paragraphs (b), (c), and (d) of this section:

(1) Aromatic Cascara Fluidextract.

(2) Cascara Sagrada Fluidextract.

(3) Orally ingested homeopathic drug products.

[60 FR 13595, Mar. 13, 1995, as amended at 61 FR 58630, Nov. 18, 1996]

Subpart C—Labeling

§ 328.50 Principal display panel of all OTC drug products intended for oral ingestion that contain alcohol.

(a) The amount (percentage) of alcohol present in a product shall be stated in terms of percent volume of absolute alcohol at 60 ° F (15.56 ° C) in accordance with § 201.10(d)(2) of this chapter.

(b) A statement expressing the amount (percentage) of alcohol present in a product shall appear prominently and conspicuously on the ''principal display panel,'' as defined in § 201.60 of this chapter. For products whose principal display panel is on the immediate container label and that are not marketed in another retail package (e.g., an outer box), the statement of the percentage of alcohol present in the product shall appear prominently and conspicuously on the ''principal display panel'' of the immediate container label.

(c) For products whose principal display panel is on the retail package and the retail package is not the immediate container, the statement of the percentage of alcohol present in the product shall also appear on the immediate container label; it may appear anywhere on that label in accord with section 502(e) of the Federal Food, Drug, and Cosmetic Act.

(d) The statement expressing the amount (percentage) of alcohol present in the product shall be in a size reasonably related to the most prominent printed matter on the panel or label on which it appears, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

(e) For a product to state in its labeling that it is ''alcohol free,'' it must contain no alcohol (0 percent).

(f) For any OTC drug product intended for oral ingestion containing over 5 percent alcohol and labeled for use by adults and children 12 years of age and over, the labeling shall contain the following statement in the directions section: ''Consult a physician for use in children under 12 years of age.''

(g) For any OTC drug product intended for oral ingestion containing over 0.5 percent alcohol and labeled for use by children ages 6 to under 12 years of age, the labeling shall contain the following statement in the directions section: ''Consult a physician for use in children under 6 years of age.''

(h) When the direction regarding age in paragraph (e) or (f) of this section differs from an age-limiting direction contained in any OTC drug monograph in this chapter, the direction containing the more stringent age limitation shall be used.

PART 329—HABIT-FORMING DRUGS

Subpart A—Derivatives Designated as Habit Forming

Sec.
329.1 Habit-forming drugs which are chemical derivatives of substances specified in section 502(d) of the Federal Food, Drug, and Cosmetic Act.

Subpart B—Labeling

329.10 Labeling requirements for habit-forming drugs.

Subpart C—Exemptions

329.20 Exemption of certain habit-forming drugs from prescription requirements.

AUTHORITY: 21 U.S.C. 352, 353, 355, 371.

SOURCE: 39 FR 11736, Mar. 29, 1974, unless otherwise noted.

EFFECTIVE DATE NOTE: At 67 FR 4907, Feb. 1, 2002, part 329 was removed, effective Apr. 2, 2002.

Subpart A—Derivatives Designated as Habit Forming

§ 329.1 Habit-forming drugs which are chemical derivatives of substances specified in section 502(d) of the Federal Food, Drug, and Cosmetic Act.

Each of the following chemical derivatives of a substance named in section 502(d) of the Federal Food, Drug, and Cosmetic Act is hereby designated as habit forming:

Chemical description of derivative	Common or official name of chemical derivative or its salts	Some trade or other names of chemical derivative or its salts [1]
PARENT SUBSTANCE—BARBITURIC ACID		
5-Allyl-5-*sec*-butylbarbituric acid [2]	Talbutal	Lotusate.
5-Allyl-5-cyclopentenylbarbituric acid		Cyclopal.
		Cyclopen.
5-Allyl-5-isobutylbarbituric acid	Allylbarbituric acid	Sandoptal.
	Allylisobutylbarbituric acid..	
5-Allyl-5-isopropylbarbituric acid	Aprobarbital	Alurate.
	Allylisopropylbarbituric acid	Numal.
	Allylisopropylmalonylurea..	
5-Allyl-5-isopropyl-1-methylbarbituric acid		Narconumal.
5-Allyl-5-(1-methylbutyl)barbituric acid	Secobarbital sodium	Seconal Sodium.
	Soluble secobarbital	Evronal Sodium.
5-Allyl-5-(1-methylbutyl)-2-thiobarbituric acid	Sodium thiamylal	Surital Sodium.
5-Allyl-1-methyl-5-(1-methyl-2-pentynyl) barbituric acid.	Sodium methohexital	Brevital Sodium.
5-(2-Bromoallyl)-5-isoprophyl-1-methylbarbituric acid.		Eunarcon.
5-(2-Bromoallyl)-5-(1-methylbutyl)-barbituric acid.	β-Bromoallyl *sec*-amylbarbituric acid	Sigmodal.
		Rectidon.
		R239.
5-*sec*-Butyl-5-(2-bromoallyl)-barbituric acid	Butallylonal	Pernoston.
		Pernocton.
5-(1-Cyclohepten-1-yl)-5-ethylbarbituric acid	Heptabarbital	Medomin.
5,5-Diallylbarbituric acid	Diallyl barbituric acid	Dial.
		Allobarbital.
		Allobarbitone.
		Curral.
		Diadol.
5,5-Diethylbarbituric acid	Barbital	Deba.
	Barbitone	Dormonal.
	Diethylbarbituric acid	Hypnogene.
	Diethylmalonylurea	Malonal.
		Medinal.
		Sedeval.
		Veronal.
		Uronal.
		Vesperal.
5,5-Diethyl-1-methylbarbituric acid	Metharbital	Gemonil.
1,5-Dimethyl-5-(1-cyclohexenyl)-barbituric acid	Hexobarbital sodium	Cyclonal Sodium.
		Dorico Soluble.
		Evipal Sodium.
		Evipan Sodium.
		Hexanastab.
		Hexobarbitone Sodium.
		Methenexyl Sodium.
5,5-Dipropylbarbituric acid	Dipropylbarbituric acid	Proponal.
5-Ethyl-5-butylbarbituric acid	Butethal	Etoval.
	Butobarbital	Neonal Butobarbital.
		Soneryl.
5-Ethyl-5-*sec*-butylbarbituric acid	Butabarbital sodium	Butisol Sodium.
5-Ethyl-5-(1-cyclohexenyl)-barbituric acid	Cyclobarbital	Cyclobarbitone.
		Namuron.
		Palinum.
		Phanodorm.
		Phanodorn.
		Tetrahydro phenobarbital.
5-Ethyl-5-cyclopentenyl-barbituric acid		Pentenal.
5-Ethyl-5-hexylbarbituric acid	Hexethal sodium	Hebaral.
		Ortal Sodium.
5-Ethyl-5-isoamylbarbituric acid	Amobarbital	Amytal.
5-Ethyl-5-isopropylbarbituric acid	Probarbital	Ipral.
5-Ethyl-5-(1-methylbutyl)-barbituric acid	Pentobarbital sodium	844.
	Soluble pentobarbital	Embutal.
		Nembutal.
		Napethal.
		Pentyl.
5-Ethyl-5-(1-methylbutyl)-2-thiobarbituric acid	Thiopental sodium	Intraval Sodium.
	Thiopentone sodium	Nesdonal Sodium.
		Pentothal Sodium.
		Thiothal Sodium.
5-Ethyl-5-(1-methyl-1-butenyl)-barbituric acid	Vinbarbital	Delvinal Sodium.
5-Ethyl-5-phenylbarbituric acid	Phenobarbital	Barbenyl.

