Drug Enforcement Administration, Justice

way the disposal of controlled substances through procedures provided in laws and regulations adopted by any State.


§ 1307.22 Disposal of controlled substances by the Administration.

Any controlled substance delivered to the Administration under § 1307.21 or forfeited pursuant to section 511 of the Act (21 U.S.C. 881) may be delivered to any department, bureau, or other agency of the United States or of any State upon proper application addressed to the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537. The application shall show the name, address, and official title of the person or agency to whom the controlled drugs are to be delivered, including the name and quantity of the substances desired and the purpose for which intended. The delivery of such controlled drugs shall be ordered by the Administrator, if, in his opinion, there exists a medical or scientific need therefor.


SPECIAL EXEMPT PERSONS

§ 1307.31 Native American Church.

The listing of peyote as a controlled substance in Schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the Native American Church, and members of the Native American Church so using peyote are exempt from registration. Any person who manufactures peyote for or distributes peyote to the Native American Church, however, is required to obtain registration annually and to comply with all other requirements of law.

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

GENERAL INFORMATION

Sec.
1308.01 Scope of part 1308.
1308.02 Definitions.

§ 1308.01 Scope of part 1308.

Schedules of controlled substances established by section 202 of the Act (21 U.S.C. 812), as they are changed, updated, and republished from time to time, are set forth in this part.
§ 1308.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.


§ 1308.03 Administration Controlled Substances Code Number.

(a) Each controlled substance, or basic thereof, has been assigned an “Administration Controlled Substances Code Number” for purposes of identification of the substances or class on certain Certificates of Registration issued by the Administration pursuant to §1301.35 of this chapter and on certain order forms issued by the Administration pursuant to §1305.05(d) of this chapter. Applicants for procurement and/or individual manufacturing quotas must include the appropriate code number on the application as required in §§1300.12(b) and 1302.22(a) of this chapter. Applicants for import and export permits must include the appropriate code number on the application as required in §§1312.12(a) and 1312.22(a) of this chapter. Authorized registrants who desire to import or export a controlled substance for which an import or export permit is not required must include the appropriate Administration Controlled Substances Code Number beneath or beside the name of each controlled substance listed on the DEA Form 236 (Controlled Substance Import/Export Declaration) which is executed for such importation or exportation as required in §§1312.18(c) and 1312.27(b) of this chapter.

(b) Except as stated in paragraph (a) of this section, no applicant or registrant is required to use the Administration Controlled Substances Code Number for any purpose.


Schedules

§ 1308.11 Schedule I.

(a) Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

(b) Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation (for purposes of paragraph (b)(34) only, the term isomer includes the optical and geometric isomers):

1. Acetyl-alpha-methadol (except levo-alpha-methadol, also known as levo-acetylmethadol, levomethadyl acetate, or LAAM) ........................................ 9603
2. Acetylmethadol ...................................................... 9601
3. Alphaprodine ......................................................... 9602
4. Alphacetylmethadol (except levo-alpha-acetylmethadol, also known as levo-acetylmethadol) .......................................................... 9603
5. Alphameprodine ...................................................... 9604
6. Alphamethadol ....................................................... 9605
7. Alpha-methylfentanyl (N-[1-(alpha-methyl-beta-phenethyl)-4-piperidinyl]-phenylacetamide) .......................... 9612
8. Alpha-methylfentanyl (N-[1-(beta-phenethyl)-4-piperidinyl]-phenylacetamide) ............... 9614
9. Benzethidine .......................................................... 9606
10. Betacetylmethadol ................................................... 9607
11. Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-phenylacetamide) ................ 9830
12. Beta-hydroxy-3-methylfentanyl (other name: N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-phenylacetamide) ............... 9831
13. Betamethadol ......................................................... 9609
14. Betaprodine .......................................................... 9611
15. Betaprodine ......................................................... 9611
16. Clonitazene ......................................................... 9612
17. Dextromoramide .................................................... 9613
18. Dimoramide ........................................................... 9615
19. Diethylthiambutene .................................................. 9616
20. Difenoxin ............................................................. 9618
21. Dimephadon ........................................................... 9619
22. Dimethanthone ...................................................... 9620
23. Dimethionylthiambutene .......................................... 9621
24. Diethylthiambutene .................................................. 9622
25. Dipipanone ............................................................ 9622
26. Ethylthiambutene .................................................... 9623
27. Etionoxalene ......................................................... 9624
28. Ethylthiambutene .................................................... 9625
29. Furicetide ........................................................... 9626
30. Hydroxybuphedrine .................................................. 9627
31. Ketobemidone ........................................................ 9628
32. Levomoramide ....................................................... 9629
33. Levophenacylmorphan ............................................. 9631
34. Methylfentanyl (N-[(3-methyl)-1-(2-phenylethyl)-4-piperidinyl]-N-phenylacetamide) .......................... 9813
35. Methylfentanyl (N-[(3-methyl)-1-(2-thienyl)-ethyl-4-piperidinyl]-N-phenylacetamide) ............... 9833
36. Morphine ............................................................ 9632
37. MPPP (1-methyl-4-phenyl-4-propionoxypiperidine) .................................................. 9661
38. Noracetylmethadol .................................................. 9633
39. Norlevantorphanol ................................................... 9634
40. Normethadone ........................................................ 9635
41. Norpupanone ........................................................... 9636
42. Para-fluorofentanyl (N-[(4-fluorophenyl)N-[(1-(2-phenethyl)-4-piperidinyl]-N-phenylacetamide) ............... 9812
43. PEPAP (1-[1-(2-phenethyl)-4-piperidinyl]-4-acetoxyphenylacetamide) .................. 9663

