RULES AND REGULATIONS

CHARTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 121—FOOD ADDITIVES

Picoloram

In response to a food additive petition (FAP 495652) submitted jointly by the Montana Department of Agriculture, Helena, MT 59601, and the North Dakota Department of Agriculture, Bismarck, ND 58501, a notice was published by the Environmental Protection Agency in the Federal Register of May 6, 1974 (39 FR 15879), proposing establishment of the herbicide picloram (4-amino-3,5,6-trichloropicolinic acid) in flour at 1 part per million and in milled fractions (except flour) at 2 parts per million resulting from application of the herbicide to growing barley and wheat.

No requests for referral to an advisory committee were received. One comment was received from the State of Nebraska, Department of Agriculture, requesting that the proposed tolerances for picloram be extended to cover residues in the same processed foods resulting from the same use pattern in Nebraska. It is concluded that the proposal reflecting this change be adopted. (For a related document, see this issue of the Federal Register, page 21146.)


Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 346(d), 346a(d), and 346b(d)), the authority transferred to the Administrator of the Environmental Protection Agency (39 FR 15632) and the authority delegated by the Administrator to the Deputy Assistant Administrator for Pesticide Programs (39 FR 18085), part 121 is amended by adding the following new section to Subpart D:

§ 121.1256 Picloram.

The following interim tolerances are established for residues of the herbicide picloram (4-amino-3,5,6-trichloropicolinic acid) resulting from application of 2,4-D-picoloram mixtures to growing barley and wheat during the 1974 growing season in the States of Montana, Nebraska, and North Dakota:

- 2 parts per million in milled fractions (except flour) of barley and wheat;
- 1 part per million in flour of barley and wheat.

Any person who will be adversely affected by the foregoing order may at any time on or before July 22, 1974, file with the Hearing Clerk, Environmental Protection Agency, Room 1015E, 4th & M Streets, SW., Waterside Mail, Washington, D.C. 20460, written objections thereto in quintuplicate. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof.

Effective date. This order shall become effective on June 20, 1974.

(Sec. 409(d), 72 Stat. 1707; 21 U.S.C. 348(d))

Dated: June 14, 1974.

HENRY J. KORP,

Deputy Assistant Administrator
for Pesticide Programs.

[FR Doc.74-14124 Filed 6-19-74; 8:15 am]

SUBCHAPTER D—DRUGS FOR HUMAN USE

PART 331—ANTACID PRODUCTS FOR THE OVER-THE-COUNTER (OTC) HUMAN USE

PART 332—ANTIFLATULENT PRODUCTS FOR THE OVER-THE-COUNTER (OTC) HUMAN USE

Final Order for Antacid and Antiflatulent Products Generally Recognized as Safe and Effective and Not Misbranded

Correction

In FR Doc. 74-12688 appearing on page 19862 in the issue of Tuesday, June 4, 1974, make the following corrections:

1. On page 19864 change the second sentence in the fifth paragraph of the third column to read “The Commissioner concurs that an in vitro test should be adopted now and that research should promptly begin on an in vivo test.”

2. On page 19874, the last two lines of the first column should read “(e.g., 2 grams per day in antacid products).”

3. The second line of § 331.22 should be changed to read “(NaOH) and hydrochloric acid (HCl).”

4. The third line of the formula appearing in § 331.23(b)(d)(h) should be changed to read “(NaOH). Total mEq per labeled minimum.”

CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

Annual Publication

The Comprehensive Drug Abuse Prevention and Control Act of 1970, in section 202(a) (21 U.S.C. 812(a)), requires that the schedules of controlled sub-
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1. Section 1308.33(c) (1) and (2) of Title 21 of the Code of Federal Regulations be amended to read as follows:

§ 1308.33 Schedule III.

(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 .................. 2122 (ii) Ecobarbital .................. 2315 (iii) Phenobarbital .......... 2570 or any salt thereof and one or more active medicinal ingredients which are not listed in any schedule.

(2) Any suppository dosage form containing: (i) Amobarbital .................. 2122 (ii) Ecobarbital .................. 2315 (iii) Phenobarbital .......... 2570 or any salt or any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.

