

**Drug Enforcement Administration, Justice**

**§ 1308.23**

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**

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

[38 FR 8255, Mar. 30, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 41 FR 16553, Apr. 20, 1976; 41 FR 53477, Dec. 7, 1976; 46 FR 51603, Oct. 21, 1981; 47 FR 45867, Oct. 14, 1982; 54 FR 2100, Jan. 19, 1989; 55 FR 12162, Mar. 30, 1990; 62 FR 13968, Mar. 24, 1997]

**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 form or concentration that the packaged quantity does not present any sig-

nificant 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