21 CFR Ch. II (4-1-98 Edition)
(c) Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine .............................................................. 9319
(2) Acetyldihydrocodeine ............................................... 9051
(3) Benzomorphone ...................................................... 9052
(4) Codeine methylbromide .......................................... 9070
(5) Codeine-N-Oxide .................................................. 9053
(6) Cyprenorphone ...................................................... 9054
(7) Desomorphine ...................................................... 9055
(8) Dihydrocodeine .................................................... 9145
(9) Drotophen ........................................................... 9335
(10) Etorphone (except hydrochloride salt) ..................... 9056
(11) Heron ................................................................. 9520
(12) Hydromorphone .................................................. 9301
(13) Methyldorphone .................................................. 9302
(14) Methyldihydrocodeine .......................................... 9304
(15) Morphine methylbromide ....................................... 9305
(16) Morphine methylsulfonate ...................................... 9306
(17) Morphine-N-Oxide ............................................... 9307
(18) Normorphine ..................................................... 9312
(19) Nicocodine ........................................................ 9309
(20) Nicomorphine ..................................................... 9312
(21) Nomorphine ........................................................ 9313
(22) Pholcodine ........................................................ 9314
(23) Thebacin .......................................................... 9315

(d) Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers is possible within the specific chemical designations (for purposes of this paragraph only, the term “isomer” includes the optical, positional, and geometric isomers):

(1) alpha-ethyltryptamine ............................................ 7249
Some trade or other names: etryptamine; Monase; α-ethyl-1H-indole-3-ethanamine; 3-(2-aminobutyl) indole; α-ET; and AET.
(2) 4-bromo-2,5-dimethoxyamphetamine ...................... 7391
Some trade or other names: 4-bromo-2,5-dimethoxy-N,N-dimethylamphetanilne; 4-bromo-2,5-DMA
(3) 4-Bromo-2,5-dimethoxyphenethylamine .................... 7392
Some trade or other names: 2-(4-bromo-2,5-dimethoxyphenyl)-1-aminomethane; alpha-desmethyl DOB; 2C-B, Nexus.
(4) 2,5-dimethoxyamphetamine .................................... 7396
Some trade or other names: 2,5-dimethoxy-N,N-dimethylaniline; MDEA; “STP”
(5) 2,5-dimethoxy-4-ethylamphetamine ....................... 7396
Some trade or other names: MDE, MDEA
(6) 4-methoxyamphetamine .......................................... 7411
Some trade or other names: 4-methoxy-N,N-dimethylaniline; paramethoxyamphetamine, PMA
(7) 5-methoxy-3,4-methylenedioxyamphetamine ............ 7401
(8) 4-methyl-3,5-dimethoxyamphetamine ...................... 7395
Some trade or other names: 4-methyl-2,5-dimethoxy-N,N-dimethylaniline; “DOM”; and “STP”
(9) 3,4-methylenedioxyamphetamine ............................ 7400
(10) 3,4-methylenedioxymethamphetamine (MDMA) .... 7405
(11) 3,4-methylenedioxyn-N-ethylamphetamine (also known as N-ethyl-alpha-methyl-3,4-methylenedioxymethylaniline, N-ethyl MDA, MDE, MDEA ......................................................... 7404
(12) N-hydroxy-3,4-methylenedioxymethamphetamine (also known as N-hydroxy-alpha-methyl-3,4-methylenedioxymethylaniline, and N-hydroxy MDA .................................................. 7402
(13) 3,4,5-trimethoxyamphetamine ............................... 7390
(14) Butylone ................................................................ 7433
Some trade and other names: 3-(β-dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-indolol; N,N-dimethylserotonin; 5-hydroxy-N,N-dimethyltryptamine; mappine
(15) Diethyltryptamine ................................................ 7434
Some trade and other names: N,N-Diethyltryptamine; DET
(16) Dimethoxyamphetamine ........................................ 7435
Some trade or other names: DMT
(17) Isoborneol .................................................................. 7260
Some trade and other names: 7-Ethyl-6,6,7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5H-pyrido[1′,2′:1,2] azepino[5,4-b] indole; Tabernanthe iboga
(18) Lysergic acid diethylamide ...................................... 7315
(19) Marshuana ........................................................... 7360
(20) Mesoxaline ........................................................... 7381
(21) Panaxynol—7374; some trade or other names: 3-aza-6H-dibenzo[b,d]pyran: Synexyl
(22) Peyote ................................................................. 7415
Meaning all parts of the plant presently classified botanically as Lophophora williamsii Lemaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds or extracts (Interpret 21 USC 812(c), Schedule II(c) (12))
(23) N-ethyl-α-piperidinyl benzilate .............................. 7482
(24) N-methyl-α-piperidinyl benzilate ............................ 7484
(25) Psilocin ................................................................ 7437
(26) Psilocybin ............................................................... 7438
(27) Tetrahydrocannabinols ......................................... 7370

81
§ 1308.12 Schedule II.

(a) Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the Controlled Substances Code Number set forth opposite it.

(b) Substances, vegetable origin or chemical synthesis. Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrophan, nalbuphine, nalmefene, naloxone, and naltrexone, and their respective salts, but including the following:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Code Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw opium</td>
<td>9600</td>
</tr>
<tr>
<td>Opium extracts</td>
<td>9610</td>
</tr>
<tr>
<td>Opium fluid</td>
<td>9620</td>
</tr>
</tbody>
</table>

(2) Opium and opium alkaloids.