Effective date. The Administrator regards the above-ordered change in § 1308.33(c) (1) and (2) as a change in form only, and does not consider it to be a substantive rule-making change which would necessitate the solicitation and receipt of comments or objections. There being no occasion requiring the solicitation or receipt of such comments or objections, the above-ordered change shall take effect upon publication of this order. This order is effective on June 20, 1974, and operates to the extent of affecting only those sections of Part 1308 listed below, which actually designate schedules and enumerate substances listed therein as being controlled under the Act, and all other sections of Part 1308 remain in full force and effect and are not repealed by virtue of their exclusion from, or the issuing of, this publication.

Dated: June 12, 1974.

JOHN R. BARTLETT, JR., Administrator.

Drug Enforcement Administration.

Sections 1308.11 through 1308.15 are republished to read as follows:

§ 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 material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which con-
§ 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 produced 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:

- Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding nux oxide hydrochloride, but including the following:
  - Raw opium
  - Opium extracts
  - Opium fluid extracts
  - Powdered opium
  - Granulated opium
  - Tincture of opium
  - Apomorphine
  - Corden
  - Ethylmorphine
  - Ethylmorphine hydrochloride
  - Hydromorphone
  - Hydromorphone hydrochloride
  - Methadone
  - Methadone hydrobromide
  - Methadone hydrochloride
  - Methadone maleate
  - Methadone nitrate
  - Methadone acetate
  - Methadone citrate
  - Methadone sulfate
  - Methadone erucate
  - Methadone tetracaine

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

- Coca leaves (9049) and any salt, compound, derivative, or preparation of coca leaves, and any compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include denatured coca leaves or extraction of coca leaves, which extractions do not contain cocaine (9041) or ecgonine (9180).

- Opium, except specifically excepted or unless listed in another schedule any of the following opiates, including its isomers, esters, ethers, others, salts and salts of isomers, esters, ethers and others whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

- These compounds, mixtures, or preparations in dosage unit form containing any stimulant substance listed in schedule II which compounds, mixtures, or preparations were listed on August 26, 1974, as excludable compounds under § 1308.33, and any other drug of the quinoline competition shown in the last list for those drugs or which is the same except that it contains a lesser quantity of controlled substances.
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§ 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) 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) Barbituric acid, 2145
(2) Barbituric acid, 2145
(3) Chloral hydrate, 2145
(4) Ethyl chloride, 2145
(5) Ethyl chloride, 2145
(6) Methohexital, 2145
(7) Meprobamate, 2145
(8) Methaqualone, 2145
(9) Paraldehyde, 2145
(10) Pentobarbital, 2145

(c) Fenfluramine. — Any material, compound, mixture, 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 within the specific chemical designation:

(1) Fenfluramine, 1070

(d) 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 (whether optical, position, 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) Dextroamphetamine, 1038
(2) Phenmetrazine, 1640

§ 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 containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following listed quantities of narcotic drugs or salts thereof, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug 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.

[FR Doc. 74-3417 Filed 8-19-74; 7:45 am]

Title 21A—National Defense Appendix

CHAPTER VI—DOMESTIC AND INTERNATIONAL BUSINESS ADMINISTRATION, DEPARTMENT OF COMMERCE

[DDB/EDC Notice 1]

BDC NOTICE 1—RATIFICATION OF BUREAU OF COMPETITIVE ASSESSMENT AND BUSINESS POLICY ACTIONS

JUNE 14, 1974.

This notice is found necessary and appropriate to promote the national defense and is issued pursuant to the Defense Production Act of 1950, as amended. In the formulation of this notice, consultation with industry representatives was impracticable since the notice has no substantive effect on industry.

Sec. 1. What this notice does.
Sec. 2. Existing regulations, orders, and other actions of the Bureau of Competitive Assessment and Business Policy.
Sec. 3. Repeals of the DPA regulations.
Sec. 4. Use of Bureau of Competitive Assessment and Business Policy and Business and Defense Services Administration forms.


Section 1. What this notice does.

The purpose of this notice is to furnish continuity in the defense mobilization activities of the United States Department of Commerce, Domestic and International Business Administration, Bureau of Domestic Commerce, which will occur under conditions in the future added to this notice.

FEDERAL REGISTER, VOL. 39, NO. 120—THURSDAY, JUNE 20, 1974