§ 1308.11

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 §§1303.2(b) and 1303.22(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. Applicants 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, and 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):

<table>
<thead>
<tr>
<th>Code Number</th>
<th>Substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>9603</td>
<td>Alphabetically methadole (except levoracetylmethadol also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM)</td>
</tr>
<tr>
<td>9607</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9610</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9613</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9614</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9615</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9616</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9617</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9618</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9619</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9620</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9621</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9622</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9623</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9624</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9625</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9626</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9627</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9628</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9629</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9630</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9631</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9632</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9633</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9634</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9635</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9636</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9637</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9638</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9639</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9640</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9641</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9642</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9643</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9644</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9645</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9646</td>
<td>Betamethadone</td>
</tr>
<tr>
<td>9812</td>
<td>Beta-hydroxy-7-fluorofentanyl (other name: N-[1-methyl-2-(2-thienyl)-4-piperidinyl]-4-phenoxypropanamide)</td>
</tr>
<tr>
<td>9813</td>
<td>Beta-hydroxy-3-fluorofentanyl (other name: N-[1-methyl-2-(2-thienyl)-4-piperidinyl]-4-phenoxypropanamide)</td>
</tr>
<tr>
<td>9814</td>
<td>Beta-hydroxy-2-fluorofentanyl (other name: N-[1-methyl-2-(2-thienyl)-4-piperidinyl]-4-phenoxypropanamide)</td>
</tr>
</tbody>
</table>

(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:
(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 wherever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this paragraph only, the term “isomer” includes the optical, position and geometric isomers):

(1) Alpha-ethyltryptamine ................................................. 7249
(2) 4-methyl-2,5-dimethoxyamphetamine .......................... 7391
(3) 4-Methyl-2,5-dimethoxy-α-methylphenethylamine; alpha- desmethyl DOE; 2C-B, Nexus. 7396
(5) 2,5-dimethoxy-4-ethylamphetamine ........................... 7399
(6) 4-methoxyamphetamine ............................................. 7411
(7) 3,4-methylenedioxyamphetamine ............................... 7400
(8) 3,4-methylenedioxy-α-methylphenethylamine; "DOM"; and "STP" .................................................. 7405
(9) 3,4-methylenedioxyamphetamine ............................... 7401
(10) 3,4-methylenedioxyamphetamine (MDMA) ............... 7405
(11) N-hydroxy-3,4-methylenedioxyamphetamine (also known as N-hydroxy-alpha-methyl-3,4-methylenedioxyphenethylamine, and N-hydroxy MDE) 7402
(12) N-hydroxy-3,4-methylenedioxyamphetamine (also known as N-hydroxy-alpha-methyl-3,4-methylenedioxyphenethylamine, and N-hydroxy MDE) 7402
(13) 3,4,5-trimethoxyamphetamine .................................. 7390
(14) Bufotenine .............................................................. 7433
(15) Diethyltryptamine .................................................... 7434
(16) Dimethyltryptamine .................................................. 7435
(17) Dihydrocodeine ....................................................... 5832
(18) N,N-diethyl-3-piperidyl benzilate ............................. 7482
(19) N,N-diethyl-3-piperidyl benzilate ............................. 7484
(20) N,N-diethyl-3-piperidyl benzilate ............................. 7484
(21) Paraethyl—7347; some trade or other names: 3- Hexy-1-hydroxy-7,8,9,10-tetrahydro-6,9,9-trimethyl- 6H-dibenzo[b,d]pyran; Synhexyl. 7415
(22) Peyote ................................................................. 7415
(23) Peyote ................................................................. 7415
(24) Peyote ................................................................. 7415
(25) Peyote ................................................................. 7415
(26) Peyote ................................................................. 7415
(27) Tetrahydrocannabinols ............................................ 7370

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 any compound, mixture, salts, derivative, mixture, or preparation of such plant, its seeds or extracts (Interpret 21 USC 812(c), Schedule I(c) (12))