(3) Opium and opium alkaloids, excepting apomorphine, thebaine-derived butorphanol, dextrophan, nalbuphine, nalmefene, naloxone, and naltrexone, and their respective salts, but including the following:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Code Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw opium</td>
<td>9600</td>
</tr>
<tr>
<td>Opium extracts</td>
<td>9610</td>
</tr>
<tr>
<td>Opium fluid</td>
<td>9620</td>
</tr>
</tbody>
</table>
Drug Enforcement Administration, Justice

| (4) Powdered opium | 9639 |
| (5) Granulated opium | 9640 |
| (6) Tincture of opium | 9630 |
| (7) Codeine | 9050 |
| (8) Ethylmorphine | 9190 |
| (9) Ethosome hydrochloride | 9059 |
| (10) Hydrocodone | 9193 |
| (11) Hydromorphone | 9150 |
| (12) Metopon | 9260 |
| (13) Morfine | 9300 |
| (14) Oxycodone | 9143 |
| (15) Oxymorphone | 9652 |
| (16) Thebaaine | 9333 |

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (b) (2) of this section, except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves (9040) and any salt, compound, derivative or preparation of coca leaves (including cocaine (9043) and ecgonine (9080) and their salts, isomers, derivatives and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.

(5) Concentrate of poppy straw (the crude extract of poppy straw in ether liquid, solid or powder form which contains the phenanthrene alkaloids of the opium poppy), 9670.

(c) Opiates. Unless specifically excepted or unless in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

| (1) Amphetamine, its salts, optical isomers, and salts of its optical isomers | 1100 |
| (2) Methamphetamine, its salts, isomers, and salts of its isomers | 1105 |
| (3) Phenmetrazine and its salts | 1631 |
| (4) Methylphenidate | 1724 |

(e) Depressants. Unless specifically excepted or unless in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

| (1) Amylobarbital | 2125 |
| (2) Glutethimide | 2550 |
| (3) Pentobarbital | 2270 |
| (4) Phenacyclidine | 7471 |
| (5) Seocobarbital | 2315 |

(f) Hallucinogenic substances.

| (1) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved drug product | 7369 |

[g] Immediate precursors. Unless specifically excepted or unless listed in
§ 1308.13 Schedule III.

(a) Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

(b) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

1. Immediate precursor to amphetamine and methamphetamine:
   - (i) Phenylacetone
   - (ii) Phenylethylamine
   - (iii) Phenylpropylamine
   - (iv) Pethylenediamine

2. Immediate precursors to phenylcyclidine (PCP):
   - (i) 1-phenylcyclohexylamine
   - (ii) 1-piperidinocyclohexanecarbonitrile

3. Any compound, mixture or preparation containing:
   - (i) Amobarbital
   - (ii) Secobarbital
   - (iii) Pentobarbital
   - (iv) Barbituric acid
   - (v) 1,5-benzodiazepine-4-carboxaldehyde
   - (vi) Methylhexylpyrazolone
   - (vii) 2-ethylamino-2-(2-thienyl)-cyclohexanone
   - (viii) 1H-pyrazolo[3,4-d]-1,4-benzodiazepine

4. Any suppository dosage form containing:
   - (i) Amobarbital
   - (ii) Secobarbital
   - (iii) Pentobarbital
   - (iv) Phendimetrazine
   - (v) Clortermine
   - (vi) Chlorphentermine

5. Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

6. Not more than 300 milligrams of dihydrocodeine (hydrocodeine) per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

7. Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

8. Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

9. Not more than 300 milligrams of ethylamphetamine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

10. Phencyclidine (PCP):

(d) Narcotic Drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

1. Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

2. Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

3. Not more than 300 milligrams of dihydrocodeine (hydrocodeine) per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

4. Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

5. Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

6. Not more than 300 milligrams of ethylamphetamine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
of isomers is possible within the existence of such salts, isomers, and salts of isomers and salts of isomers whenever the existence of such salts of isomers is possible within the specific chemical designation:

(1) Anabolic Steroids ........................................ 4000

§ 1308.14 Schedule IV.

(a) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

(b) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(1) Not more than 1 milligram of dextromethorphan per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts ........................................... 9809

(2) Not more than 50 milligrams of morphine per 100 milligrams or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts ........................................... 9810

(f) Anabolic steroids. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts of isomers is possible within the specific chemical designation:

(1) Anabolic Steroids ........................................ 4000

(d) Fenfluramine. Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible:

(1) Fenfluramine ........................................... 1670

(e) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:

(1) Cathine ((+)-norpseudoephedrine) ................................................ 1230

(2) Diethylpropion ........................................... 1610
§ 1308.15

(3) Fenfluramine ............................................................ 1760
(4) Fenproporex ............................................................. 1575
(5) Mazindol ................................................................... 1605
(6) Mefenorex ................................................................. 1580
(7) Pemoline (including organometallic complexes and chelates thereof) ......................................................... 1530
(8) Phenetermine .............................................................. 1640
(9) Pimozide ........................................................................ 1750
(10) Sibutramine ............................................................ 1675
(11) SPA (-)-1-dimethylamino-1,2-diphenylethane) ..... 1635

(f) Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts:

(1) Pentazocine .............................................................. 9709
(2) Butorphanol (including its optical isomers) .............. 9720

[39 FR 22143, June 20, 1974]

EDITORIAL NOTE: For Federal Register citations affecting §1308.14, see the List of CFR Sections Affecting this volume.

§ 1308.15 Schedule V.

