is presented or displayed under customary conditions of purchase.

(d) A drug shall not be considered to be misbranded by reason of failure of its label to bear the statement "Warning—May be habit forming":

(1) If such drug is not suitable for internal use, and is distributed and sold exclusively for such external use as involves no possibility of habit formation; or

(2) If the only substance or derivative subject to section 502(d) of the act contained in such drug is chlorobutanol, which is present solely as a preservative and in a quantity not more than 0.5 percent by weight, and such drug is for parenteral use only; or

(3) If the only substance or derivative subject to section 502(d) of the act contained in such drug is chlorobutanol which is present as an analgesic or as an analgesic and a preservative in a quantity not more than 3.0 percent, and such drug contains one or more other active ingredients and is for parenteral use only.

CROSS REFERENCE: For the Spanish-language version of the required labeling statement, see § 1.108 of this chapter.

[20 F.R. 9531, Dec. 20, 1955, as amended at 27 F.R. 2798, Mar. 27, 1962; 28 F.R. 5719, June 12, 1963]

§ 165.5 Exemption of certain habit-forming drugs from prescription requirements.

The prescription-dispensing requirements of section 503(b)(1)(A) of the act are not necessary for the protection of the public health with respect to the following drugs subject to section 502(d):

(a) The following exempt narcotic preparations:

(1) Pharmaceutical preparations containing not more than 129.6 milligrams (2 grains) opium per 29.5729 cubic centimeters (1 fluid ounce) or per 28.3 grams (1 avoirdupois ounce);

(2) Pharmaceutical preparations containing not more than 16.2 milligrams (¼ grain) morphine, or any of its salts, per 29.5729 cubic centimeters (1 fluid ounce) or per 28.3 grams (1 avoirdupois ounce);

(3) Pharmaceutical preparations containing not more than 64.8 milligrams (1 grain) codeine, or any of its salts, per 29.5729 cubic centimeters (1 fluid ounce) or per 28.3 grams (1 avoirdupois ounce);

(4) Pharmaceutical preparations containing not more than 32.4 milligrams (½ grain) dihydrocodeine, or any of its salts, per 29.5729 cubic centimeters (1 fluid ounce) or per 28.3 grams (1 avoirdupois ounce);

(5) Pharmaceutical preparations containing not more than 16.2 milligrams (¼ grain) ethylmorphine, or any of its salts, per 29.5729 cubic centimeters (1 fluid ounce) or per 28.3 grams (1 avoirdupois ounce);

Provided, That the preparations described in this paragraph contain one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the preparation valuable medicinal qualities other than those possessed by the narcotic drug alone.

(b) Drugs containing chlorobutanol, intended for external use only.

(c) Epinephrine solution, 1 percent, preserved with chlorobutanol and intended for use solely as a spray.

(d) Combination drugs listed in § 166.8 (a) of this chapter as exempted from section 511 of the act.

[20 F.R. 9535, Dec. 20, 1955, as amended at 21 F.R. 5576, July 25, 1956; 32 F.R. 203, Jan. 10, 1967. Redesignated at 27 F.R. 2799, Mar. 27, 1962]

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

Sec.

AUTHORITY: The provisions of this Part 166 issued under secs. 201(v), 511, 701, 52 Stat. 1055, as amended, 79 Stat. 227 et seq; 21 U.S.C. 321(v), 360a, 371.

§ 166.1 Definitions and interpretations.

(a) The term "act" means the Federal Food, Drug, and Cosmetic Act approved June 25, 1938 (52 Stat. 1040 et seq., as amended; 21 U.S.C. 301–392).

(b) "Department" means the Department of Health, Education, and Welfare.

(c) "Secretary" means the Secretary of Health, Education, and Welfare.

(d) "Commissioner" means the Commissioner of Food and Drugs.

(e) "Person" includes individuals, partnerships, corporations, and associations.

(f) The Bureau of Drug Abuse Control is the organizational unit established within the Food and Drug Administration charged with the administration of the Drug Abuse Control Amendments of 1965 (Public Law 89–74, 79 Stat. 226 et seq.).

(g) The term "depressant or stimulant drug" means any drug which contains any quantity of:

(1) Barbituric acid or any of the salts of barbituric acid.

(2) Any derivative of barbituric acid which has been designated by the Commissioner under section 502(d) of the act as habit-forming.

(3) Amphetamine or any of its optical isomers.

(4) Any salt of amphetamine or any salt of an optical isomer of amphetamine.

(5) Any substance which the Commissioner, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system.

(6) Any substance which the Commissioner, after investigation, has found to have, and by regulation designates as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(h) The terms "manufacture, compounding, or processing of a drug," "manufacturing, compounding, or processing of a depressant or stimulant drug," and "manufacture, compound, or process any depressant or stimulant drug" as used in sections 301(q)(1), 304(a)(2)(D), and 511(a) of the act mean the manufacture, preparation, propagation, compounding, or processing of a drug by chemical, physical, biological, or by any other means, including manipulation, sampling, testing, or control procedures applied to the final product or to any part of the process. The terms include labeling, relabeling, repackaging, or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer.

(i) The term "wholesaling, jobbing, or distributing of depressant or stimulant drugs" covers any system of selling or distributing of any depressant or stimulant drug to any person who is not the ultimate user or consumer of the drug. Wholesalers include jobbers and medical supply houses who may not be required to obtain licenses as drug wholesalers under some State laws.

(j) The term "controlled substance" means those drugs or substances designated under section 201(v) of the act and the regulations thereunder as subject to the Drug Abuse Control Amendments of 1965 (Public Law 89–74, 79 Stat. 226 et seq.), and includes such substances in bulk, in finished form, semiprocessed form, in finished packages, and preparations containing any amounts of such substances.

[31 F.R. 1071, Jan. 27, 1966]

§ 166.2 Criteria applicable to terms used or defined in § 166.1.

(a) In determining whether a drug has a "stimulant effect" on the central nervous system, the Commissioner will consider, among other relevant factors, whether there is substantial evidence that the drug may produce any of the following:

(1) Extended wakefulness.

(2) Elation, exhilaration, or euphoria (exaggerated sense of well-being).

(3) Alleviation of fatigue.

(4) Insomnia, irritability, or agitation.

(5) Apprehension or anxiety.

(6) Flight of ideas, loquacity, hypomania, or transient deliria.

(b) In determining whether a drug has a "depressant effect" on the central nervous system, the Commissioner will consider, among other relevant factors, whether there is substantial evidence

that the drug may produce any of the following:

(1) Calming effect or relief of emotional tension or anxiety.

(2) Drowsiness, sedation, sleep, stupor, coma, or general anesthesia.

(3) Increase of pain threshold.

(4) Mood depression or apathy.

(5) Disorientation, confusion, or loss of mental acuity.

(c) In determining whether a drug is "habit forming," the Commissioner will consider, among other relevant factors, whether there is substantial evidence that the drug may produce any of the following:

(1) A psychological or physical dependence on the drug (compulsive use).

(2) Euphoria (exaggerated sense of well-being).

(3) Personality changes.

(4) Transient psychoses, deliria, twilight state, or hallucinoses.

(5) Chronic brain syndrome.

(6) Increased tolerance or a need or desire to increase the drug dosage.

(7) Physical dependence or a psychic dependence evidenced by a desire to continue taking the drug for the sense of improved well-being that it engenders.

(8) Pharmacological activity similar or identical to that of drugs previously designated as habit forming.

(d) In determining whether a drug has a "hallucinogenic effect," the Commissioner will consider, among other relevant factors, whether there is substantial evidence that it may produce hallucinations, illusions, delusions, or alteration of any of the following:

(1) Orientation with respect to time or place.

(2) Consciousness, as evidenced by confused states, dreamlike revivals of past traumatic events, or childhood memories.

(3) Sensory perception, as evidenced by visual illusions, synesthesia, distortion of space and perspective.

(4) Motor coordination.

(5) Mood and affectivity, as evidenced by anxiety, euphoria, hypomania, ecstasy, autistic withdrawal.

(6) Ideation, as evidenced by flight of ideas, ideas of reference, impairment of concentration and intelligence.

(7) Personality, as evidenced by depersonalization and dereallzation, impairment of conscience and of acquired social and cultural customs.

(e) The Commissioner may determine that a substance has a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect if:

(1) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community; or

(2) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or

(3) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or

(4) The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

[31 F.R. 1071, Jan. 27, 1966]

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

(a) The Commissioner designates all drugs, unless exempted by regulations in this part, containing any amount of the following substances as depressant or stimulant drugs:

(1) Barbituric acid or any salt of barbituric acid.

(2) Derivatives of barbituric acid which have been designated in § 165.1 of this chapter as habit forming pursuant to section 502(d) of the act.

(3) Dextroamphetamine, levoamphetamine, or amphetamine (racemic) or any salt of dextroamphetamine, levoamphetamine, or amphetamine (racemic). Amphetamine is known chemically as *d-*, *l-*, or *dl-*α-methylphenethylamine. It has been declared by such designations

as *d*-amphetamine, *l*-amphetamine, or *dl*-amphetamine followed by the name of the salt. The following is a partial list of amphetamine products:

Established name	*Some trade or other names*
Amphetamine phosphate	Actemin, Aktedron, Amphate, Biphetamine, Dietamine, Monophos, Profetamine Phosphate, Racephen, Raphetamine Phosphate.
Amphetamine salts or optical isomers of amphetamine salts.	
Amphetamine sulfate	Alentol, Amphoids-S, Benzedrine Sulfate, Linampheta, Psychoton, Simpamina, Amphedrine Sulfate.
Dextroamphetamine carboxymethylcellulose salt.	
Dextroamphetamine hydrochloride	
Dextroamphetamine phosphate	Dextro-Profetamine.
Dextroamphetamine sulfate	Adrizine, Am-Dex, D-Amfetasul, Amitrene, Amphedrine, Ampherex, Amphex, Amsustain, D-Ate Ph. 747, Betafedrina, d-Betaphedrine, Cendex Cenules, D-Citramine, Cradex, Dadex, D.A.S., Dexalone, Dexamphetamine, Dexedrine, Dex-OB, Dex-Sule, Dexten, Dextrosule, Diocurb, Domafate, Evrodex, Hetamine, Lowedex, Maxiton, Medex, Nilox, Obesedrin, Obesonil, Pellcaps, Pomadex, Simpamina-D, Sympamin, Tydex, Zamitam Plateau.
Dextroamphetamine tannate	Tanphetamin, Synatan.
Dibasic amphetamine phosphate	Bar-Dex.
Dibasic dextroamphetamine phosphate.	
Levoamphetamine	Ad-Nil, Amphedrine-M, Lavabo, Levamphetamine, Levonor.
Levoamphetamine succinate	Cydril.

(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.
Phenmetrazine and its salts	Preludin.

(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 betaine	Beta-Chlor.
Chloral hydrate	Chloral.
Chlordiazepoxide and its salts.	Librium.
Chlorhexadol	Lora.
Diazepam	Valium.
Ethchlorvynol	Placidyl.
Ethinamate	Valmid.
Glutethimide	Doriden.
Lysergic acid	
Lysergic acid amide	
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	
Petrichloral	Pericior.
Sulfondiethylmethane	Tetronal.
Sulfonethylmethane	Trional.
Sulfonmethane	Sulfonal.

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

(3) Hallucinogenic effect:

Established name	*Some trade and other names*
Bufotenine and its salts.	3-(β-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-indolol; *N,N*-dimethylserotonin; 5-hydroxy-*N*-dimethyltryptamine; mappine.
DET and its salts	*N,N*-Diethyltryptamine.
DMT	Dimethyltryptamine.
Ibogaine and its salts.	7-Ethyl-6,6α,7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5H-pyrido [1′,2′:1,2] azepino [4,5-b] indole; tabernanthe iboga.
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.