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains

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

83
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. Gamma-hydroxybutyric acid (some other names include GHB, gamma-hydroxybutyrate; 4-hydroxybutyric acid; sodium oxybate; sodium oxybutyrate)
2. Medloqualone
3. Methaqualone

(f) 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. N-[1-benzyl-4-piperidyl]-N-phenylpropanamide (thenylfentanyl), its optical isomers, salts and salts of isomers
2. Methcathinone
3. Fenethylline
4. Methamphetamines
5. Methamphetamine
6. N-ethylamphetamine
7. N-allyl-5-phenyl-2-oxazolamine
8. N,N-dimethylamphetamine (also known as N,N-alpha-trimethyl-benzeneethanamine; N,N-alpha-trimethylphenethylamine)
9. N,N-alpha-trimethylpiperidines
10. N,N-dimethylamphetamines

(g) Temporary listing of substances subject to emergency scheduling. Any material, compound, mixture or preparation which contains any quantity of the following substances:

1. N-[1-benzyl-4-piperidyl]-N-phenylpropanamide (benzfentanyl), its optical isomers, salts and salts of isomers
2. N-[2-thienyl(methyl)-4-piperidyl]-N-phenylpropanamide (thienylfentanyl), its optical isomers, salts and salts of isomers

§ 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, nalbuphine, naloxone, and naltrexone, and their respective salts, but including the following:

   1. Raw opium
   2. Opium extracts
   3. Opium fluid
   4. Powdered opium
   5. Granulated opium
   6. Tincture of opium
   7. Codeine
   8. Dihydrocodeine
   9. Ethylmorphine
   10. Metadon hydrochloride
   11. Hydrocodone
   12. Hydromorphone
   13. Metopon
   14. Morphine
   15. Oxycodone
   16. Oxymorphone
   17. Thebaïne

   (2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (b) (1) of this section, except that these substances shall not include the isoquinoline alkaloids of opium.

3. Opium poppy and poppy straw.

4. Coca leaves (including cocaine (9041) and eugonine (9180) 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

Editorial Note: For Federal Register citations affecting §1308.11, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.
§ 1308.13

(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:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Code Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine, its salts, optical isomers, and salts of its optical isomers</td>
<td>100</td>
</tr>
<tr>
<td>Methamphetamine, its salts, isomers, and salts of its isomers</td>
<td>1105</td>
</tr>
<tr>
<td>Phenmetrazine and its salts</td>
<td>1631</td>
</tr>
<tr>
<td>Methylphenidate</td>
<td>1724</td>
</tr>
</tbody>
</table>

(c) Opiates. Unless specifically excepted or unless listed in another schedule any of the following opiates, including its 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, dextropropoxyphene and levopropoxyphene excepted:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Code Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amobarbital</td>
<td>2125</td>
</tr>
<tr>
<td>Glutethimide</td>
<td>2550</td>
</tr>
<tr>
<td>Pentobarbital</td>
<td>2270</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>2315</td>
</tr>
</tbody>
</table>

(d) Hallucinogenic substances.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Code Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nabilone</td>
<td>7379</td>
</tr>
</tbody>
</table>

(3) Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Code Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCC</td>
<td>8603</td>
</tr>
</tbody>
</table>

(4) Methylphenidate | 1724 |

[Another name for nabilone: (+)-trans-3-(1,1-dimethylheptyl)-6,6,7,8,10,10a-hexahydro-1-hydroxy-6,6-dimethyl-9H-dibenzo[6,6]pyran-9-one]
the central nervous system, including its salts, isomers (whether optical, positional, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under §1308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances

(2) Benzphetamine

(3) Chlorphentermine

(4) Clortermine

(5) Phendimetrazine

(c) Depressants. 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 depressant effect on the central nervous system:

(1) Any compound, mixture or preparation containing:
   (i) Amobarbital
   (ii) Secobarbital
   (iii) Pentobarbital
   or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule

(2) Any suppository dosage form containing:
   (i) Amobarbital
   (ii) Secobarbital
   (iii) Pentobarbital
   or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.