(a) Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs and their salts, as set forth below:

(1) Buprenorphine .......................................................... 9064

(c) Narcotic drugs containing non-narcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:

(1) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.
(2) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.
(3) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.
(4) Not more than 0.5 milligram of diphenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(d) Stimulants. Unless specifically excepted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:

(1) Pyrovalerone .......................................................... 1485
(2) [Reserved]


EXCLUDED NONNARCOTIC SUBSTANCES

§ 1308.21 Application for exclusion of a nonnarcotic substance.

(a) Any person seeking to have any nonnarcotic substance which may, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301), be lawfully sold over the counter without a prescription, excluded from any schedule, any material, compound, mixture, or preparation containing any of the following nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.
(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

Drug Enforcement Administration, Justice

§ 1308.23

Administrator shall notify the applicant of his acceptance or nonacceptance of his application, and if not accepted, the reason therefore. The Administrator need not accept an application for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of paragraph (b) of this section. If the application is accepted for filing, the Administrator shall issue and publish in the Federal Register his order on the application, which shall include a reference to the legal authority under which the order is issued and the findings of fact and conclusions of law upon which the order is based. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order within 60 days of the date of publication of his order in the Federal Register. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

(d) The Administrator may at any time revoke any exclusion granted pursuant to section 201(g) of the Act (21 U.S.C. 811(g)) by following the procedures set forth in paragraph (c) of this section for handling an application for an exclusion which has been accepted for filing.

§ 1308.22 Excluded substances.

The following nonnarcotic substances which may, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301), be lawfully sold over the counter without a prescription, are excluded from all schedules pursuant to section 201(g) (1) of the Act (21 U.S.C. 811(g) (1)):

EXCLUDED NONNARCOTIC PRODUCTS

<table>
<thead>
<tr>
<th>Company</th>
<th>Product Name</th>
<th>NDC code</th>
<th>Form</th>
<th>Controlled Substance</th>
<th>Amount (mg or mg/ ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bioline Laboratories</td>
<td>Theophed</td>
<td>00719-1945</td>
<td>TB</td>
<td>Phenobarbital</td>
<td>8.00</td>
</tr>
<tr>
<td>Goldline Laboratories</td>
<td>Gulphed Elixir</td>
<td>00182-1377</td>
<td>EL</td>
<td>Phenobarbital</td>
<td>4.00</td>
</tr>
<tr>
<td>Goldline Laboratories</td>
<td>Tedrigen Tablets</td>
<td>00182-0134</td>
<td>TB</td>
<td>Phenobarbital</td>
<td>8.00</td>
</tr>
<tr>
<td>Hawthorne Products Inc</td>
<td>Choate’s Leg Freeze</td>
<td>LQ</td>
<td>Chloral hydrate</td>
<td>246.67</td>
<td></td>
</tr>
<tr>
<td>Parke-Davis &amp; Co</td>
<td>Tedral</td>
<td>00071-0230</td>
<td>TB</td>
<td>Phenobarbital</td>
<td>8.00</td>
</tr>
<tr>
<td>Parke-Davis &amp; Co</td>
<td>Tedral Elixir</td>
<td>00071-0242</td>
<td>EX</td>
<td>Phenobarbital</td>
<td>40.00</td>
</tr>
<tr>
<td>Parke-Davis &amp; Co</td>
<td>Tedral S.A.</td>
<td>00071-0231</td>
<td>TB</td>
<td>Phenobarbital</td>
<td>8.00</td>
</tr>
<tr>
<td>Parke-Davis &amp; Co</td>
<td>Tedral Suspension</td>
<td>00071-0237</td>
<td>SU</td>
<td>Phenobarbital</td>
<td>80.00</td>
</tr>
<tr>
<td>Parmed Pharmacy</td>
<td>Asma-Ese</td>
<td>00349-2018</td>
<td>TB</td>
<td>Phenobarbital</td>
<td>8.10</td>
</tr>
<tr>
<td>Rondex Labs</td>
<td>Azma-Aids</td>
<td>00367-3153</td>
<td>TB</td>
<td>Phenobarbital</td>
<td>8.00</td>
</tr>
<tr>
<td>Smith Kline Consumer</td>
<td>Benzodex</td>
<td>49692-0928</td>
<td>IN</td>
<td>Propylhexedrine</td>
<td>250.00</td>
</tr>
<tr>
<td>Sterling Drug, Inc</td>
<td>Bronkolor</td>
<td>00057-1004</td>
<td>EL</td>
<td>Phenobarbital</td>
<td>0.80</td>
</tr>
<tr>
<td>Sterling Drug, Inc</td>
<td>Bronkotabs</td>
<td>00057-1005</td>
<td>TB</td>
<td>Phenobarbital</td>
<td>8.00</td>
</tr>
<tr>
<td>Vicks Chemical Co</td>
<td>Vicks Inhaler</td>
<td>23900-0010</td>
<td>IN</td>
<td>I-Desoxyephedrine</td>
<td>113.00</td>
</tr>
<tr>
<td>White Hall Labs</td>
<td>Primatene (P-tablets)</td>
<td>00573-2940</td>
<td>TB</td>
<td>Phenobarbital</td>
<td>8.00</td>
</tr>
</tbody>
</table>


Exempt Chemical Preparations

§ 1308.23 Exemption of certain chemical preparations; application.