[31 F.R. 1072, Jan. 27, 1966; 31 F.R. 1240, Feb. 1, 1966, as amended at 31 F.R. 4679, Mar. 19, 1966; 31 F.R. 9492, July 13, 1966; 31 F.R. 10029, July 23, 1966; 31 F.R. 12436, Sept. 20, 1966; 32 F.R. 13403, Sept. 23, 1967]

NOTE: The provisions of § 166.3(c) as they apply to any drug because it contains any amount of chlordiazepoxide or its salts, or diazepam were stayed, 31 F.R. 7174, May 17, 1966.

§ 166.4 Procedure for the issuance, amendment, or repeal of regulations defining substauces as habit forming or as having a potential for abuse.

(a) Under the provisions of section 201(v)(2) and (3) of the act, the Commissioner, under authority delegated to him by the Secretary (§ 2.120 of this chapter), is authorized to conduct investigations and promulgate regulations for the purpose of:

(1) Designating any drug containing any quantity of any substance as habit forming because of its stimulant effect on the central nervous system; or

(2) Designating any drug containing any quantity of any substance as having a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(b) Proceedings for the issuance, amendment, or repeal of regulations issued pursuant to section 201(v) of the act are subject to the public procedures provided in section 701(e) of the act and the provisions for judicial review set forth in sections 701 (f) and (g).

(c) The procedures to be followed for filing petitions requesting the issuance, amendment, or repeal of any regulation provided for in section 201(v)(2) and (3) of the act, publication of proposals in the FEDERAL REGISTER, comments thereon, publication of orders, filing objections, requests for a public hearing, procedures governing public hearings, proposed orders, exceptions, final orders, and judicial review are set forth in Part 2 of this chapter.

[31 F.R. 1072, Jan. 27, 1966, as amended at 31 F.R. 3397, Mar. 4, 1966]

§ 166.5 Substances exempt from the definition of depressant or stimulant drug.

Any substance now included or which may be hereafter included within the classification stated in section 4731 of the Internal Revenue Code of 1954 (26 U.S.C. 4731) and marihuana as defined in section 4761 of the Internal Revenue Code of 1954 (26 U.S.C. 4761) is not a depressant or stimulant drug as defined in this part.

[31 F.R. 1072, Jan. 27, 1966]

§ 166.6 Registration of producers and certain wholesalers of depressant or stimulant drugs.

Section 510 of the act requires every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, processing, wholesaling, jobbing, selling, or distributing of any depressant or stimulant drug to register with the Commissioner his name, place of business, and all such establishments. The procedure for registration is prescribed in Part 132 of this chapter.

[31 F.R. 1072, Jan. 27, 1966]

§ 166.7 Procedures for exempting depressant or stimulant drugs from the provisious of section 511 of the act.

(a) Section 511(f)(1) of the act authorizes the Commissioner, under authority delegated to him by the Secretary (§ 2.120 of this chapter), to exempt by regulation any depressant or stimulant

drug from all or part of section 511 of the act upon a finding that regulation of the manufacture, compounding, processing, possession, or distribution of such drug is not necessary for the protection of the public health.

(b) A proposal to exempt any depressant or stimulant drug from the application of all or part of section 511 of the act may be initiated by the Commissioner or by any interested person. Any interested person may file a petition seeking such exemption, stating reasonable grounds therefor. Upon receipt of such a petition, or on his own initiative at any time, the Commissioner will publish a notice of proposed rulemaking and invite written comments. After consideration of all available data, including any comments submitted, the Commissioner may issue a regulation granting or refusing the exemption effective on a date specified therein. Whenever the Commissioner concludes, either at the time of publication of the notice of proposed rulemaking or after considering the written comments submitted, that granting or refusing the exemption requires a more thorough development of the facts than is possible in a written presentation, he may call a public hearing for that purpose. When such a public hearing is called, the procedural regulations for public hearings contained in Part 2 of this chapter shall apply. If the Commissioner for good cause finds, and incorporates the finding and a brief statement of the reasons therefor in an order, that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, he may issue the final regulation forthwith.

[31 F.R. 1072, Jan. 27, 1966, as amended at 31 F.R. 3397, Mar. 4, 1966]

§ 166.8 Combination drugs; exemptions from certain requirements of section 511 of the act.

The following combination drugs are exempt from specified requirements of section 511 of the act:

(a) The following drugs in unit dosage form, and any other drug of the quantitative composition shown below for one of the following drugs or which is the same except that it contains a lesser quantity of controlled substances, and which may be lawfully sold over-the-counter without a prescription, are exempt from the requirements of section 511 (b), (c), and (e) and the record-keeping requirements of section 511(d) (1) of the act:

EXEMPTED OVER-THE-COUNTER DRUGS

Trade name or other designation	Composition	Manufacturer or supplier
Amodrine	Tablet: Pheuobarbital, 8 mg.; aminophylline, 100 mg.; racephedrine hydrochloride, 25 mg.	G. D. Searle & Co.
Bronkaid	Tablet: Phenobarbital, 8 mg.; ephedrine sulfate, 24 mg.; glyceryl guaiacolate, 100 mg.; theophylline, 100 mg.; thenyldiamine, 10 mg.	Drew Pharmacal Co., Inc.
Bronkotab Elixir	Elixir (5 cc.): Phenobarbital, 4 mg.; ephedrine sulfate, 12 mg.; glyceryl guaiacolate, 50 mg.; theophylline, 15 mg.; chlorpheniramine maleate, 1 mg.	Breou Laboratories Inc.
Bronkotabs	Tablet: Phenobarbital, 8 mg.; ephedrine sulfate, 24 mg.; glyceryl guaiacolate, 100 mg.; theophylline, 100 mg.; thenyldiamine, 10 mg.	Do.
Primatene	Tablet: Phenobarbital, ¼ gr.; ephedrine, ⅜ gr.	Whitehall Laboratories.
Tedral	Tablet: Pheuobarbital, 8 mg.; theophylline, 130 mg. ephedrine hydrochloride, 24 mg.	Warner-Chilcott Laboratories.
Tedral anti-H	Tablet: Phenobarbital, 8 mg.; chlorpheniramine maleate, 2 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Do.
Tedral one-half Strength	Tablet: Phenobarbital, 4 mg.; theophylline, 65 mg., ephedrine hydrochloride, 12 mg.	Do.
Tedral Pediatric Suspension	Suspension (5 cc.): Pheuobarbital, 4 mg.; ephedrine hydrochloride, 12 mg.; theophylline, 65 mg.	Do.
Tedral suppositories double strength.	Suppository: Phenobarbital, 16 mg.; theophylline, 260 mg.; ephedrine hydrochloride, 48 mg.	Do.
Tedral suppositories regular strength.	Suppository: Phenobarbital, 8 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Do.
Verequad	Tablet: Pheuobarbital, 8 mg.; theophylline calcium salicylate, 130 mg.; ephedrine hydrochloride, 24 mg.; glyceryl guaiacolate, 100 mg.	Knoll Pharmaceutical Co.
Verequad	Suspension (5 cc.): Phenobarbital, 4 mg.; theophylline calcium salicylate, 65 mg.; ephedrine hydrochloride, 12 mg.; glyceryl guaiacolate, 50 mg.	Do.

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(b) The following drugs in unit dosage form, and any other drug of the quantitative composition shown below for one of the following drugs or which is the same except that it contains a lesser quantity of controlled substances, and which are restricted by law to dispensing on prescription, are exempt from the requirements of section 511 (c) and (e) and the recordkeeping requirements of section 511(d) (1) of the act:

EXEMPTED PRESCRIPTION DRUGS

Trade name or other designation	Composition	Manufacturer or supplier
A.E.A	Tablet: Amobarbital, 25 mg.; aminophylline, 120 mg.; ephedrine hydrochloride, 25 mg.	Haack Laboratories, Inc.
Aladrine	Tablet or solution (5 cc.): Secobarbital, 16 mg.; ephedrine sulfate, 8 mg.	Merit Pharmaceutical Co. Inc.
Alased	Tablet: Phenobarbital, 16.2 mg.; homatropine methylbromide, 3.6 mg.; aluminum hydroxide gel, dried, 7½ gr.; magnesium trisilicate, 2½ gr.	Norgine Laboratories, Inc.
Alcitex	Tablet: Phenobarbital, ⅛ gr.; atropine sulfate, 1/6000 gr.; calcium carbonate, 3½ gr.; magnesium carbonate, 2½ gr.; cerium oxalate, ½ gr.	Paul B. Elder Co., Inc.
Algoson	Tablet: Butabarbital sodium, 7.5 mg.; acetaminophen, 300 mg.	McNeil Laboratories Inc.
Alhydrox	Tablet: Phenobarbital, ⅛ gr.; aluminum hydroxide, 5 gr.; atropine sulfate, 1/300 gr.	Physicians Supply Co.
Alkasans	Tablet: Phenobarbital, 8.0 mg.; atropine sulfate, 0.06 mg.; kaolin-alumina gel, 500 mg.	P. J. Noyes Co.
Alsical	Powder (60 gr.): Phenobarbital, ¼ gr.; belladonna extract, ⅛ gr.; calcium carbonate, 24 gr.; magnesium trisilicate, 15 gr.; magnesium oxide, 10 gr.; aluminum hydroxide gel, dried, 10 gr.	Dorsey Laboratories.
Alubelap	Tablet: Phenobarbital, 8 mg.; aluminum hydroxide gel, dried, 300 mg.; belladonna extract, 4 mg.	Haack Laboratories Inc.
Aludrox SA Suspension	Suspension (5 cc.): Butabarbital, 8 mg.; ambutonium bromide, 2.5 mg.	Wyeth Laboratories.
Aludrox SA Tablets	Tablet: Butabarbital, 8 mg.; ambutonium bromide, 2.5 mg.	Do.
Alu-Mag	Tablet: Phenobarbital, ⅛ gr.; aluminum hydroxide gel, dried, 2½ gr.; magnesium trisilicate, 2½ gr.; belladonna leaf extract, ⅛ gr.	Norsal Laboratories, Inc.
Alumazen	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.06 mg.; magnesium trisilicate, 500 mg.; aluminum hydroxide gel, dried, 250 mg.; saccharin sodium, 0.12 mg.	The Zemmer Co.
Aluminum hydroxide, magnesium trisilicate, and kaolin with phenobarbital and atropine sulfate.	Tablet: Phenobarbital, ⅛ gr.; aluminum hydroxide, 2 gr.; magnesium trisilicate, 4 gr.; kaolin, colloidal, 2 gr.; atropine sulfate, 1/300 gr.	Buffalo Pharmaceutical Supply Corp.
Aminodrox with Phenobarbital	Tablet: Phenobarbital, 15 mg.; aminophylline, 0.1 gm.; aluminum hydroxide gel, dried, 0.12 gm.	The S. E. Massengill Co.
Aminodrox-Forte with Phenobarbital.	Tablet: Phenobarbital, 15 mg.; aminophylline, 200 mg.; aluminum hydroxide gel, dried, 250 mg.	Do.
Aminophylline and Amytal	Capsule: Amobarbital, 32 mg.; aminophylline, 0.1 gm.	Eli Lilly and Co.
Aminophylline with pentobarbital.	Suppository: Pentobarbital sodium, 100 mg.; aminophylline, 500 mg.	G. D. Searle & Co.
Aminophylline and phenobarbital.	Tablet: Phenobarbital, 15 mg.; aminophylline, 100 mg.	The Zemmer Co.
Do	Tablet: Phenobarbital, ¼ gr.; aminophylline, 100 mg.	The Blue Line Chemical Co.
Aminophylline with phenobarbital.	Tablet: Phenobarbital, 16 mg.; aminophylline, 100 mg.	H. E. Dubin Laboratories, Inc.
Do	Tablet: Phenobarbital, 15 mg.; aminophylline, 100 mg.	G. D. Searle & C.
Do	Tablet: Phenobarbital, 15 mg.; aminophylline, 200 mg.	Do.
Aminophylline with phenobarbital.	Tablet: Phenobarbital, 30 mg.; aminophylline, 200 mg.	G. D. Searle & Co.
Amobarbital and PETN	Capsule: Amobarbital, 50 mg.; pentaerythritol tetranitrate, 30 mg.	Meyer Laboratories, Inc.
Ampyrox with Butabarbital Sodium (AMPYROX).	Tablet: Butabarbital sodium, 15 mg.; scopolamine methylnitrate, 2 mg.	Paul B. Elder Co., Inc.
Ampyrox with Butabarbital Sodium, Elixir.	Elixir (5 cc.): Butabarbital sodium, 10 mg.; scopolamine methylnitrate, 1 mg.	Do.
Amsed (NAP-37)	Tablet: Phenobarbital, ¼ gr.; hyoscine hydrobromide, 0.0072 mg.; atropine sulfate, 0.024 mg.; hyoscyamine hydrobromide, 0.128 mg.	North American Pharmacal, Inc.
Amsodyne	Tablet: Phenobarbital, ¼ gr.; extract belladonna leaves, ⅛ gr.; aspirin, 5 gr.; caffeine, ¼ gr.	Paul B. Elder Co., Inc.

EXEMPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Antacia No. 3 with Phenobarbital and Atropine.	Tablet: Phenobarbital, ⅛ gr.; atropine sulfate, 1/300 gr.; calcium carbonate, 5 gr.; magnesium hydroxide, 5 gr.	Meyers and Co.
Antispasmodic	Tablet (purple): Phenobarbital, 16.2 mg.; hyoscyamine sulfate, 0.1037 mg.; homatropine methylbromide, 0.567 mg.; hyoscine hydrobromide, 0.0065 mg.	Hydrex Co., Inc.
Antispasmodic-Enzyme	Tablet: Phenobarbital, 8.1 mg.; hyoscyamine sulfate, 0.0519 mg.; homatropine methylbromide, 0.2885 mg.; hyoscine hydrobromide, 0.0033 mg.; pancreatin, 100 mg.; pepsin, 150 mg.	Do.
Antrocol	Tablet or capsule: Phenobarbital, 16 mg.; atropine sulfate, 0.324 mg.; colloidal sulfur, 22 mg.	Wm. P. Poythress & Co., Inc.
Aqualin-Plus, Children	Suppository: Pentobarbital sodium, ¾ gr.; theophylline, 1⅛ gr.	The Wm. A. Webster Co.
Aqualin-Plus No. 1	Suppository: Pentobarbital sodium, ¾ gr.; theophylline, 3¾ gr.	Do.
Aqualin-Plus No. 2	Suppository: Pentobarbital sodium, 1½ gr.; theophylline, 7½ gr.	Do.
Aqualin-Plus No. 2A	Suppository: Pentobarbital sodium, ¾ gr.; theophylline, 7½ gr.	Do.
Asmabar	Tablet: Butabarbital, 20 mg.; ephedrine sulfate, 25 mg.; theophylline hydroxide, 130 mg.	The Blue Line Chemical Co.
Asmacol	Tablet: Butabarbital, 15 mg.; aminophylline, 180 mg.; phenylpropanolamine hydrochloride, 25 mg.; chlorpheniramine maleate, 2 mg.; aluminum hydroxide gel, dried, 60 mg.; magnesium trisilicate, 60 mg.	The Vale Chemical Co., Inc.
Asperease, Modified with Phenobarbital.	Tablet: Phenobarbital, 0.008 gm.; acetylsalicylic acid, 0.5 gm.	P. J. Noyes Co.
Atropal	Tablet: Phenobarbital, ⅛ gr.; atropine sulfate, 1/500 gr.; magnesium trisilicate, 2½ gr.; aluminum hydroxide gel, dried, 2½ gr.	Neisler Laboratories, Inc.
Atrosilital	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.12 mg.; magnesium trisilicate, 0.5 gm.; saccharin sodium, 0.12 mg.	The Zemmer Co.
Banthine with Phenobarbital	Tablet: Phenobarbital, 15 mg.; methantheline bromide, 50 mg.	G. D. Searle & Co.
Barbatro No. 1	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.12 mg.	The S. E. Massengill Co.
Barbatro No. 2	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.25 mg.	Do.
Barbeloid	Tablet: Amobarbital sodium, 20 mg.; hyoscyamine sulfate, 0.125 mg.; hyoscine hydrobromide, 0.007 mg.; homatropine methylbromide, 0.5 mg.	The Vale Chemical Co., Inc.
Barbidonna Elixir	Elixir (5 cc.): Phenobarbital, 16 mg.; hyoscyamine sulfate, 0.1286 mg.; atropine sulfate, 0.0250 mg.; scopolamine hydrobromide, 0.0074 mg.	Mallinckrodt Pharmaceuticals, Division of Mallinckrodt Chemical Works.
Barbidonna Tablets	Tablet: Phenobarbital, 16 mg.; hyoscyamine sulfate, 0.1286 mg.; atropine sulfate, 0.0250 mg.; scopolamine hydrobromide, 0.0074 mg.	Do.
Barboma Elixir	Elixir (100 cc.): Phenobarbital, 0.4 gm.; homatropine methylbromide, 33.8 mg.	The Blue Line Chemical Co.
Barboma Tablets	Tablet: Phenobarbital, ¼ gr.; homatropine methylbromide, 1/48 gr.	Do.
Bardase	Tablet or elixir (4 cc.): Phenobarbital, 16.2 mg.; hyoscyamine sulfate, 0.1 mg.; hyoscine hydrobromide, 0.007 mg.; atropine, 0.020 mg.; Taka-Diastase, 162.0 mg.	Parke, Davis & Co.
Bar-Don Elixir	Elixir (30 cc.): Phenobarbital, 100 mg.; hyoscyamine hydrobromide, 0.60 mg.; hyoscine hydrobromide, 0.042 mg.; atropine sulfate, 0.12 mg.	Warren-Teed Pharmaceuticals Inc.
Bar-Don Tablets	Tablet: Phenobarbital, 16.670 mg.; hyoscyamine hydrobromide, 0.10 mg.; hyoscine hydrobromide, 0.007 mg.; atropine sulfate, 0.020 mg.	Do.
Belap No. 0	Tablet: Phenobarbital, 8 mg.; belladonna extract, 8 mg.	Haack Laboratories, Inc.
Belap No. 1	Tablet: Phenobarbital, 15 mg.; belladonna extract, 8 mg.	Do.
Belap Ty-Med	Tablet: Amobarbital, 50 mg.; homatropine methylbromide, 7.5 mg.	Do.
Belladenal	Tablet: Phenobarbital, 50 mg.; bellafoline, 0.25 mg.	Sandoz Pharmaceuticals.
Do	Elixir (15 cc.): Phenobarbital, 15.6 mg.; bellafoline, 0.078 mg.	Do.
Bellatol Elixir	Elixir (5 cc.): Butabarbital sodium, 20 mg.; tincture belladonna, 0.83 cc.	The Zemmer Co.

EXEMPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Bellergal	Tablet: Phenobarbital, 20 mg.; ergotamine tartrate, 0.3 mg.; levorotatory alkaloids of belladonna, 0.1 mg.	Sandoz Pharmaceuticals.
Do	Tablet: Phenobarbital, 40 mg.; ergotamine tartrate, 0.6 mg.; levorotatory alkaloids of belladonna, 0.2 mg.	Do.
Beplete with Belladonna Elixir.	Elixir (4 cc.): Phenobarbital, 15 mg.; vitamin B_1, 1.5 mg.; vitamin B_2, 1 mg.; vitamin B_6, 0.33 mg.; vitamin B_{12}, 1.66 mg.; niacinamide, 10 mg.; pantothenol, 0.2 mg.; belladonna alkaloids, 0.2 mg.	Wyeth Laboratories.
Bexadonna	Tablet: Phenobarbital, 16 mg.; homatropine methylbromide, 10 mg.; hyoscine hydrobromide, 0.0065 mg.; hyoscyamine sulfate, 0.1 mg.	Bexar Pharmaceuticals.
Bilamide	Tablet: Phenobarbital, ⅛ gr.; dried ox bile, 2 gr.; dehydrocholic acid, 2 gr.; homatropine methylbromide, 1/48 gr.	Norgine Laboratories, Inc.
Binitrin	Tablet: Butabarbital sodium, 15.0 mg.; nitroglycerin, 0.3 mg.; pentaerythritol tetranitrate, 10.0 mg.	The Vale Chemical Co., Inc.
Bioxatphen	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.06 mg.; bismuth subnitrate, 120 mg.; cerium oxalate, 120 mg.	The Zemmer Co.
Bismuth, belladonna, and phenobarbital.	Capsule: Phenobarbital, ¼ gr.; bismuth subgallate, 5 gr.; extract belladonna leaf, ⅛ gr.	The Bernard Co.
Buffadyne A–S	Tablet: Amobarbital, 15 mg.; aspirin, 300 mg.; phenacetin, 150 mg.; caffeine, 30 mg.; homatropine methylbromide, 2.5 mg.; aluminum hydroxide gel, 75 mg.; magnesium hydroxide, 45 mg.	Lemmon Pharmacal Co.
Buffadyne with Barbiturates	Tablet: Secobarbital sodium, 8 mg.; amobarbital, 8 mg.; aspirin, 300 mg.; phenacetin, 150 mg.; caffeine, 30 mg.; aluminum hydroxide gel, 75 mg.; magnesium hydroxide, 45 mg.	Do.
Bunesia	Tablet: Butabarbital sodium, 10 mg.; homatropine methylbromide, 2.5 mg.; magnesium hydroxide, 300 mg.	McNeil Laboratories, Inc.
Buren	Tablet: Butabarbital, 15 mg.; phenazopyridine hydrochloride, 150 mg.; scopolamine hydrobromide, 0.0065 mg.; atropine sulfate, 0.0194 mg.; hyoscyamine sulfate, 0.1037 mg.	B. F. Ascher & Co., Inc.
Burrizem	Tablet: Butabarbital sodium, 10 mg.; reserpine, 0.1 mg.; rutin, 20 mg.; mannitol hexanitrate, 30 mg.	The Zemmer Co.
Butabarbital and hyoscyamine sulfate.	Tablet or elixir (5 cc.): Butabarbital, 15 mg.; hyoscyamine sulfate, 0.125 mg.	Meyer Laboratories, Inc.
Do	Capsule: Butabarbital, 45 mg.; hyoscyamine sulfate, 0.375 mg.	Do.
Butibel	Tablet or elixir (5 cc.): Butabarbital sodium, 15 mg.; belladonna extract, 15 mg. (hyoscyamine sulfate, 0.138 mg.; hyoscine hydrobromide, 0.027 mg.; atropine sulfate, 0.067 mg.).	Do.
Butibel R–A	Tablet: Butabarbital sodium, 30 mg.; belladonna extract, 30 mg.	Do.
Butibel-Gel Suspension	Suspension (15 cc.): Butabarbital sodium, 7.5 mg.; belladonna extract, 7.5 mg. (total alkaloids 0.187 mg.); activated attapulgite, 1.5 gm.; pectin, 75 mg.	Do.
Butibel-Gel Tablets	Tablet: Butabarbital sodium, 7.5 mg.; belladonna extract, 7.5 mg. (total alkaloids 0.0935 mg.); activated attapulgite, 500 mg.; pectin, 45 mg.	Do.
Butibel-Zyme	Tablet: Butabarbital sodium, 15 mg.; belladonna extract, 15 mg. (total alkaloids 0.187 mg.); proteolytic enzyme standardized, 10 mg.; amylolytic enzyme standardized, 20 mg.; cellulolytic enzyme standardized, 5 mg.; lipolytic enzyme standardized, 100 mg.; iron ox bile (45% cholic acid), 30 mg.	Do.
Butizetic	Tablet: Butabarbital sodium, 15 mg.; acetaminophen, 200 mg.; phenacetin, 150 mg.; caffeine, 30 mg.	Do.
Cafergot P–B	Tablet: Phenobarbital sodium, 30 mg.; ergotamine tartrate, 1 mg.; caffeine, 100 mg.; levorotatory alkaloids of belladonna, 0.125 mg.	Sandoz Pharmaceuticals.
Do	Suppository: Pentobarbital, 60 mg.; ergotamine tartrate, 2 mg.; caffeine, 100 mg.; levorotatory alkaloids of belladonna, 0.25 mg.	Do.
Cal-Ma-Phen	Tablet: Phenobarbital, ¼ gr.; calcium-carbonate, 5 gr.; magnesium hydroxide, 5 gr.; atropine sulfate, 1/600 gr.	Physicians Supply Co.

EXEMPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Cantil with Phenobarbital	Tablet: Phenobarbital, 16 mg.; mepenzolate bromide, 25 mg.	Lakeside Laboratories, Inc.
Carbonates No. 3 with Phenobarbital and Atropine.	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.11 mg.; calcium carbonate, 224 mg.; magnesium carbonate, 160 mg.; bismuth subcarbonate, 32 mg.	P. J. Noyes Co.
Cardalin-Phen	Tablet: Phenobarbital, ¼ gr.; aminophylline, 5 gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ½ gr.	Neisler Laboratories, Inc.
Cardilate-P	Tablet: Phenobarbital, 15 mg.; erythrityl tetranitrate, 10 mg.	Burroughs Wellcome & Co. (U.S.A.) Inc.
Cholarace	Tablet: Pentobarbital, 27.5 mg.; oxtriphylline, 200 mg.; racephedrine, 20 mg.	Warner-Chilcott Laboratories.
Co-Elorine 25	Capsule: Amobarbital, 8 mg.; tricyclamol chloride, 25 mg.	Eli Lilly and Co.
Co-Elorine 100	Capsule: Amobarbital, 16 mg.; tricyclamol chloride, 100 mg.	Do.
Cold Preparation, Special	Tablet: Phenobarbital, 8.1 mg.; chlorpheniramine maleate, 2 mg.; pseudoephedrine hydrochloride, 60 mg.; salicylamide, powder, 300 mg.	Knight Pharmacal Co.
Corenil	Tablet: Racemic methamphetamine hydro chloride, 1.25 mg.; clistin (carbinoxamine maleate), 2 mg.; belladonna extract, 8 mg.	McNeil Laboratories, Inc.
Covadil	Tablet: Butabarbital sodium, 20 mg.; pentaerythritol tetranitrate, 15 mg.	The Blue Line Chemical Co.
Dactil with Phenobarbital	Tablet: Phenobarbital, 16 mg.; piperidolate hydrochloride, 50 mg.	Lakeside Laboratories, Inc.
Dainite	Tablet: Pentobarbital sodium, ¼ gr. aminophylline, 3 gr.; ephedrine hydrochloride, ¼ gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ¼ gr	Neisler Laboratories, Inc.
Dainite-KI	Tablet: Phenobarbital, ¼ gr.; aminophylline, 3 gr.; ephedrine hydrochloride, ¼ gr.; potassium iodide, 5 gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ¼ gr.	Do.
Dainite Night	Tablet: Phenobarbital, ⅜ gr.; pentobarbital sodium, ½ gr.; aminophylline, 4 gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ¼ gr.	Do.
Dainite Pediatric	Tablet: Phenobarbital, ⅛ gr.; aminophylline, 1 gr.; ephedrine hydrochloride, 1/12 gr.; aluminum hydroxide gel, dried, ½ gr.; benzocaine, ⅛ gr.	Do.
Darlton PB	Tablet: Phenobarbital, 15 mg.; oxyphencyclimine hydrochloride, 5 mg.	Pfizer Laboratories.
Diatraegus	Tablet: Diallylbarbituric acid, ¼ gr.; nitroglycerin, 1/250 gr.; sodium nitrite, 1 gr.; tincture crataegus, 2 minims	Buffington's, Inc.
Dia-Tropine	Tablet: Diallylbarbituric acid, ¼ gr.; atropine sulfate, 1/600 gr.; magnesium carbonate, 2½ gr.; calcium carbonate, 3½ gr.; bismuth subcarbonate, 1 gr.	Do.
Dilantin with Phenobarbital	Capsule: Phenobarbital, ¼ gr.; diphenylhydantoin sodium, 0.1 gm.	Parke, Davis & Co.
Do	Capsule: Phenobarbital, ½ gr.; diphenylhydantoin sodium, 0.1 gm.	Do.
Dolonil	Tablet: Butabarbital, 15 mg.; phenazopyridine hydrochloride, 150 mg.; hyoscyamine hydrobromide, 0.3 mg.	Warner-Chilcott Laboratories.
Donabarb	Tablet: Phenobarbital, ¼ gr.; powder extract belladonna, ⅙ gr.	Paul B. Elder Co., Inc.
Donaphen, New Special Donaphen.	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.024 mg.; scopolamine hydrobromide, 0.0072 mg.; hyoscyamine hydrobromide, 0.128 mg.	Burt Krone Co.
Donna-Sed Elixir	Elixir (5 cc.): Phenobarbital, 16.2 mg.; hyoscyamine hydrobromide, 0.1037 mg.; atropine sulfate, 0.0194 mg.; hyoscine hydrobromide, 0.0065 mg.	North American Pharmacal, Inc.
Donnasep	Tablet: Phenobarbital, 8.1 mg.; phenazopyridine hydrochloride, 50.0 mg., metbenamine mandelate, 500 mg.; hyoscyamine sulfate, 0.0519 mg.; atropine sulfate, 0.0097 mg.; hyoscine hydrobromide, 0.0033 mg.	A. H. Robins Co., Inc.
Donphen	Tablet: Phenobarbital, 15 mg.; hyoscyamine sulfate, 0.1 mg.; atropine sulfate, 0.02 mg.; scopolamine hydrobromide, 6 μg.	Lemmon Pharmacal Co.
Dormitol-HM	Tablet: Phenobarbital, ¼ gr.; homatropine methylbromide, 1/64 gr.; strontium bromide, 1 gr.	Buffington's Inc.
Dynapin with Phenobarbital	Tablet: Phenobarbital, 15 mg.; nitroglycerin, 0.5 mg.; pentaerythritol tetranitrate, 15 mg.	Key Pharmacal Co.

EXEMPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Edrisal	Tablet: Dextroamphetamine sulfate, 2.5 mg.; aspirin, 0.16 gm.; phenacetin 0.16 gm.	Smith Kline & French Laboratories.
Elmaloin with Phenobarbital	Capsule: Phenobarbital, 15 mg.; diphenylhydantoin, 1½ gr.	Paul B. Elder Co., Inc.
Ephedrine and sodium phenobarbital.	Tablet: Sodium phenobarbital, ¼ gr.; ephedrine sulfate, ⅜ gr.	The Vale Chemical Co., Inc.
Ephedrine sulfate and phenobarbital.	Tablet: Phenobarbital, 15 mg.; ephedrine sulfate, 25 mg.	The Zemmer Co.
Ephedrine with Phenobarbital.	Tablet: Phenobarbital, ¼ gr.; ephedrine sulfate, ⅜ gr.	P. J. Noyes Co.
Ercafital	Tablet: Phenobarbital, 7.5 mg.; ergotamine tartrate, 0.5 mg.; caffeine, 50 mg.	The Blue Line Chemical Co.
Ethrava-trate	Tablet: Mephobarbital, 10 mg.; pentaerythrityl tetranitrate, 20 mg.; ethaverine hydrochloride, 30 mg.	North American Pharmacal, Inc.
Eu-Phed-Amin	Tablet: Phenobarbital, 30 mg.; aminophylline, 0.1 gm.; ephedrine sulfate, 30 mg.; extract euphorbia, 0.1 gm.	Warren-Teed Pharmaceuticals, Inc.
Eu-Phed-Ital	Tablet: Phenobarbital sodium, 30 mg.; ephedrine sulfate, 30 mg.; extract euphorbia, 0.12 gm.	Do.
Fensobel	Tablet: Phenobarbital, 8.1 mg.; belladonna extract, 2.95 mg.; aluminum hydrochloride gel, dried, 63 mg.; magnesium trisilicate, 63 mg.; bismuth subcarbonate, 32.5 mg.; magnesium carbonate, 252 mg.; precipitated calcium carbonate, 203.5 mg.; malt diastase, 12.5 mg.; peppermint oil, 3 mg.	United States Vitamin & Pharmaceutical Corp.
Franol	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; benzylephedrine hydrochloride, 32 mg.	Winthrop Laboratories.
Genegesic Capsules	Capsule: Methamphetamine hydrochloride ,1.2 mg.; chlorpheniramine maleate, 3.8 mg.; phenacetin, 120.0 mg.; salicylamide, 180.0 mg.; caffeine, 30.0 mg.; ascorbic acid, 50.0 mg.	General Pharmaceutical Products, Inc.
Homechol	Tablet: Pentobarbital sodium, 8.0 mg.; homatropine methylbromide, 2.5 mg.; dehydrocholic acid, 60.0 mg., ox bile extract, 150.0 mg.	Lemmon Pharmacal Co.
Homadonna	Tablet or elixir (5 cc.): Phenobarbital, 16 mg.; homatropine methylbromide, 2.5 mg.	Mallinckrodt Pharmaceuticals, Division of Mallinckrodt Chemical Works.
Homopent	Tablet: Pentobarbital sodium, 15 mg.; homatropine methylbromide, 2.5 mg.; magnesium trisilicate, 300 mg.	Lemmon Pharmacal Co.
Hovizyme	Tablet: Methamphetamine hydrochloride, 0.5 mg.; conjugated estrogen-equine, 0.125 mg.; methyl testosterone, 1.25 mg.; amylase, 10.0 mg.; protease, 5.0 mg.; cellulase, 2.0 mg.; nicotinyl alcohol tartrate, 7.5 mg.; dehydrocholic acid, 50.0 mg.; ascorbic acid, 50.0 mg.; ferrous fumarate, 6.0 mg.	Ayerst Laboratories.
H-P-A (Modified)	Tablet: Phenobarbital, ¼ gr.; aspirin, 5 gr.; extract hyoscyamus, ⅛ gr.	Paine Drug Co.
Hybephen	Tablet: Phenobarbital, 15 mg.; hyoscyamine sulfate, 0.1277 mg.; atropine sulfate, 0.0233 mg.; hyoscine hydrobromide, 0.0094 mg.	The S. E. Massengill Co.
Hybephen Elixir	Elixir (5 cc.): Phenobarbital, 15 mg.; hyoscyamine sulfate, 0.1277 mg.; atropine sulfate, 0.0233 mg.; hyoscine hydrobromide, 0.0094 mg.	Do.
Hydrochol Plus	Tablet: Amobarbital, 15 mg.; dehydrocholic acid, 200 mg.; scopolamine methylnitrate, 0.8 mg.; ox bile desiccated, 50 mg.	Paul B. Elder Co., Inc.
Hytrona Antispasmodic Elixir	Elixir (5 cc.): Phenobarbital, 16 mg.; belladonna alkaloids, 0.2 mg.	Pitman-Moore.
Hytrona Antispasmodic Tablets.	Tablet: Phenobarbital, 16 mg.; belladonna alkaloids, 0.2 mg.	Do.
Ilocalm	Tablet: Mephobarbital, 30 mg.; methscopolamine nitrate, 2.5 mg.; *d*-calcium pantothenate, 25 mg.	Warren-Teed Pharmaceuticals Inc.
Isordil with Phenobarbital	Tablet: Phenobarbital, 15 mg.; isosorbide dinitrate, 10 mg.	Ives Laboratories Inc.
Isufranol	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; benzylephedrine, 32 mg.; isoproterenol hydrochloride, 10 mg.	Winthrop Laboratories.
Isufranol, Mild	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; benzylephedrine, 32 mg.; isoproterenol hydrochloride, 5 mg.	Do.
Isuprel Compound Elixir	Elixir (15 cc.): Phenobarbital, 6 mg.; isoproterenol hydrochloride, 2.5 mg.; ephedrine sulfate, 12 mg.; theophylline, 45 mg.; potassium iodide, 150 mg.	Do.

EXEMPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Kaphebel	Tablet: Phenobarbital, 1/8 gr.; belladonna root, 1/4 gr.; kaolin colloidal, 7 1/2 gr.	Paul B. Elder Co., Inc.
Kanumodic	Tablet: Pentobarbital, 8 mg.; methscopolamine nitrate, 2 mg.; cellulase, 9 mg.; pancreatin, 500 mg.; glntamic acid hydrochloride, 200 mg.; ox bile extract, 100 mg.; pepsin, 150 mg.	Dorsey Laboratories.
Kavatrate	Tablet: Phenobarbital sodium, 1/4 gr.; veratrum veride, 1/4 gr.; mistletoe, 1/2 gr.; hawthorn tincture, 30 minims; sodium nitrite, 1 gr.	Key Pharmacal Co.
Kie with Phenobarbital	Tablet: Phenobarbital, 16 mg.; potassium iodide, 400 mg.; ephedrine sulfate, 24 mg.	Laser Inc.
Kiophyllin	Tablet: Phenobarbital, 15 mg.; aminophyllin, 150 mg.; potassium iodide, 125 mg.	G. D. Searle & Co.
Luftodil Suspension	Suspension (5 cc.): Phenobarbital, 8 mg.; theophylline, 50 mg.; ephedrine hydrochloride, 12 mg.; glyceryl guaiacolate, 100 mg.	Mallinckrodt Pharmaceuticals, Division of Mallinckrodt Chemical Works.
Luftodil Tablets	Tablet: Phenobarbital, 16 mg.; theophylline, 100 mg.; ephedrine hydrochloride, 24 mg.; glyceryl guaiacolate, 200 mg.	Do.
Lufyllin-EP	Tablet: Phenobarbital, 16 mg.; lufyllin (dyphylline), 100 mg.; ephedrine hydrochloride; 16 mg.	Do.
Magnesium hydroxide-phenobarbital compound.	Tablet: Phenobarbital sodium, 15 mg.; magnesium hydroxide, 300 mg.; atropine sulfate with aromatics, 0.12 mg.	McNeil Laboratories, Inc.
Malglyn Compound	Tablet or suspension (5 cc.): Phenobarbital, 16.2 mg.; belladonna alkaloids, 0.162 mg.; dihydroxy aluminum aminoacetate, 0.5 gm.	Brayten Pharmaceutical Co.
Manniphen	Tablet: Phenobarbital, 16 mg.; mannitol hexanitrate, 32 mg.	The Vale Chemical Co., Inc.
Manniphen with Rutin	Tablet: Phenobarbital, 16 mg.; mannitol hexanitrate, 32 mg.; rutin, 20 mg.	Do.
Mannitol hexanitrate with phenobarbital.	Tablet: Phenobarbital, 1/4 gr.; mannitol hexanitrate, 1/2 gr.	P. J. Noyes Co.
Do	Tablet: Phenobarbital, 1/4 gr.; mannitol hexanitrate, 1/2 gr.	The Blue Line Chemical Co.
Maxitol	Tablet: Phenobarbital, 15 mg.; mannitol hexanitrate, 15 mg.; rutin, 15 mg.; ascorbic acid, 15 mg.	Burt Krone Co.
Mediatric	Tablet or capsule: Methamphetamine hydrochloride, 1 mg.; conjugated estrogens-equine, 0.25 mg.; methyltestosterone, 2.5. mg.	Ayerst Laboratories.
Mediatric Liquid	Solution (15 cc.): Methamphetamine hydrochloride, 1 mg.; conjugated estrogens-equine, 0.25 mg.; methyltestosterone, 2.5. mg.	Do.
Meprane Phenobarbital	Tablet: Phenobarbital, 16 mg.; promethestrol dipropionate, 1 mg.	Reed & Carnrick.
Mesopin-PB	Tablet or elixir (5 cc.): Phenobarbital, 15 mg.; homatropine methylbromide, 5 mg.	Endo Laboratories Inc.
Metamine with Butabarbital	Tablet: Butabarbital, 16.2 mg.; trolnitrate phosphate, 2 mg.	Pfizer Laboratories.
Do	Tablet: Butabarbital, 48.6 mg.; trolnitrate phosphate, 10 mg.	Do.
Mexal	Tablet: Phenobarbital, 16 mg.; mannitol hexanitrate, 32 mg.	The S. E. Massengill Co.
Monomeb	Tablet: Mephobarbital, 32 mg.; penthienate bromide, 5 mg.	Winthrop Laboratories.
Mudrane	Tablet: Phenobarbital, 21 mg.; potassium iodide, 195 mg.; aminophylline, 130 mg.; ephedrine hydrochloridc, 16 mg.	Wm. P. Poythress & Co., Inc.
Mudrane GG Elixir	Elixir (5 cc.): Phenobarbital, 5.4 mg.; theophylline, 20 mg.; ephedrine hydrochloride, 4 mg.; glyceryl guaiacolate, 26 mg.	Do.
Nactisol	Tablet: Butabarbital sodium, 15 mg.; poldine methylsulfate, 4 mg.	McNeil Laboratories, Inc.
Natrona Compound	Tablet: Phenobarbital, 15 mg.; extract hawthorn berries, 30 mg.; extract mistletoe, 15 mg.; sodium nitrite, 60 mg.; sodium bicarbonate, 0.2 gm.	The Zemmer Co.
Neocholan	Tablet: Phenobarbital, 8 mg.; dehydrocholic acid, 250 mg.; bile extract, 15 mg.; homatropine methylbromide, 1.2 mg.	Pitman-Moore.
Nergestic	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.10 mg.; magnesium trisilicate. 0.5 gm.	The S. E. Massengill Co.
Nitrased	Tablet: Secobarbital, 15 mg.; nitroglycerin, 0.4 mg.; pentaerythrityl tetranitrate, 15 mg.	Lemmon Pharmacal Co.
Nophesan Tablets	Tablet: Phenobarbital, 8 mg.; acetylsalicylic acid, 300 mg.	P. J. Noyes Co.
Novalene	Tablet: Phenobarbital, 16 mg.; ephedrine sulfate, 24 mg.; potassium iodide, 162 mg.; calcium lactate, 162 mg.	Lemmon Pharmacal Co.

EXEMPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Oxsorbil-PB	Capsule: Phenobarbital, 7.5 mg.; belladonna extract, 7.5 mg.; dehydrochloic acid, 32 mg.; desoxycholic acid, 32 mg.; ox bile extract, 65 mg.; sorbitan monooleate, 160 mg.; oleic acid, 180 mg.	Ives Laboratories, Inc.
Paminal Elixir	Elixir (5 cc.): Phenobarbital, 8 mg.; methscopolamine bromide, 1.25 mg.	The Upjohn Co.
Pamine PB Elixir	Elixir (5 cc.): Phenobarbital, 8 mg.; methscopolamine bromide, 1.25 mg.	Do.
Pamine PB, Half Strength	Tablet: Phenobarbital, 8 mg.; methscopolamine bromide, 1.25 mg.	Do.
Pediatric Piptal Antipyretic	Solution (0.6 cc.): Phenobarbital 3 mg.; pipenzolate bromide, 5 mg.; acetaminophen, 60 mg.	Lakeside Laboratories, Inc.
Pediatric Piptal with Phenobarbital.	Solution (0.5 cc.): Phenobarbital, 3 mg.; pipenzolate bromide, 2 mg.	Do.
Pencetylon	Tablet: Phenobarbital, ¼ gr.; acetylsalicylic acid, 5 gr.	Paul B. Elder Co., Inc.
Pentaerythrityl tetranitrate with phenobarbital.	Tablet: Phenobarbital, 16 mg.; pentaerythrityl tetranitrate, 10 mg.	P. J. Noyes Co.
Do	Tablet: Phenobarbital, 16 mg.; pentaerythrityl tetranitrate, 20 mg.	Do.
Pentatrol with Phenobarbital	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	North American Pharmacal Co.
Pentraline	Tablet: Butabarbital sodium, 10 mg.; reserpine, 0.05 mg.; pentaerythrityl tetranitrate, 10 mg.	McNeil Laboratories, Inc.
Perbuzem	Tablet: Butabarbital sodium, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	The Zemmer Co.
Peribar L-A No. 1	Tablet: Phenobarbital, 48.6 mg.; pentaerythrityl tetranitrate, 30 mg.	Whittier Laboratories, Inc.
Peritrate with Phenobarbital	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	Warner-Chilcott Laboratories.
Do	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 20 mg.	Do.
Peritrate with Phenobarbital SA.	Tablet: Phenobarbital, 45 mg.; pentaerythrityl tetranitrate, 80 mg.	Do.
Phedorine	Tablet: Diallylbarbituric acid, 16 mg.; extract stramonium, 8 mg. (alkaloids 0.0015 gr.); ephedrine, 8 mg.; theophylline, 100 mg.	Buffington's, Inc.
Phenaphen Plus	Tablet: Phenobarbital, 16.2 mg.; phenacetin, 194 mg.; aspirin, 162 mg.; hyoscyamine sulfate, 0.031 mg.; pheniramine maleate, 12.5 mg.; phenylephrine hydrochloride, 10 mg.	A. H. Robins Co., Inc.
Phenobarbital and atropine.	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/500 gr.	The Blue Line Chemical Co.
Do	----do----	Meyers & Co.
Do	----do----	Paine Drug Co.
Do	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/250 gr.	The Vale Chemical Co., Inc.
Phenobarbital with atropine sulfate	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.06 mg.	The Zemmer Co.
Phenobarbital with atropine sulfate No. 2	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.12 mg.	Do.
Phenobarbital and atropine sulfate.	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/200 gr.	Buffington's, Inc.
Phenobarbital & Atropine No. 1.	Tablet: Phenobarbital, 16 mg.; atropine sulfate, 0.13 mg.	Pitman-Moore.
Phenobarbital & Atropine No. 2.	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.65 mg.	Do.
Phenobarbital and Atropine Tablets.	Tablet: Phenobarbital, 8 mg.; atropine sulfate 1/1000 gr.	P. J. Noyes Co.
Do	Tablet: Phenobarbital, 16 mg.; atropine sulfate, 1/500 gr.	Do.
Phenobarbital and Atropine Tablets No. 2.	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/200 gr.	Do.
Phenobarbital and Atropine Tablets No. 3.	Tablet: Phenobarbital, ½ gr.; atropine sulfate, 1/300 gr.	Do.
Phenobarbital and belladonna.	Tablet: Phenobarbital, ¼ gr.; belladonna leaves ½ gr. (total alkoids 0.0015 gr.).	The Vale Chemical Co., Inc.
Do	Tablet: Phenobarbital, ¼ gr.; belladonna extract, 1/8 gr.	Paine Drug Co.
Do	Tablet: Phenobarbital, 16 mg.; belladonna extract, 8 mg.	Eli Lilly and Co.
Phenobarbital and Belladonna No. 2.	Tablet: Phenobarbital, ¼ gr.; belladonna extract, 1/8 gr. (alkaloids 0.00156 gr.).	The Upjohn Co.
Phenobarbital with mannitol hexanitrate.	Tablet: Phenobarbital, 7.5 mg., mannitol hexanitrate, 15 mg.; ascorbic acid powder, 25 mg.; rutin, 25 mg.	Paul B. Elder Co., Inc. (Harold M. Harter, D.V.M.)
Phenobarbital and mannitol hexanitrate.	Tablet: Phenobarbital, ¼ gr.; mannitol hexanitrate, ½ gr.	Meyer Drug & Surgical Supply Co.
Phenobarbital Sodium Atropine No. 1.	Tablet: Phenobarbital sodium, 8 mg.; atropine sulfate, 60 μg.	McNeil Laboratories, Inc.

EXEMPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Phenobarbital Sodium Atropine No. 2.	Tablet: Phenobarbital sodium, 15 mg.; atropine sulfate, 120 μg.	McNeil Laboratories, Inc.
Phenobarbital Sodium Atropine No. 3.	Tablet: Phenobarbital sodium, 20 mg.; atropine sulfate, 200 μg.	Do.
Phenobarbital and sodium nitrite.	Tablet: Phenobarbital, ¼ gr.; sodium nitrite, 1 gr.	P. J. Noyes Co.
Phenobarbital Theocalcin	Tablet: Phenobarbital, 15 mg.; theobromine calcium salicylate, 0.5 gm.	Knoll Pharmaceutical Co.
Phenodonna Tablets	Tablet: Phenobarbital, ¼ gr.; tincture belladonna, 6 minims.	Flint Medical & Surgical Supply Co.
Phenodrox	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/600 gr.; magnesium trisilicate, 4 gr.; aluminum hydroxide gel, dried, 4 gr.	North American Pharmacal Inc.
Phyldrox	Tablet: Phenobarbital, 15 mg.; neothylline, 100 mg.; ephedrine sulfate, 25 mg.	Lemmon Pharmacal Co.
Piptal PHB Elixir	Elixir (5cc.): Phenobarbital, 16 mg.; pipenzolate bromide, 5 mg.	Lakeside Laboratories, Inc.
Piptal PHB Tablets	Tablet: Phenobarbital, 16 mg.; pipenzolate bromide, 5 mg.	Do.
Prantal with Phenobarbital	Tablet: Phenobarbital, 16 mg.; diphemanil methylsulfate, 100 mg.	Schering Corp.
Premarin with Phenobarbital	Tablet: Phenobarbital, 32 mg.; conjugated estrogens-equine, 0.625 mg.	Ayerst Laboratories.
Probanthine with phenobarbital.	Tablet: Phenobarbital, 15 mg.; probanthine, 15 mg.	G. D. Searle & Co.
Probital	Tablet: Phenobarbital, 15 mg.; probanthine, 7.5 mg.	Do.
Propemite	Tablet: Pentobarbital sodium, 12 mg.; sodium nitrite, 60 mg.; hawthorn berries extract, 120 mg.; mistletoe extract, 60 mg.	The Zemmer Co.
Prydonnal Spansule	Capsule: Phenobarbital, 65 mg.; belladonna alkaloids, 0.4 mg. (hyoscyamine sulfate, 0.305 mg.; atropine sulfate, 0.06 mg., scopolamine hydrobromide, 0.035 mg.).	Smith Kline & French Laboratories.
Quadrinal	Tablet: Phenobarbital, 24 mg.; ephedrine hydrochloride 24 mg.; theophylline calcium salicylate, 130 mg.; potassium iodide, 300 mg.	Knoll Pharmaceutical Co.
Do	Suspension (5 cc.): Phenobarbital, 12 mg.; ephedrine hydrochloride, 12 mg.; theophylline calcium salicylate, 65 mg.; potassium iodide, 160 mg.	Do.
Quintrate with Nitroglycerin and Phenobarbital.	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 20 mg.; nitroglycerin, 0.4 mg.	Paul B. Elder Co., Inc. (Glynn A. Beard).
Quintrate with Phenobarbital	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	Do.
Do	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 20 mg.	Do.
Rheastat	Suspension (1 fluid ounce (32 cc.)): Phenobarbital, 16 mg.; hyoscyamine sulfate, 0.1286 mg.; atropine sulfate, 0.0250 mg.; scopolamine hydrobromide, 0.0074 mg.; kaolin, colloidal, 5.76 gm.; pectin, 320 mg.; sodium (as Cl), 6 meq.; potassium (as Cl), 4 meq.	Mallinckrodt Pharmaceuticals Division of Mallinckrodt Chemical Works.
Robinul-PH	Tablet: Phenobarbital, 16.2 mg.; glycopyrrolate, 1.0 mg.	A. H. Robins Co., Inc.
Robinul-PH Forte	Tablet: Phenobarbital, 16.2 mg.; glycopyrrolate, 2.0 mg.	Do.
Ruhexatal	Tablet: Phenobarbital, 15 mg.; mannitol hexanitrate, 30 mg.; ascorbic acid, 10 mg.; rutin, 20 mg.	Lemmon Pharmacal Co.
Rutol	Tablet: Phenobarbital, 8.0 mg.; mannitol hexanitrate, 16 mg.; rutin, 10 mg.	Pitman-Moore.
Salisil with Phenobarbital	Tablet: Phenobarbital, ¼ gr.; acetylsalicylic acid, 5 gr.; magnesium trisilicate, 2 gr.	Paul B. Elder Co., Inc.
Sebella	Tablet: Phenobarbital, ⅛ gr.; aluminum hydroxide, 5 gr.; belladonna extract, ⅛ gr.	Wyeth Laboratories.
Sed-Tens	Tablet (12 hr.): Amobarbital, 50 mg.; homatropine methylbromide, 7.5 mg.	Lemmon Pharmacal Co.
Sibena	Tablet: Butabarbital sodium, 16 mg.; simethicone, 25 mg.; belladonna extract, 16 mg. (total alkaloids 0.20 mg.).	Plough Laboratories, Inc.
Sodium nitrite with phenobarbital.	Tablet: Phenobarbital sodium, ⅛ gr.; sodium nitrite, 1 gr.; sodium bicarbonate, 2 gr.; hawthorn berries, fluid extract, ½ minim.	Paine Drug Co.
Do	Tablet: Phenobarbital, ¼ gr.; sodium nitrite, 1 gr.	Buffalo Pharmaceutical Supply Corp.
Spasticol PB	Tablet: Phenobarbital, 15 mg.; homatropine methylbromide, 2.5 mg.	Key Pharmaceuticals, Inc.
Spastosed	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.13 mg.; calcium carbonate, 227 mg.; magnesium hydroxide, 162 mg.	North American Pharmacal, Inc.

EXEMPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Special Formula 711	Tablet: *d*-Amphetamine sulfate, 2.5 mg.; mephenesin, 500 mg.; salicylamide, 300 mg.	Detroit First Aid Co.
Syntrin	Tablet: Pentobarbital, 8 mg.; aspirin, 324 mg	Wm. P. Poythress & Co., Inc.
TCS	Tablet: Phenobarbital 16, mg.; theobromine salicylate, 0.4 gm.; calcium salicylate, 0.06 gm.	Do.
Tedral-25	Tablet: Butabarbital, 25 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Warner-Chilcott Laboratories.
Tedral S.A	Tablet: Phenobarbital, 25 mg.; theophylline, 180 mg.; ephedrine hydrochloride, 48 mg.	Do.
Tensodin	Tablet: Phenobarbital, 15 mg.; ethaverine hydrochloride, 30 mg.; theophylline calcium salicylate, 200 mg.	Knoll Pharmaceutical Co.
Tensophen	Tablet: Phenobarbital, 16 mg.; nitroglycerin, 0.26 mg.; sodium nitrite, 32 mg.; podophyllin, 1 mg.; extract beef bile, 16 mg.	P. J. Noyes Co.
Thedrizem	Tablet: Phenobarbital, 8 mg.; theophylline, hydrous, 100 mg.; ephedrine hydrochloride, 25 mg.	The Zemmer Co.
Theobarb	Tablet: Phenobarbital, 32 mg.; theobromine, 325 mg.	Mallinckrodt Pharmaceuticals, Division of Mallinckrodt Chemical Works.
Theobarb-R	Tablet: Phenobarbital, 10 mg.; reserpine, 0.1 mg.; theobromine, 324 mg.	Do.
Theobarb Special	Tablet: Phenobarbital, 16 mg.; theobromine, 325 mg.	Do.
Theobromine and phenobarbital.	Tablet: Phenobarbital, 16 mg.; theobromine, 0.3 gm.	P. J. Noyes Co.
Theobromine-Phenobarbital	Tablet: Phenobarbital, 30 mg.; theobromine, 0.3 gm.	The S. E. Massengill Co.
Do	Tablet: Phenobarbital, 32 mg.; theobromine, 324 mg.	The Upjohn Co.
Theobromine-Phenobarbital Compound.	Tablet: Phenobarbital, ¼ gr.; theobromine, 2½ gr.; potassium iodide, 2½ gr.; potassium bicarbonate, 2 gr.	Do.
Theobromine with Phenobarbital No. 1.	Tablet: Phenobarbital, 15 mg.; theobromine, 324 mg.	Buffington's Inc.
Theobromine and sodium acetate with phenobarbital.	Tablet: Phenobarbital, ¼ gr.; theobromine and sodium acetate, 3 gr.	Paul B. Elder Co., Inc.
Theobromine sodium salicylate with phenobarbital.	Tablet: Phenobarbital, 15 mg.; theobromine sodium salicylate, 300 mg.	The Zemmer Co.
Theocardone No. 1	Tablet: Phenobarbital, 15 mg.; theobromine, 300 mg.	Haack Laboratories, Inc.
Theocardone No. 2	Tablet: Phenobarbital, 30 mg.; theobromine, 300 mg.	Do.
Theodide	Tablet: Phenobarbital, ¼ gr.; potassium iodide, 2½ gr.; theobromine sodium salicylate, 2½ gr.	The Vale Chemical Co., Inc.
Theoglycinate with Phenobarbital.	Tablet: Phenobarbital, 16 mg.; theophyllin-sodium glycinate, 324 mg.	Brayten Pharmaceutical Co.
Theoglycinate with Racephedrine and Phenobarbital.	Tablet: Phenobarbital, 16 mg.; theophylline-sodium glycinate, 324 mg.; racephedrine hydrochloride, 24 mg.	Do.
Theoplaphen	Tablet: Phenobarbital, 15 mg.; theobromine sodium salicylate, 0.2 gm.; calcium lactate, 0.1 gm.	The S. E. Massengill Co.
Theominal	Tablet: Phenobarbital, 32 mg.; theobromine, 320 mg.	Winthrop Laboratories.
Theominal M	Tablet: Phenobarbital, 15 mg.; theobromine, 320 mg.	Do.
Theominal R.S	Tablet: Phenobarbital, 10 mg.; theobromine, 320 mg.; alseroxylon, 1.5 mg.	Do.
Theophen	Tablet: Phenobarbital, ¼ gr.; theobromine sodium salicylate, 5 gr.; calcium carbonate, 2½ gr.	The Vale Chemical Co., Inc.
Theorate	Tablet: Phenobarbital, 16.2 mg.; theobromine, 324 mg.	Whittier Laboratories, Inc.
Thora-Dex No. 1	Tablet: Dextroamphetamine sulfate, 2 mg.; chlorpromazine hydrochloride, 10 mg.	Smith Kline & French Laboratories.
Thora-Dex No. 2	Tablet: Dextroamphetamine sulfate, 5 mg.; chlorpromazine hydrochloride, 25 mg.	Do.
Thymodyne	Tablet: Phenobarbital, 32 mg.; theophylline anhydrous, 130 mg.; ephedrine sulfate, 24 mg.	P. J. Noyes Co.
Trocinate with Phenobarbital	Tablet: Phenobarbital, 16 mg.; thiphenamil hydrochloride, 100 mg.	Wm. P. Poythress & Co., Inc.
Tricoloid	Tablet: Phenobarbital, 16 mg.; tricyclamol chloride, 50 mg.	Burroughs Wellcome & Co.
Triophen	Tablet: Phenobarbital, ⅛ gr.; atropine sulfate, 1/500 gr.; magnesium trisilicate, 7 gr.	The Vale Chemical Co., Inc.
Unitensen-Phen	Tablet: Phenobarbital, 15 mg.; cryptenamine, 1 mg.	Neisler Laboratories, Inc.
Valpin-PB	Tablet or elixir (5 cc.): Phenobarbital, 8 mg.; anisotropine methylbromide, 10 mg.	Endo Laboratories Inc.

EXEMPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Vasorutin	Tablet: Diallylbarbituric acid, ¼ gr.; nitroglycerin, 1/250 gr.; sodium nitrite, 1 gr.; tincture crataegus, 2 minims; rutin, 20 mg.	Buffington's, Inc.
Veraflex	Tablet: Phenobarbital, 15 mg.; cryptenamine, 65 CSR (carotid sinus reflex) units; rutin, 20 mg.	Neisler Laboratories, Inc.
Veralzein	Tablet: Phenobarbital, 15 mg.; veratrum viride, 50 mg.; sodium nitrite, 60 mg.	The Zemmer Co.
Veratrite	Tablet: Phenobarbital, ¼ gr.; cryptenamine, 40 CSR (carotid sinus reflex) units; sodium nitrite, 1 gr.	Neisler Laboratories, Inc.
Veritag	Tablet: Phenobarbital, 16 mg.; veratrum viride, 40 mg.; sodium nitrite, 65 mg.	S. J. Tutag and Co.
Vertegus	Tablet: Phenobarbital, ¼ gr.; veratrum viride, ¾ gr.; sodium nitrite, 1 gr.; mistletoe, ½ gr.; hawthorn berries, ½ gr.	Burt Krone Co.
Veruphen	Tablet: Phenobarbital, 15 mg.; rutin, 20 mg.; veratrum viride, 15 mg.; sodium nitrite, 60 mg.	The Zemmer Co.
Viritin	Tablet: Phenobarbital, 15 mg.; mannitol hexanitrate, 30 mg.; veratrum viride alkaloids, 1.5 mg.; rutin, 20 mg.	Lemmon Pharmacal Co.
Weytabs No. 1	Tablet: *dl*-Desoxyephedrine hydrochloride, 5 mg.; thyroid, 60 mg.; atropine sulfate, 0.125 mg.; aloin, 15 mg.	The Vale Chemical Co., Inc.
Weytabs No. 2	Tablet: *dl*-Desoxyephedrine hydrochloride, 5 mg.; thyroid, 60 mg.; atropine sulfate, 0.125 mg.	Do.
Weytabs No. 3	Tablet: Phenobarbital, 15 mg.; *dl*-desoxyephedrine hydrochloride, 5 mg.; thyroid 60 mg.	Do.
W-T	Powder (4 gm.): Phenobarbital, 15 mg.; belladonna extract, 10 mg. (0.12 mg. belladonna alkaloids); benzocaine, 15 mg.; calcium carbonate, 1.55 gm.; magnesium oxide, 0.5 gm.; aluminum hydroxide gel, dried, 60 mg.	Warren-Teed Pharmaceuticals Inc.
W-T	Tablet: Phenobarbital, 1/16 gr.; belladonna extract, 1/24 gr.; benzocaine, 1/16 gr.; calcium carbonate, 6 gr.; magnesium trisilicate, 3¾ gr.; aluminum hydroxide gel, dried, 2½ gr.; chlorophyll extract, 1%.	Do.
Xaniophen	Tablet: Phenobarbital, 16.2 mg.; theobromine, 162 mg.; ethylenediamine dihydriodide, 32.4 mg.	Pitman-Moore.
Zallogen Compound	Tablet: Phenobarbital, 8 mg.; tocamphyl, 75 mg.; homatropine methylbromide, 2.5 mg.	The S. E. Massengill Co.
Zantrate	Tablet: Cyclopentenylallylbarbituric acid, ½ gr.; ephedrine sulfate, 3/8 gr.; theophylline anhydrous, 2 gr.	The Upjohn Co.
Zem-Dab	Tablet: Butabarbital sodium, 10 mg.; dehydrocholic acid, 60 mg.; ox bile desiccated, 120 mg.; homatropine methylbromide, 2.5 mg.	The Zemmer Co.
No. 23	Tablet: Phenobarbital, ½ gr.; aminophylline, 3 gr.	Stayner Corp.
No. 35	Tablet: Phenobarbital, ⅛ gr.; aminophylline, 1.5 gr.; ephedrine sulfate, 3/8 gr.	Do.
No. 36	Tablet: Pentabarbital sodium, ¾ gr.; ephedrine sulfate, 3/8 gr.; aminophylline, 3 gr.	Do.
No. 65	Tablet: Phenobarbital, ¼ gr.; extract belladonna, ¼ gr.	Do.
No. 66	Tablet: Phenobarbital, ¼ gr.; extract belladonna, ¼ gr.	Do.
No. 75	Tablet: Phenobarbital, ¼ gr.; belladonna, 1/6 gr.	Bariatric Corp.
No. 88	Tablet: Phenobarbital, ¼ gr.; aminophylline, 1.5 gr.	Stayner Corp.
No. 89	Tablet: Phenobarbital, ½ gr.; aminophylline, ⅓ gr.	Do.
No. 111	Tablet: Phenobarbital, ½ gr.; ephedrine sulfate, 3/8 gr.	Do.
No. 136	Tablet: Phenobarbital, 20 mg.; homatropine methylbromide, 5 mg.	Do.
No. 643	Tablet: Phenobarbital, ⅛ gr.; theophylline, 2 gr.; ephedrine hydrochloride, 3/8 gr.	Do.
Rx. No. 4104	Tablet: Phenobarbital, ¼ gr.; calcium carbonate, 7½ gr.; magnesium oxide, 4 gr.; atropine sulfate, 1/300 gr.	The Zemmer Co.
Rx. No. 4105	Tablet: Phenobarbital, ¼ gr.; calcium carbonate, 10 gr.; atropine sulfate, 1/300 gr.	Do.
Rx. No. 4108	Capsule: Phenobarbital, ¼ gr.; atropine sulfate, 1/300 gr.; calcium carbonate, 6½ gr.; magnesium oxide, heavy, 2 gr.	Do.
Rx. No. 4123	Capsule: Phenobarbital, ¼ gr.; bismuth subgallate, 5 gr.; extract belladonna, 1/6 gr.	Do.

EXEMPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Rx. No. 4126	Capsule: Pentabarbital sodium, 15 mg.; extract belladonna, 10 mg.	The Zemmer Co.
Rx. No. 4143	Capsule: Phenobarbital, ¼ gr.; aminophylline, 1.5 gr.; potassium iodide, 1 gr.	Do.
Rx. No. 4152	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/400 gr.	Do.
Rx. No. 4155	Tablet: Phenobarbital, ⅙ gr.; atropine sulfate, 1/1000 gr.; aluminum hydroxide gel. 3¾ gr.; kaolin, 3¾ gr.	Do.
Rx. No. 4170	Tablet: Phenobarbital, ½ gr.; atropine sulfate, 1/400 gr.; calcium carbonate. 10 gr.	Do.
Rx. No. 4184	Capsule: Sodium butabarbital, 15 mg.; belladonna extract, 15 mg.	Do.

[32 F.R. 197, Jan. 10, 1967, as amended at 32 F.R. 4406, Mar. 23, 1967]

§§ 166.9–166.15 [Reserved]

§ 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 reguiation in this part.

(b) *Contents of records.* The records required under section 511 (d)(1) of the act, and by regulations in this part, shall be considered incomplete and inadequate unless such records contain sufficient information to clearly show the kind and quantity of all stocks of each drug subject to these record-keeping requirements including, but not limited to, the following information:

(1) *Information required in initial inventory record.* (i) The kind and quantity, to the nearest unit weight consistent with the unit size, of all bulk depressant or stimulant drugs used in or capable of use in the production of drugs as defined in section 201(v) of the act, on hand as of February 1, 1966.

(ii) The kind and quantity of drugs in production on February 1, 1966, identified by batch number or other appropriate identifying number including the physical form which such in-process drugs are intended to take upon completion of the manufacturing process; for example, granulations, tablets, capsules, solutions, etc.

(iii) The kind and quantity of all such drugs in finished form on hand on February 1, 1966, including returned merchandise, transfers from other locations, orders prepared for shipment or deiivery, or otherwise within the control of the registrant; for example, drugs in any controlled warehouse, or drugs in possession of employees and intended for distribution as professional samples. These records shall describe the finished form (for example, 10-milligram tablets or 10-milligram concentration per fluid ounce, if liquid), the number of units or volume in each package or container (for example, 100-tablet bottle or 3 fluid ounces), and the location of stocks.

(2) *Information required in continuing records of receipt or manufacture, compounding, or processing of controlled drugs.* (i) The kind and quantity, expressed in the nearest unit weight consistent with the unit size, of all bulk depressant or stimulant drugs in or capable of use in the production of drugs, as defined in section 201(v) of the act, on hand and in production, including the name and address of the person or firm from whom the drugs or substance is received and the date and quantity of material received. If any of this material is disposed of in any manner, or in any form, the details of disposition, including the name and address of the person to whom delivered, the date, quantity, and form in which disposed.

(ii) The kind and quantity of any depressant or stimulant drug as defined in section 201(v) of the act, in tablet, capsule, liquid, or any other finished form produced that is on hand, in production, or received. These records shall describe the form (tablet, capsule, etc.), the strength or potency per unit (for example, 10-milligram tablets), and the number of units in each package or container (for example, 100-tablet bottle), and the date of production, receipt, repackaging, or relabeling. These records shall include the name and address of the person from whom any such controlled substance was received and the date, quantity, and kind of the material received.

(iii) Production records shall show date of manufacture, compounding, or processing, theoretical and actual yield, the quantity of loss during manufacture, if any, the quantity used for quality control, the identity by batch number or other appropriate identification and quantity of any product reworked for any reason and such other information as is necessary to account for all controlled substances used in the manufacturing process.

(3) *Information required in continuing records of wholesaling, jobbing, distributing, retailing, or other disposition.* The records required by section 511(d) of the act to be kept by each person selling, delivering, or otherwise disposing of any depressant or stimulant drug shall include the following information:

(i) The kind and quantity of each such drug received including imports, the name and address of the person from whom the drug is received, and the registration number, if any, assigned to any such person pursuant to section 510(e) of the act, and the date any such drug was received.