Chemical description of derivative	Common or official name of chemical derivative or its salts	Some trade or other names of chemical derivative or its salts [1]
	Phenobarbitone	Barbiphenyl.
	Phenylethylmalonylurea	Dormiral.
		Euneryl.
		Gardenal.
		Luminal.
		Nunol.
		Neurobarb.
		Phenonyl.
		Somonal.
5-Ethyl-5-phenyl-1-methylbarbituric acid	Mephobarbital	Mebaral.
		Phemitone.
		Prominal.
5-Ethyl-5-(1 piperidyl)-barbituric acid		Eldoral.
5-Isopropyl-5-(2-bromoallyl)-barbituric acid	Propallylonal	Noctal.
		Nostal.
5-(1-Methylbutyl)-5-[2-(methylthio)ethyl]-2-thiobarbituric acid.	Methitural (sodium salt)	Methioturiate.
		Neraval.
		Thiogenal.
5-Methyl-5-phenylbarbituric acid	Phenylmethylbarbituric acid	Rutonal.
All lithium, sodium, potassium, magnesium, calcium, strontium, and ammonium salts of the foregoing chemical derivatives of barbituric acid.		
PARENT SUBSTANCE—CANNABIS (MARIHUANA)		
	Extract of cannabis.	
	Fluid extract of cannabis.	
	Tincture of cannabis.	
PARENT SUBSTANCE—BROMAL		
Tribromoacetaldehyde hydrate	Bromal hydrate.	
Tribromomethane	Bromoform.	
2-(Tribromomethyl)-2-propanol	Tribromo-*tert*-butyl alcohol	Acetone-Bromoform.
		Brometone.
PARENT SUBSTANCE—CARBROMAL		
a-Bromo-*a*-ethylbutyryl-acetylurea	Acetylcarbromal	A basin.
		Acetyl Adalin.
		N-Acetyl-*N*-bromodiethylacetylurea.
		N-Acetyl-*N'*-*a*-bromo-*a*-ethylbutyryl carbamide.
a-Bromoisovalerylurea	Bromisovalum	Bromisoval.
		a-Bromo-β-dimethyl-propanoylurea.
		Bromural.
		Bromvaletone.
		Brovalurea.
		B. V. U.
		Dormigene.
		Isobromyl.
		2-Monobromoisovalerylurea.
		Pivadorm.
		Uvaleral.
a-Bromo-*a,a*-diethylacetamide	Diethylbromo acetamide	Neuronal.
a-Allylisovaleryl-urea		Allyl-isopropyl-acetyl-carbamide.
		(2-Isopropyl-4-pentenoyl)-urea.
		Sedormid.
PARENT SUBSTANCE—CHLORAL		
Trichloroacetaldehyde hydrate	Chloral	2,2,2-Trichloro-1,1-ethanediol.
	Chloral hydrate	Trichloroethylidene glycol.
Trichloroethylideneimine	Chloralimide.	
N-(β-Trichloro-*a*-hydroxyethyl)-formamide	Chloralformamide	Chloralamide.
		Chloramide.
a-(β-trichloro-*a*-hydroxyethyl)-*D*-glucoside	*a*-Chloralose	A-D-Glucochloralose.
		Anhydro-Glucochloral.
		Glucochloral.
		Chloralosone.

Chemical description of derivative	Common or official name of chemical derivative or its salts	Some trade or other names of chemical derivative or its salts [1]
2-(Trichloromethyl)-2-propanol	Chlorbutanol Chlorbutol Chlorobutanol	Acetone chloroform. Chloretone. Methaform. Sedaform. 1,1,1-trichloro-2-methyl 2-propanol. β,β,β-trichloro-*tert*-butylalcohol.
PARENT SUBSTANCE—COCAINE		
All salts of cocaine obtained by combining cocaine with any acid.	Cocaine hydrochloride Cocainium chloride..	
PARENT SUBSTANCE—CODEINE		
Codeine methylbromide Dihydrocodeinone Dihydrohydroxycodeinone All salts of the foregoing chemical derivatives of codeine obtained by combining any such derivative of codeine with any acid.	Eucodin. Eucodal	 Dicodid. Oxycodone hydrochloride. 14-hydroxydihydrocodeinone.
PARENT SUBSTANCE—HEROIN		
All salts of heroin obtained by combining heroin with any acid.		
PARENT SUBSTANCE—MORPHINE		
Dihydromorphine Dihydromorphinone Ethylmorphine All salts of the foregoing chemical derivatives of morphine and all salts of morphine obtained by combining any such derivative or morphine with any acid.	Paramorphan. Dihydromorphinone hydrochloride Dihydromorphinonium chloride Ethylmorphine hydrochloride Ethylmorphinium chloride..	 Dilaudid. Dimorphone. Hydromorphone hydrochloride. Dionin.
PARENT SUBSTANCE—OPIUM		
	Extract of opium. Fluidextract of opium. Camphorated opium tincture. Deodorized opium tincture. Laudanum. Opium tincture. Paregoric. Tincture of opium.	
PARENT SUBSTANCE—PARALDEHYDE		
Metaldehyde.		
PARENT SUBSTANCE—SULFONMETHANE		
2,2-Diethylsulfonylbutane 3,3-Diethylsulfonylpentane	Sulfonethylmethane Sulfondiethylmethane.	Diethylsulfonmethylethyl-methane. Ethylsulfonal. 2,2-*bis*-(Ethylsulfonyl)-butane. Methylsufonal. Sulfonethlylmethanum. Trional.

[1] This list of trade or other names is not a complete list of the many proprietary names under which the designated habit-forming chemical derivatives are distributed.

[2] The name ''butalbital'' is obsolete for this compound; ''butalbital'' is the nonproprietary name assigned by the United States Adopted Name Council and the World Health Organization for 5-allyl-5-isobutylbarbituric acid.