(a) The Administrator may, by regulation, exempt from the application of all or any part of the Act any chemical preparation or mixture containing one or more controlled substances listed in any schedule, which preparation or mixture is intended for laboratory, industrial, educational, or special research purposes and not for general administration to a human being or other animal, if the preparation or mixture either:

(1) Contains no narcotic controlled substance and is packaged in such a

§ 1308.23  21 CFR Ch. II (4-1-98 Edition)

form or concentration that the packaged quantity does not present any significant potential for abuse (the type of packaging and the history of abuse of the same or similar preparations may be considered in determining the potential for abuse of the preparation or mixture); or

(2) Contains either a narcotic or non-narcotic controlled substance and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion, or concentration, that the preparation or mixture does not present any potential for abuse. If the preparation or mixture contains a narcotic controlled substance, the preparation or mixture must be formulated in such a manner that it incorporates methods of denaturing or other means so that the preparation or mixture is not liable to be abused or have ill effects, if abused, and so that the narcotic substance cannot in practice be removed.

(b) Any person seeking to have any preparation or mixture containing a controlled substance and one or more noncontrolled substances exempted from the application of all or any part of the Act, pursuant to paragraph (a) of this section, may apply to the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(c) An application for an exemption under this section shall contain the following information:

(1) The name, address, and registration number, if any, of the applicant;

(2) The name, address, and registration number, if any, of the manufacturer or importer of the preparation or mixture, if not the applicant;

(3) The exact trade name or other designation of the preparation or mixture;

(4) The complete qualitative and quantitative composition of the preparation or mixture (including all active and inactive ingredients and all controlled and noncontrolled substances);

(5) The form of the immediate container in which the preparation or mixture will be distributed with sufficient descriptive detail to identify the preparation or mixture (e.g., bottle, packet, vial, soft plastic pillow, agar gel plate, etc.);

(6) The dimensions or capacity of the immediate container of the preparation or mixture;

(7) The label and labeling, as defined in part 1300 of this chapter, of the immediate container and the commercial containers, if any, of the preparation or mixture;

(8) A brief statement of the facts which the applicant believes justify the granting of an exemption under this paragraph, including information on the use to which the preparation or mixture will be put;

(9) The date of the application; and

(10) Which of the information submitted on the application, if any, is deemed by the applicant to be a trade secret or otherwise confidential and entitled to protection under subsection 402(a)(8) of the Act (21 U.S.C. 842(a)(8)) or any other law restricting public disclosure of information.

(d) The Administrator may require the applicant to submit such documents or written statements of fact relevant to the application as he deems necessary to determine whether the application should be granted.

(e) Within a reasonable period of time after the receipt of an application for an exemption under this section, the Administrator shall notify the applicant of his acceptance or nonacceptance of his application, and if not accepted, the reason therefor. The Administrator need not accept an application for filing unless any of the requirements prescribed in paragraph (c) or requested pursuant to paragraph (d) is lacking or is not set forth as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of paragraphs (c) and (d) of this section. If the application is accepted for filing, the Administrator shall issue and publish in the Federal Register his order on the application, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order within 60 days of the date of publication of his order in the Federal Register.
§ 1308.24 Exempt chemical preparations.

(a) The chemical preparations and mixtures approved pursuant to §1308.23 are exempt from application of sections 302, 303, 305, 306, 307, 308, 309, 1002, 1003 and 1004 of the Act (21 U.S.C. 822-823, 825-829, 952-954) and §1301.74 of this chapter, to the extent described in paragraphs (b) to (h) of this section. Substances set forth in paragraph (j) of this section shall be exempt from the application of sections 305, 306, 307, 308, 309, 1002, 1003 and 1004 of the Act (21 U.S.C. 825-829, 952-954) and §§1301.71—1301.73 and 1301.74 (a), (b), (d), (e) and (f) of this chapter to the extent as hereinafter may be provided.

(b) Registration and security: Any person who manufactures an exempt chemical preparation or mixture must be registered under the Act and comply with all relevant security requirements regarding controlled substances being used in the manufacturing process until the preparation or mixture is in the form described in paragraph (i) of this section. Any other person who handles an exempt chemical preparation after it is in the form described in paragraph (i) of this section is not required to be registered under the Act to handle that preparation, and the preparation is not required to be stored in accordance with security requirements regarding controlled substances.

(c) Labeling: In lieu of the requirements set forth in part 1302 of this chapter, the label and the labeling of an exempt chemical preparation must be prominently marked with its full trade name or other description and the name of the manufacturer or supplier as set forth in paragraph (i) of this section, in such a way that the product can be readily identified as an exempt chemical preparation. The label and labeling must also include in a prominent manner the statement “For industrial use only” or “For chemical use only” or “For in vitro use only—not for human or animal use” or “Diagnostic reagent—for professional use only” or a comparable statement warning the person reading it that human or animal use is not intended. The symbol designating the schedule of the controlled substance is not required on either the label or the labeling of the exempt chemical preparation, nor is it necessary to list all ingredients of the preparation.

(d) Records and reports: Any person who manufactures an exempt chemical preparation or mixture must keep complete and accurate records and file all reports required under part 1304 of this chapter regarding exempt chemical preparations, the manufacturer need only record the name, address, and registration number, if any, of each person to whom the manufacturer distributes any exempt chemical preparation. Each importer or exporter of an exempt narcotic chemical preparation must submit a semiannual report of the total quantity of each substance imported or exported in each calendar half-year within 30 days of the close of the period to the Drug and Chemical Evaluation Section, Drug Enforcement Administration, Department of Justice.
§ 1308.25 Exclusion of a veterinary anabolic steroid implant product; application.