(3) Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof

(4) Chlorhexadol

(5) Any drug product containing gamma hydroxybutyric acid, 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

(e) 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 isquinoline 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 dihydromorphine (hydrocodeine) per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isquinoline alkaloid of opium

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

(7) Not more than 500 milligrams of opium per 100 milliliters or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts

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

(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

(g) Hallucinogenic substances.

(1) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product—7369.
§ 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 difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit .......................................................... 9167

2. Dextropropoxyphene (alpha-4-dimethylamino-2-diphenyl-3-methyl-2-propoxybutane) .......................... 9278

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

1. Alprazolam ........................................................... 2882

2. Barbital ......................................................... 2145

3. Bromazepam ..................................................... 2748

4. Camazepam ....................................................... 2749

5. Chloral betaine .................................................. 2460

6. Chloral hydrate .................................................. 2465

7. Chlordiazepoxide ............................................... 2744

8. Clotazam .......................................................... 2751

9. Clozaepate ....................................................... 2768

10. Clotazepam ...................................................... 2752

11. Clonazepam ...................................................... 2753

12. Clorazolam ...................................................... 2754

13. Delorazepam .................................................... 2755

14. Diazepam ........................................................ 2765

15. Estazolam ........................................................ 2756

16. Ethchlorvynol ................................................... 2540

17. Ethinamate ...................................................... 2545

18. Ethyl lofazepate ................................................ 2758

19. Fluclazepam ...................................................... 2759

20. Flunitrazepam ................................................... 2763

21. Flurazepam ...................................................... 2767

22. Halazepam ....................................................... 2762

23. Haloxazolam ..................................................... 2771

24. Ketazolam ....................................................... 2772

25. Loprazolam ...................................................... 2773

26. Lorazepam ....................................................... 2774

27. Lormetazepam ................................................... 2775

28. Mebutamate ...................................................... 2800

29. Medazepam ....................................................... 2836

30. Meprobamate ..................................................... 2820

31. Methohexital .................................................... 2264

32. Methylphenobarbital (mepobarbital) ....................... 2250

33. Midaizinol ....................................................... 2884

34. Nimetazepam ..................................................... 2837

35. Nitrazepam ....................................................... 2834

36. Nordiazepam ..................................................... 2838

37. Oxazepam ........................................................ 2835

38. Oxazepam ....................................................... 2839

39. Paraldehyde ..................................................... 2585

40. Petichloral ...................................................... 2591

41. Phenobarbital ................................................... 2265

42. Pinazepam ....................................................... 2883

43. Prazeepam ....................................................... 2764

44. Quazepam ....................................................... 2861

45. Temazepam ....................................................... 2925

46. Tetrazepam ....................................................... 2886

47. Triazolam ....................................................... 2887

48. Zaklofen ......................................................... 2781

49. Zolpidem ......................................................... 2783

(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. Caffine (+)-norpseudoephedrine) .......................... 1200

2. Diethylpropion .................................................. 1610

3. Fenfluramine ..................................................... 1760

4. Fenpropopex ..................................................... 1575

5. Mazindol ........................................................ 1605

6. Mefenoxem ....................................................... 1580

7. Modafinil ........................................................ 1680

8. Pemoline (including organometallic complexes and chelates thereof) ............................................ 1530

9. Phenetermine .................................................... 1640

10. Pipanol .......................................................... 1750

11. Sulbauramine ..................................................... 1675

12. SPA (+)-1-dimethylaminol-1-diphenylethene) ........... 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. Pentazoxide ................................................... 9709

2. Butorphanol (including its optical isomers) .......... 9720
§ 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 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.
(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.
(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.
(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.
(6) Not more than 0.5 milligram of difenoxin 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]

§ 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, pursuant to section 201(g)(1) of the Act (21 U.S.C. 811(g)(1)), may apply to the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537.

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

(1) The name and address of the applicant;
(2) The name of the substance for which exclusion is sought; and
(3) The complete quantitative composition of the substance.

(c) Within a reasonable period of time after the receipt of an application for an exclusion under this section, the 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