(ii) The kind and quantity of each such drug sold, delivered, or otherwise disposed of, including the name and address of the person to whom such drug was sold, delivered, or otherwise disposed of, the identity of any common carrier or transportation firm used in effecting such delivery, and the registration number, if any, assigned to any such person pursuant to section 510(e) of the act, and the date any such sale, delivery, or other disposition took place, including drugs exported to other countries.

(iii) (*a*) The term "kind" as used in this section means the established name, chemical name, or trade name for drugs which contain a single active ingredient, and for those drugs (for which there is no established or trade name) containing more than one active component, the established name, chemical name, or trade name for each active ingredient.

(*b*) The word "quantity" as used in this section means the number of individual packages or containers of the controlled substance (for example, 100 bottles, 5 dozen bottles), a description of the quantity of contents of each individual package or container (for example, 100-tablet bottle, 50-pound drum), and a statement of the potency of a single unit within the individual package or container (for example, 10-milligram tablet), resulting in the following type of quantity designation (fifty 100-tablet bottles of 10-milligram tablets; two 50-pound drums of 10-milligram tablets; 3 dozen 25-tablet bottles of 10-milligram tablets). If the semiprocessed controlled substance is a granulation, a meaningful quantitative statement of the amount of such substance present is required.

(iv) With regard to the records required by section 511(d)(1) of the act, the law states "no separate records nor set form or forms for any of the foregoing records shall be required as long as records containing the required information are available."[1] Ordinary business records kept by legitimate businessmen are maintained so that inspection of the records is possible and practicable in a reasonable length of time. Among others, an automatic data processing system will be considered adequate providing the system is capable of separating and identifying all records containing the specific information required by section 511(d) of the act and the regulations contained in this part in a reasonable time, or provided the system itself is capable of producing such information in a reasonable time. Other recordkeeping systems that permit the records specified in section 511(d)(1) of the act to be identified and reviewed or copied in a reasonable time also will be regarded as adequate. To account for controlled drugs dispensed on prescription, either

[1] The purpose of this provision as shown by reports of the Congressional Committees that considered the legislation is to insure that the ordinary business records kept by legitimate businessmen will be considered as adequate records.

the usual consecutively numbered prescription file, or a separate prescription file, will be acceptable.

[31 F.R. 1073, Jan. 27, 1966, as amended at 31 F.R. 4679, Mar. 19, 1966]

§ 166.17 Persons required to establish, prepare, and maintain records specified in section 511(d)(1) of the act.

Pursuant to the provisions of section 511 (a) and (d)(1) of the act, persons engaged in one or more or any combination of the following activities in relation to depressant or stimulant drugs, as defined in section 201(v) of the act and regulations thereunder, are required to establish and maintain the initial inventory records and the continuing records described in this part:

(a) Persons engaged in manufacturing, preparation, propagation, compounding, or processing of such drugs in bulk, tablet, capsule, liquid, or other finished form.

(b) Persons, other than those exempted under section 511(d)(3) of the act, engaged in selling, transporting, delivering, wholesaling, jobbing, warehousing, distributing, or otherwise disposing of such drugs to any person who is not the ultimate user or consumer of the drug.

(c) Persons, other than those exempted under section 511(d)(3) of the act, engaged in manipulation, sampling, testing, repackaging, or otherwise changing the container, wrapper, or labeling of such drugs in furtherance of the distribution of such drugs from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer.

(d) Pharmacies, hospitals, clinics, and public health agencies who have on hand or maintain a stock of such drugs for dispensing by registered pharmacists upon prescriptions, or for use by or under the supervision of practitioners licensed by law to administer such drugs in the course of their professional practice.

(e) Laboratories or research or educational institutions who use such drugs in research, teaching, or chemical analysis.

(f) Practitioners licensed by law to prescribe or administer such drugs, while acting in the course of their professional practice, who regularly engage in dispensing any such drug or drugs to their patients for which the patients are charged, either separately or together with charges for other professional services. The maintaining of small supplies of these drugs for dispensing or administering in the course of professional practice in emergency or special situations (for example, as a stopgap measure to tide patients over until a regular supply of drugs can be obtained by prescription from a pharmacy, or dispensing as trial doses to patients), will not be considered as regularly engaged in dispensing for a fee.

[31 F.R. 1074, Jan. 27, 1966]

§ 166.18 Label symbol.

(a) All depressant and stimulant drugs within the meaning of section 201(v) of the act, which have not been exempted by the Commissioner from the requirements of section 511 (c) and (e) and the recordkeeping requirements of section 511(d)(1) of the act, shall bear the following symbol or modification:

The symbol in outline form is for use as a large, open-letter overprint.

(b) This symbol shall be prominently placed on the principal panel of the label and/or on the panel normally displayed on the shelf by users of the immediate container and on any retail carton or wrapper for such container of each such drug: *Provided, however,* That:

(1) The symbol is not required on the retail carton or wrapper if it is easily legible through such carton or wrapper; or

(2) In the case of ampules or other containers too small or otherwise unable to accommodate a label, the symbol may appear on the outer container from which they are removed for dispensing or use.

(c) The symbol shall be of contrasting color to the background on which it appears (no particular color is required), large enough for easy identification, placed preferably to the right of the title and adjacent to it, and at least as large as the largest letter in the title of the drug. Large open letter overprinting of the symbol will be regarded as meeting the requirements.

(d) Compliance with the requirements of this section shall be as follows:

(1) All drugs subject to control on February 1, 1966, as set forth in paragraph (a) of this section, and packaged

after September 1, 1966, must bear the symbol.

(2) All drugs brought under control after February 1, 1966, as set forth in paragraph (a) of this section, which are packaged on or after 180 days from the effective date of such control, shall bear the symbol.

Any drug not subject to control whose labeling bears the symbol shall be deemed misbranded under section 502 (a) of the act.

[31 F.R. 4448, Mar. 16, 1966, as amended at 32 F.R. 203, Jan. 10, 1967, 32 F.R. 4407, Mar. 23, 1967]

§ 166.19 Advisory committees; appointment; procedure; fees.

(a) *Selection, appointment, qualifications, compensation.* (1) Whenever the Commissioner deems necessary the referral to an advisory committee of any matter, with regard to determining whether a regulation under section 201 (v)(2)(C) or (3) of the act should be proposed, issued, amended, or repealed, whether such referral is made upon the Commissioner's own initiative or upon the request of an interested person, the Commissioner will request the National Academy of Sciences to select qualified experts willing to serve on the advisory committee. All such experts shall have had sufficient training and experience in pharmacology, psychiatry, internal medicine, anesthesiology, organic chemistry, sociology, psychology, or in other appropriate science to qualify them on the subject matter to be referred to them. The Commissioner will request the National Academy of Sciences, when it furnishes the names of such experts, to supply a biographical sketch showing the background of their experience and their connection, if any, with academic and commercial institutions.

(2) Each advisory committee shall consist of not less than three experts qualified in the subject matter to be referred to the committee and of adequately diversified professional backgrounds. The Commissioner may specify a larger number to serve. He shall appoint one member of the committee as chairman, and the chairman shall be the spokesman for the committee responsible for receiving and forwarding reports and for other functions of the Committee.

(3) The Commissioner shall appoint the experts so selected and fix their compensation not to exceed the maximum permitted by other authority per day for each day or part thereof spent in committee meetings and in traveling to and from committee meetings held outside the city of their residence, plus necessary traveling and subsistence expenses while the experts are serving away from their places of residence. Subsistence expenses shall not exceed $30 per day.

(b) *Procedure.* (1) The Commissioner shall submit to the chairman of the advisory committee all available materials and information relevant to the matter that has been referred to the committee. If the referral of a matter to an advisory committee is made upon the request of an interested person, the Commissioner shall furnish such person with copies of all materials and information that are furnished to the committee, except those materials which may have been transmitted to the Commissioner by such person and such scientific literature readily available in scientific libraries. The chairman of the committee shall acknowledge receipt of the information and readiness of the committee to act. The date of acknowledgment of receipt of such information shall be considered the beginning of the period allowed for consideration by the committee. A copy of this acknowledgment shall be forwarded by the chairman of the committee to the interested person requesting referral of the matter to the committee. When the Commissioner on his own initiative has referred to an advisory committee any matter concerning a drug which is the subject of a new-drug application, the chairman shall forward a copy of the acknowledgment to any holder of such an application.

(2) A secretariat to the advisory committees will be established by the Commissioner. The secretariat shall furnish members of the committee with copies of any data received by the chairman. If the chairman of the committee believes that a meeting of the committee is necessary before making a recommendation, he shall so inform the Commissioner. Such meetings shall be held in Washington, D.C., or at such other place as the Commissioner shall furnish a suitable meeting place for the committee. If a meeting is held, the secretariat shall keep the minutes and provide clerical assistance.

(3) As soon as practicable, the advisory committee shall make an independent study of the data, and not later than 60 days after acknowledged receipt of such materials and information (unless the time has been extended as provided in subparagraph (4) of this paragraph), the chairman shall certify to the Commissioner the report and recommendations of the committee, including any minority report, together with all underlying data and a statement of the reasons or basis for the recommendations. The report will include copies of all material considered by the committee, except that in the case of scientific literature readily available in scientific libraries proper reference may be made to it instead of furnishing actual copies. A copy of the report of the advisory committee will be supplied to the interested person who requested the referral to the advisory committee, if any there be.

(4) If at any time within 60 days the chairman believes that the advisory committee needs more time, he shall so inform the Commissioner in writing, in which case he shall certify to the Commissioner such report as provided for in subparagraph (3) of this paragraph within an additional 30 days.

(5) The chairman of the committee, after consultation with the committee members, will inform the National Academy of Sciences of the committee's opinion concerning the member who may best represent the committee at a hearing, if one occurs.

(6) More than one referral may be handled by a committee concurrently.

(7) An interested person whose request for a referral of a matter to an advisory committee has been granted in accordance with the provisions of this section, as well as representatives of the Department of Health, Education, and Welfare, shall have a right to consult with the committee in connection with such referred matter. Such person shall notify the chairman and, if practicable, make appointments through him. If any interested person discusses with or offers information to a committee member concerning a referred matter, such committee member shall make a written report of the discussion or offer and submit it to the committee to be made a part of the file of the committee.

(8) Except for discussions with authorized persons, the committee shall not disclose information, material, or data referred to it prior to publication of a regulation unless such disclosure is specifically authorized by the Commissioner.

(c) *Fees.* (1) In the event of a referral of a matter under section 511(g) of the act to an advisory committee, the costs shall be borne by the person who requests the referral of the matter to the committee.

(2) The cost of the advisory committee shall include expenses of the secretariat, compensation of members, necessary travel and subsistence expenses of members, costs of duplicating documents referred to the committee, and other expenses arising by reason of referrals to the committee.

(3) An advance deposit shall be made in the amount of $2,500 to cover the costs. Further advance deposits of $2,500 each shall be made upon request of the Commissioner when necessary to prevent arrears in the payment of such costs. Any deposits in excess of actual expenses will be refunded to the depositor.

(4) All deposits and fees required by the regulations in this section shall be paid by money order, bank draft, or certified check drawn to the order of the Food and Drug Administration, collectible at par at Washington, D.C. All deposits and fees shall be forwarded to the Fiscal Branch, Food and Drug Administration, Department of Health, Education, and Welfare, Washington, D.C., 20204, for deposit to the appropriation "Revolving Fund for Certification and Other Services, Food and Drug Administration."

(5) The Commissioner may waive or refund such fees in whole or in part when in his judgment such action will promote the public interest.

(6) Any person who believes that payment of these fees will work a hardship on him may petition the Commissioner to waive or refund the fees.

[30 F.R. 13903, Nov. 3, 1965. Redesignated, 31 F.R. 1074, Jan. 27, 1966]