(a) Any person seeking to have any anabolic steroid product, which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for such administration, identified as being excluded from any schedule, pursuant to section 102(41)(B)(i) of the Act (21 U.S.C. 802(41)(B)(i)), may apply to the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(b) An application for any exclusion under this section shall be submitted in triplicate and contain the following information:

(1) The name and address of the applicant;
(2) The name of the product;
(3) The chemical structural formula or description for any anabolic steroid contained in the product;
(4) A complete description of dosage and quantitative composition of the dosage form;
(5) The conditions of use including whether or not Federal law restricts this product to use by or on the order of a licensed veterinarian;
(6) A description of the delivery system in which the dosage form will be distributed with sufficient detail to
§ 1308.31 Application for exemption of a nonnarcotic prescription product.

(a) Any person seeking to have any compound, mixture, or preparation containing any nonnarcotic controlled substance listed in §1308.12(e), or in §1308.13 (b) or (c), or in §1308.14, or in §1308.15, exempted from application of all or any part of the Act pursuant to section 201(g)(3)(A), of the Act (21 U.S.C. 811(g)(3)(A)), may apply to the Administrator, Drug Enforcement Administration, Washington, DC 20537, for such exemption.

(b) An application for an exemption under this section shall contain the following information:

(1) The complete quantitative composition of the dosage form.

(2) Description of the unit dosage form together with complete labeling.
§ 1308.32

(3) A summary of the pharmacology of the product including animal investigations and clinical evaluations and studies, with emphasis on the psychic and/or physiological dependence liability (this must be done for each of the active ingredients separately and for the combination product).

(4) Details of synergisms and antagonisms among ingredients.

(5) Deterrent effects of the noncontrolled ingredients.

(6) Complete copies of all literature in support of claims.

(7) Reported instances of abuse.

(8) Reported and anticipated adverse effects.

(9) Number of dosage units produced for the past 2 years.

(c) Within a reasonable period of time after the receipt of an application for an exemption under this section, the Administrator shall notify the applicant of his acceptance or non-acceptance of the application, and if not accepted, the reason therefor. The Administrator need not accept an application for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth so as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of paragraph (b) of this section. If accepted for filing, the Administrator shall publish in the FEDERAL REGISTER general notice of this proposed rulemaking in granting or denying the application. Such notice shall include a reference to the legal authority under which the rule is proposed, a statement of the proposed rule granting or denying an exemption, and, in the discretion of the Administrator, a summary of the subjects and issues involved. The Administrator shall permit any interested person to file written comments on or objections to the proposal and shall designate in the notice of proposed rule making the time during which such filings may be made. After consideration of the application and any comments on or objections to his proposed rulemaking, the Administrator shall issue and publish in the FEDERAL REGISTER his final order on the application, which shall set forth the findings of fact and conclusions of law upon which the order is based. This order shall specify the date on which it shall take effect, which shall not be less than 30 days from the date of publication in the FEDERAL REGISTER unless the Administrator finds that conditions of public health or safety necessitate an earlier effective date, in which event the Administrator shall specify in the order his findings as to such conditions.

(d) The Administrator may revoke any exemption granted pursuant to section 201(g)(3)(A) of the Act (21 U.S.C. 811(g)(3)(A)) by following the procedures set forth in paragraph (c) of this section for handling an application for an exemption which has been accepted for filing.


§ 1308.32 Exempted prescription products.

The compounds, mixtures, or preparations that contain a nonnarcotic controlled substance listed in § 1308.12(e) or in § 1308.13 (b) or (c) or in § 1308.14 or in § 1308.15 listed in the Table of Exempted Prescription Products have been exempted by the Administrator from the application of sections 302 through 305, 307 through 309, 1002 through 1004 of the Act (21 U.S.C. 822 through 825, 827 through 829, and 952 through 954) and §§ 1301.13, 1301.22, and §§ 1301.71 through 1301.76 of this chapter for administrative purposes only. An exception to the above is that those products containing butalbital shall not be exempt from the requirement of 21 U.S.C. 952-954 concerning importation, exportation, transshipment and in-transit shipment of controlled substances. Any deviation from the quantitative composition of any of the listed drugs shall require a petition of exemption in order for the product to be exempted. A listing of the Exempted Prescription Products may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537.

§ 1308.33 Exemption of certain anabolic steroid products; application.

(a) The Administrator, upon the recommendation of the Secretary of Health and Human Services, may, by regulation, exempt from the application of all or any part of the Act any compound, mixture, or preparation containing an anabolic steroid as defined in part 1300 of this chapter if, because of its concentration, preparation, mixture or delivery system, it has no significant potential for abuse (Pub. L. 101–647 section 1903(a)).

(b) Any person seeking to have any compound, mixture, or preparation containing an anabolic steroid as defined in part 1300 of this chapter exempted from the application of all or any part of the Act, pursuant to paragraph (a) of this section, may apply to the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

(c) An application for an exemption under this section shall be submitted in triplicate and contain the following information:

(1) The name and address of the applicant;
(2) The name of the product;
(3) The chemical structural formula or description for any anabolic steroid contained in the product;
(4) The complete description of dosage and quantitative composition of the dosage form;
(5) A description of the delivery system, if applicable;
(6) The indications and conditions for use in which species, including whether or not this product is a prescription drug;
(7) Information to facilitate identification of the dosage form, such as shape, color, coating, and scoring;
(8) The label and labeling of the immediate container and the commercial containers, if any, of the product;
(9) The units in which the dosage form is ordinarily available; and
(i) The facts which the applicant believes justify:

(i) A determination that the product has no significant potential for abuse and
(ii) a granting of an exemption under this section.

