*d*-Lysergic acid diethylamide.
Mescaline and its salts.	
Peyote	
Psilocybin; psilocibin	
Psilocyn; psilocin	

The listing of peyote in this subparagraph does not apply to non-drug use in bona fide religious ceremonies of the Native American Church; however, persons supplying the product to the Church are required to register and maintain appropriate records of receipts and disbursements of the article.

§ 166.8 Combination drugs; temporary exemption from recordkeeping requirements of section 511(d)(1) of the act.

* * * * *

(b) Drugs containing amphetamines or barbiturates or any of the controlled drugs listed in § 166.3 (b) or (c)(1), combined with other drugs, except that this exemption shall not apply to any of these drugs combined with each other.

§ 166.16 Records required to be maintained under section 511(d) of the act.

(a) *Types of records*—(1) *Initial inventory.* Section 511(d) (1) of the act requires every person engaged in manufacturing, compounding, processing, selling, delivering, or otherwise disposing of any depressant or stimulant drug, as defined in section 201(v) of the act, to prepare upon the effective date of the section a complete and accurate record of

all stocks of each such drug on hand and to keep such records for 3 years.

(i) An inventory is required as of February 1, 1966, of each drug containing any amount of barbiturate or amphetamine, unless exempted by regulation in this part.

(ii) An inventory is required of any drug on the effective date of an order issued after February 1, 1966, that designates such drug under section 201(v) of the act as a depressant or stimulant drug subject to control, unless exempted by regulation in this part.

Any person who will be adversely affected by the foregoing order may at any time within 30 days following the date of its publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C., 20201, written objections thereto, preferably in quintuplicate. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing, and such objections must be supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof.

Effective date. This order shall become effective 60 days from the date of its publication in the FEDERAL REGISTER, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced by publication in the FEDERAL REGISTER.

(Secs. 201(v), 511, 701, 52 Stat. 1055, as amended, 79 Stat. 227 et seq.; 21 U.S.C. 321 (v), 360a, 371)

Dated: March 16, 1966.

JAMES L. GODDARD,
Commissioner of Food and Drugs.

[F.R. Doc. 66-2910; Filed, Mar. 18, 1966; 8:46 a.m.]

Title 38—PENSIONS, BONUSES, AND VETERANS' RELIEF

Chapter I—Veterans Administration

PART 3—ADJUDICATION

Subpart A—Pension, Compensation, and Dependency and Indemnity Compensation

MISCELLANEOUS AMENDMENTS

1. In § 3.304, the headnote, paragraph (a), and that portion of paragraph (b) preceding subparagraph (1) are amended to read as follows:

§ 3.304 Direct service connection; wartime and peacetime.

(a) *General.* The basic considerations relating to service connection are stated in § 3.303. The criteria in this section apply only to disabilities which may have resulted from service in a period of war or service rendered on or after February 1, 1955.

(b) *Presumption of soundness.* The veteran will be considered to have been in sound condition when examined, accepted and enrolled for service, except as to defects, infirmities, or disorders noted at entrance into service, or where clear and unmistakable (obvious or manifest) evidence demonstrates that an injury or disease existed prior thereto. Only such conditions as are recorded in examination reports are to be considered as noted (38 U.S.C. 311; Public Law 89-358).

* * * * *

2. In § 3.305, the headnote and paragraph (a) are amended to read as follows:

§ 3.305 Direct service connection; peacetime service before February 1, 1955.

(a) *General.* The basic considerations relating to service connection are stated in § 3.303. The criteria in this section apply only to disabilities which may have resulted from service other than in a period of war before February 1, 1955.

* * * * *

3. In § 3.307, the headnote and paragraph (a) are amended to read as follows:

§ 3.307 Presumptive service connection for chronic or tropical disease; wartime and service on or after February 1, 1955.

(a) *General.* A chronic or tropical disease listed in § 3.309 will be considered to have been incurred in service under the circumstances outlined in this section even though there is no evidence of such disease during the period of service. No condition other than one listed in § 3.309(a) will be considered chronic.

(1) *Service.* The veteran must have served 90 days or more during a war period or after January 31, 1955. The requirement of 90 days service means active, continuous service within or extending into or beyond a war period, or which began before and extended beyond January 31, 1955, or began after that date.

(2) *Separation from service.* For the purpose of subparagraphs (3) and (4) of this paragraph the date of separation from wartime service will be the date of discharge or release during a war period, or if service continued after the war, the end of the war period. In claims based on service on or after February 1, 1955, the date of separation will be the date of discharge or release from the period of service on which the claim is based.

(3) *Chronic disease.* The disease must have become manifest to a degree of 10 percent or more within 1 year (for Hansen's disease (leprosy) and tuberculosis, within 3 years; multiple sclerosis, within 7 years) from the date of separation from service as specified in subparagraph (2) of this paragraph.

(4) *Tropical disease.* The disease must have become manifest to a degree of 10 percent or more within 1 year from date of separation from service as specified in subparagraph (2) of this paragraph, or at a time when standard accepted treatises indicate that the incubation period commenced during such service. The resultant disorders or diseases originating because of therapy administered in connection with a tropical disease or as a preventative may also be service connected (38 U.S.C. 312; Public Law 89-358).

* * * * *

4. Section 3.308 is revised to read as follows:

§ 3.308 Presumptive service connection; peacetime service before February 1, 1955.

(a) *Chronic disease.* There is no provision for presumptive service connection for chronic disease as distinguished from tropical diseases referred to in paragraph (b) of this section based on peacetime service before February 1, 1955.

(b) *Tropical disease.* In claims based on peacetime service before February 1, 1955, a veteran of 6 months or more service who contracts a tropical disease listed in § 3.309(b) or a resultant disorder or disease originating because of therapy administered in connection with a tropical disease or as a preventative will be considered to have incurred such disability in service when it is shown to exist to the degree of 10 percent or more within 1 year after separation from active service, or at a time when standard and accepted treatises indicate that the incubation period commenced during active service unless shown by clear and unmistakable evidence not to have been of service origin. The requirement of 6 months or more service means active, continuous service, during one or more enlistment periods (38 U.S.C. 333).

5. In § 3.309, those portions of paragraphs (a) and (b) preceding the list of diseases are amended to read as follows:

§ 3.309 Disease subject to presumptive service connection.

(a) *Chronic diseases.* The following diseases may be considered for service connection although not otherwise established as incurred in service if manifested to a compensable degree within the applicable time limits under § 3.307 following service in a period of war or following peacetime service on or after February 1, 1955.

* * * * *

(b) *Tropical diseases.* The following diseases may be considered for service connection as a result of tropical service, although not otherwise established as incurred in service if manifested to a compensable degree within the applicable time limit under §§ 3.307 or 3.308 following service in a period of war or following peacetime service.

* * * * *

6. Section 3.314 is revised to read as follows:

§ 3.314 Basic pension determinations.

(a) *Prior to World War I.* While pensions are granted based on service prior