

such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of chemical diversion will be considered in determining the feasibility of continuing to allow an employee to work in an area with access to chemicals. The employer shall inform all employees concerning this policy.

**PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES**

- Sec.
- 1310.01 Definitions.
- 1310.02 Substances covered.
- 1310.03 Persons required to keep records and file reports.
- 1310.04 Maintenance of records.
- 1310.05 Reports.
- 1310.06 Content of records and reports.
- 1310.07 Proof of identity.
- 1310.08 Excluded transactions.
- 1310.09 Temporary exemption from registration.
- 1310.10 Removal of the exemption of drugs distributed under the Food, Drug and Cosmetic Act.
- 1310.11 Reinstatement of exemption for drug products distributed under the Food, Drug and Cosmetic Act.
- 1310.14 Exemption of drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient.
- 1310.15 Exempt drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient.

AUTHORITY: 21 U.S.C. 802, 830, 871(b).

SOURCE: 54 FR 31665, Aug. 1, 1989, unless otherwise noted.

**§ 1310.01 Definitions.**

Any term used 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.

[62 FR 13968, Mar. 24, 1997]

**§ 1310.02 Substances covered.**

The following chemicals have been specifically designated by the Administrator of the Drug Enforcement Administration as the listed chemicals subject to the provisions of this part and

parts 1309 and 1313 of this chapter. Each chemical has been assigned the DEA Chemical Code Number set forth opposite it.

(a) List I chemicals

- (1) Anthranilic acid, its esters, and its salts .....8530
- (2) Benzyl cyanide .....8735
- (3) Ephedrine, its salts, optical isomers, and salts of optical isomers .....8113
- (4) Ergonovine and its salts .....8675
- (5) Ergotamine and its salts .....8676
- (6) N-Acetylanthranilic acid, its esters, and its salts .....8522
- (7) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers .....8317
- (8) Phenylacetic acid, its esters, and its salts .....8791
- (9) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers .....1225
- (10) Piperidine and its salts .....2704
- (11) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers .....8112
- (12) 3,4-Methylenedioxyphenyl-2-propanone .....8502
- (13) Methylamine and its salts .....8520
- (14) Ethylamine and its salts .....8678
- (15) Propionic anhydride .....8328
- (16) Isosafrole .....8704
- (17) Safrole .....8323
- (18) Piperonal .....8750
- (19) N-Methylephedrine, its salts, optical isomers, and salts of optical isomers (N-Methylephedrine) .....8115
- (20) N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers .....8119
- (21) Hydriodic Acid .....6695
- (22) Benzaldehyde .....8256
- (23) Nitroethane .....6724
- (24) Gamma-Butyrolactone (Other names include: GBL; Dihydro-2 (3H)-furanone; 1,2-Butanolide; 1,4-Butanolide; 4-Hydroxybutanoic acid lactone; gamma-hydroxybutyric acid lactone) .....2011
- (25) Red phosphorus .....6795
- (26) White phosphorus (Other names: Yellow Phosphorus) .....6796
- (27) Hypophosphorous acid and its salts (Including ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium hypophosphite and sodium hypophosphite) .....6797

(b) List II chemicals:

- (1) Acetic anhydride .....8519
- (2) Acetone .....6532

§ 1310.03

21 CFR Ch. II (4-1-03 Edition)

(3) Benzyl chloride .....8570  
(4) Ethyl ether .....6584  
(5) Potassium permanganate .....6579  
(6) 2-Butanone (or Methyl Ethyl Ke-  
tone or MEK) .....6714  
(7) Toluene .....6594  
(8) Hydrochloric acid (including anhy-  
drous hydrogen chloride) .....6545  
(9) Sulfuric acid .....6552  
(10) Methyl Isobutyl Ketone (MIBK)  
.....6715  
(11) Iodine .....6699

(c) The Administrator may add or delete a substance as a listed chemical by publishing a final rule in the FEDERAL REGISTER following a proposal which shall be published at least 30 days prior to the final rule.

(d) Any person may petition the Administrator to have any substance added or deleted from paragraphs (a) or (b) of this section.

(e) Any petition under this section shall contain the following information:

- (1) The name and address of the petitioner;
- (2) The name of the chemical to which the petition pertains;
- (3) The name and address of the manufacturer(s) of the chemical (if known);
- (4) A complete statement of the facts which the petitioner believes justifies the addition or deletion of the substance from paragraphs (a) or (b) of this section;
- (5) The date of the petition.

(f) The Administrator may require the petitioner to submit such documents or written statements of fact relevant to the petition as he deems necessary in making a determination.

(g) Within a reasonable period of time after the receipt of the petition, the Administrator shall notify the petitioner of his decision and the reason therefor. The Administrator need not accept a petition if any of the requirements prescribed in paragraph (e) of this section or requested pursuant to paragraph (f) of this section are lacking or are not clearly set forth as to be readily understood. If the petitioner desires, he may amend and resubmit the petition to meet the requirements of paragraphs (e) and (f) of this section.

(h) If a petition is granted or the Administrator, upon his own motion, proposes to add or delete substances as listed chemicals as set forth in para-

graph (c) of this section, he shall issue and publish in the FEDERAL REGISTER a proposal to add or delete a substance as a listed chemical. The Administrator shall permit any interested person to file written comments regarding the proposal within 30 days of the date of publication of his order in the FEDERAL REGISTER. The Administrator will consider any comments filed by interested persons and publish a final rule in accordance with his decision in the matter.

[54 FR 31665, Aug. 1, 1989, as amended at 56 FR 48733, Sept. 26, 1991; 57 FR 43615, Sept. 22, 1992; 60 FR 19510, Apr. 19, 1995; 60 FR 32460, June 22, 1995; 62 FR 5917, Feb. 10, 1997; 65 FR 21647, Apr. 24, 2000; 65 FR 47316, Aug. 2, 2000; 66 FR 52675, Oct. 17, 2001]

**§ 1310.03 Persons required to keep records and file reports.**

(a) Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction as specified by § 1310.04 and file reports as specified by § 1310.05. However, a non-regulated person who acquires listed chemicals for internal consumption or "end use" and becomes a regulated person by virtue of infrequent or rare distribution of a listed chemical from inventory, shall not be required to maintain receipt records of listed chemicals under this section.

(b) Each regulated person who manufactures a List I or List II chemical shall file reports regarding such manufacture as specified in Section 1310.05.

(c) Each regulated person who engages in a transaction with a nonregulated person which involves ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing these chemicals), and uses or attempts to use the Postal Service or any private or commercial carrier shall file monthly reports of each such transaction as specified in § 1310.05 of this part.

[54 FR 31665, Aug. 1, 1989, as amended at 56 FR 8277, Feb. 28, 1991; 61 FR 14023, Mar. 29, 1996; 67 FR 14861, Mar. 28, 2002]