(d) Within a reasonable period of time after the receipt of the application for an exemption under this section, the Administrator shall notify the applicant of his acceptance or non-acceptance of the application, and if not accepted, the reason therefor. The Administrator need not accept an application for filing if any of the requirements prescribed in paragraph (c) of this section is lacking or is not set forth so as to be readily understood. The applicant may amend the application to meet the requirements of paragraph (c) of this section. If accepted for filing, the Administrator will request from the Secretary for Health and Human Services his recommendation, as to whether such product which contains an anabolic steroid should be considered for exemption from certain portions of the Controlled Substances Act. On receipt of the recommendation of the Secretary, the Administrator shall make a determination as to whether the evidence submitted or otherwise available sufficiently establishes that the product possesses no significant potential for abuse. The Administrator shall issue and publish in the Federal Register his order on the application, which shall include a reference to the legal authority under which the order is issued, and the findings of fact and conclusions of law upon which the order is based. This order shall specify the date on which it will take effect. The Administrator shall permit any interested person to file written comments on or objections to the order within 60 days of the date of publication of his order in the Federal Register. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

(e) The Administrator may revoke any exemption granted pursuant to section 1903(a) of Public Law 101–647 by following the procedures set forth in...
§ 1308.34 Exempt anabolic steroid products.

The list of compounds, mixtures, or preparations that contain an anabolic steroid that have been exempted by the Administrator from application of sections 302 through 309 and 1002 through 1004 of the Act (21 U.S.C. 822–829 and 952–954) and §§ 1301.13, 1301.22, and 1301.71 through 1301.76 of this chapter for administrative purposes only may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537.


§ 1308.41 Hearings generally.

In any case where the Administrator shall hold a hearing on the issuance, amendment, or repeal of rules pursuant to section 201 of the Act, the procedures for such hearing and accompanying proceedings shall be governed generally by the rulemaking procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by section 201 of the Act (21 U.S.C. 811), by §§ 1308.42–1308.51, and by §§ 1316.41–1316.67 of this chapter.


Hearings

§ 1308.42 Purpose of hearing.

If requested by any interested person after proceedings are initiated pursuant to § 1308.43, the Administrator shall hold a hearing for the purpose of receiving factual evidence and expert opinion regarding the issues involved in the issuance, amendment or repeal of a rule issued pursuant to section 201(a) of the Act (21 U.S.C. 811(a)). Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law. Additional information relating to hearings to include waivers or modification of rules, request for hearing, burden of proof, time and place, and final order are set forth in part 1316 of this chapter.


§ 1308.43 Initiation of proceedings for rulemaking.

(a) Any interested person may submit a petition to initiate proceedings for the issuance, amendment, or repeal of any rule or regulation issuable pursuant to the provisions of section 201 of the Act.

(b) Petitions shall be submitted in quintuplicate to the Administrator in the following form:

________________________________________________________________________

(Date)

ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION
Department of Justice, Washington, DC 20537.

DEAR SIR: The undersigned __________ hereby petitions the Administrator to initiate proceedings for the issuance (amendment or repeal) of a rule or regulation pursuant to section 201 of the Controlled Substances Act. Attached hereto and constituting a part of this petition are the following:

(A) The proposed rule in the form proposed by the petitioner. (If the petitioner seeks the amendment or repeal of an existing rule, the existing rule, together with a reference to the section in the Code of Federal Regulations where it appears, should be included.)

(B) A statement of the grounds which the petitioner relies for the issuance (amendment or repeal) of the rule. (Such grounds shall include a reasonably concise statement of the facts relied upon by the petitioner, including a summary of any relevant medical or scientific evidence known to the petitioner.)

All notices to be sent regarding this petition should be addressed to:
________________________________________________________________________

(Name)

________________________________________________________________________

(Street Address)

________________________________________________________________________

(City and State)

Respectfully yours,
__________________________________________

(Signature of petitioner)

(c) Within a reasonable period of time after the receipt of a petition, the
Drug Enforcement Administration, Justice

§ 1308.44 Request for hearing or appearance; waiver.

(a) Any interested person desiring a hearing on a proposed rulemaking, shall, within 30 days after the date of publication of notice of the proposed rulemaking in the Federal Register, file with the Administrator a written request for a hearing in the form prescribed in §1316.47 of this chapter.

(b) Any interested person desiring to participate in a hearing pursuant to §1308.41 shall, within 30 days after the date of publication of the notice of hearing in the Federal Register, file with the Administrator a written notice of his intention to participate in such hearing in the form prescribed in §1316.48 of this chapter. Any person filing a request for a hearing need not also file a notice of appearance; the request for a hearing shall be deemed to be a notice of appearance.

(c) Any interested person may, within the period permitted for filing a request for a hearing, file with the Administrator a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding his position on the matters of fact and law involved in making to issue, amend, or repeal any rule pursuant to section 201 of the Act. Such published notice shall include a statement of the time, place, and nature of any hearings on the proposal in the event a hearing is requested pursuant to §1308.44. Such hearings may not be commenced until after the expiration of at least 30 days from the date the general notice is published in the Federal Register. Such published notice shall also include a reference to the legal authority under which the rule is proposed, a statement of the proposed rule, and, in the discretion of the Administrator, a summary of the subjects and issues involved.

§ 1308.44 Request for hearing or appearance; waiver.

(a) Any interested person desiring a hearing on a proposed rulemaking, shall, within 30 days after the date of publication of notice of the proposed rulemaking in the Federal Register, file with the Administrator a written request for a hearing in the form prescribed in §1316.47 of this chapter.

(b) Any interested person desiring to participate in a hearing pursuant to §1308.41 shall, within 30 days after the date of publication of the notice of hearing in the Federal Register, file with the Administrator a written notice of his intention to participate in such hearing in the form prescribed in §1316.48 of this chapter. Any person filing a request for a hearing need not also file a notice of appearance; the request for a hearing shall be deemed to be a notice of appearance.

(c) Any interested person may, within the period permitted for filing a request for a hearing, file with the Administrator a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding his position on the matters of fact and law involved in making to issue, amend, or repeal any rule pursuant to section 201 of the Act. Such published notice shall include a statement of the time, place, and nature of any hearings on the proposal in the event a hearing is requested pursuant to §1308.44. Such hearings may not be commenced until after the expiration of at least 30 days from the date the general notice is published in the Federal Register. Such published notice shall also include a reference to the legal authority under which the rule is proposed, a statement of the proposed rule, and, in the discretion of the Administrator, a summary of the subjects and issues involved.

§ 1308.44 Request for hearing or appearance; waiver.

(a) Any interested person desiring a hearing on a proposed rulemaking, shall, within 30 days after the date of publication of notice of the proposed rulemaking in the Federal Register, file with the Administrator a written request for a hearing in the form prescribed in §1316.47 of this chapter.

(b) Any interested person desiring to participate in a hearing pursuant to §1308.41 shall, within 30 days after the date of publication of the notice of hearing in the Federal Register, file with the Administrator a written notice of his intention to participate in such hearing in the form prescribed in §1316.48 of this chapter. Any person filing a request for a hearing need not also file a notice of appearance; the request for a hearing shall be deemed to be a notice of appearance.

(c) Any interested person may, within the period permitted for filing a request for a hearing, file with the Administrator a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding his position on the matters of fact and law involved in making to issue, amend, or repeal any rule pursuant to section 201 of the Act. Such published notice shall include a statement of the time, place, and nature of any hearings on the proposal in the event a hearing is requested pursuant to §1308.44. Such hearings may not be commenced until after the expiration of at least 30 days from the date the general notice is published in the Federal Register. Such published notice shall also include a reference to the legal authority under which the rule is proposed, a statement of the proposed rule, and, in the discretion of the Administrator, a summary of the subjects and issues involved.
§ 1308.45 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall cause to be published in the Federal Register his order in the proceeding, which shall set forth the final rule and the findings of fact and conclusions of law upon which the rule is based. This order shall specify the date on which it shall take effect, which shall not be less than 30 days from the date of publication in the Federal Register unless the Administrator finds that conditions of public health or safety necessitate an earlier effective date, in which event the Administrator shall specify in the order his findings as to such conditions.

§ 1308.46 Control required under international treaty.

Pursuant to section 201(d) of the Act (21 U.S.C. 811(d)), where control of a substance is required by U.S. obligations under international treaties, conventions, or protocols in effect on May 1, 1971, the Administrator shall issue and publish in the Federal Register an order controlling such substance under the schedule he deems most appropriate to carry out obligations. Issuance of such an order shall be without regard to the findings required by subsections 201(a) or 202(b) of the Act (21 U.S.C. 811(a) or 812(b)) and without regard to the procedures prescribed by § 1308.41 or subsections 201(a) and (b) of the Act (21 U.S.C. 811(a) and (b)). An order controlling a substance shall become effective 30 days from the date of publication in the Federal Register, unless the Administrator finds that conditions of public health or safety necessitate an earlier effective date, in which event the Administrator shall specify in the order his findings as to such conditions.

§ 1308.47 Control of immediate precursors.

Pursuant to section 201(e) of the Act (21 U.S.C. 811(e)), the Administrator may, without regard to the findings required by subsection 201(a) or 202(b) of the Act (21 U.S.C. 811(a) or 812(b)) and without regard to the procedures prescribed by § 1308.41 or subsections 201(a) and (b) of the Act (21 U.S.C. 811(a) and (b)), issue and publish in the Federal Register an order controlling an immediate precursor. The order shall designate the schedule in which the immediate precursor is to be placed, which shall be the same schedule in which the controlled substance of which it is an immediate precursor is placed or any other schedule with a higher numerical designation. An order controlling an immediate precursor shall become effective 30 days from the date of publication in the Federal Register, unless the Administrator finds that conditions of public health or safety necessitate an earlier effective date, in which event the Administrator shall specify in the order his findings as to such conditions.
and medical evaluation of the Secretary of Health and Human Services, the Administrator may place a substance into Schedule I on a temporary basis, if he determines that such action is necessary to avoid an imminent hazard to the public safety. An order issued under this section may not be effective before the expiration of 30 days from:

(a) The date of publication by the Administrator of a notice in the Federal Register of his intention to issue such order and the grounds upon which such order is to be issued, and

(b) The date the Administrator has transmitted notification to the Secretary of Health and Human Services of his intention to issue such order. An order issued under this section shall be vacated upon the conclusion of a subsequent rulemaking proceeding initiated under section 201(a) (21 U.S.C. 811(a)) with respect to such substance or at the end of one year from the effective date of the order scheduling the substance, except that during the pendency of proceedings under section 201(a) (21 U.S.C. 811(a)) with respect to the substance, the Administrator may extend the temporary scheduling for up to six months.


PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF LIST I CHEMICALS

GENERAL INFORMATION

§ 1309.01 Scope of part 1309.
Procedures governing the registration of manufacturers, distributors, importers and exporters of List I substances.