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

Subpart B—Labeling

Subpart C—Exemptions

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

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

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 Allylisobutylbarbituric acid..	Sandoptal.
5-Allyl-5-isopropylbarbituric acid	Aprobarbital Allylisopropylbarbituric acid Allylisopropylmalonylurea..	Alurate. Numal.
5-Allyl-5-isopropyl-1-methylbarbituric acid		Narconumal.
5-Allyl-5-(1-methylbutyl)barbituric acid	Secobarbital sodium Soluble secobarbital	Seconal Sodium. 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.

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]
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.
	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.		

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—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.
2-(Trichloromethyl)-2-propanol	Chlorbutanol	Acetone chloroform.
	Chlorbutol	Chloretone.
	Chlorobutanol	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	Eucodin.	
Dihydrocodeinone		Dicodid.
Dihydrohydroxycodeinone	Eucodal	Oxycodone hydrochloride. 14-hydroxydihydrocodeinone.
All salts of the foregoing chemical derivatives of codeine obtained by combining any such derivative of codeine with any acid.		

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—HEROIN		
All salts of heroin obtained by combining heroin with any acid.		
PARENT SUBSTANCE—MORPHINE		
Dihydromorphine	Paramorphan.	
Dihydromorphinone	Dihydromorphinone hydrochloride	Dilaudid.
		Dimorphone.
	Dihydromorphinonium chloride	Hydromorphone hydrochloride.
Ethylmorphine	Ethylmorphine hydrochloride	Dionin.
	Ethylmorphinium chloride..	
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.		
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	Sulfonethylmethane	Diethylsulfonmethylethyl-methane.
		Ethylsulfonal.
		2,2-*bis*-(Ethylsulfonyl)-butane.
		Methylsufonal.
		Sulfonethlylmethanum.
		Trional.
3,3-Diethylsulfonylpentane	Sulfondiethylmethane.	

[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.

Subpart B—Labeling

§ 329.10 Labeling requirements for habit-forming drugs.

(a)(1) The name of a substance or derivative required to be borne on the label of a drug by section 502(d) of the act shall be the common or usual name of such substance or derivative, unless it is designated solely by a name recognized in an official compendium and such designation complies with the provisions of section 502(c).

(2) A statement on the label of a drug of the name of a constituent, which constituent is a chemical derivative of a substance named in section 502(d) of the act, shall show the substance from which such constituent is derived and that such constituent is a derivative thereof.

(b) If the drug is in tablet, capsule, ampul, or other unit form, the statement of the quantity or proportion of such substance or derivative contained therein shall express the weight or measure of such substance or derivative in each such unit. If the drug is not in such unit form the statement shall express the weight or measure of such substance or derivative in a specified unit of weight or measure of the drug. Such statement shall be in terms

which are informative to the ordinary consumer and user of the drug.

(c) The names and quantities or proportions of all such substances and derivatives, and the statement ''Warning—May be habit forming'', shall immediately follow (without intervening written, printed, or graphic matter) the name by which such drug is titled in the part or panel of the label thereof which is presented or displayed under customary conditions of purchase.

(d) A drug shall not be considered to be misbranded by reason of failure of its label to bear the statement ''Warning—May be habit forming'':

(1) If such drug is not suitable for internal use, and is distributed and sold exclusively for such external use as involves no possibility of habit formation; or

(2) If the only substance or derivative subject to section 502(d) of the act contained in such drug is chlorobutanol, which is present solely as a preservative and in a quantity not more than 0.5 percent by weight, and such drug is for parenteral use only; or

(3) If the only substance or derivative subject to section 502(d) of the act contained in such drug is chlorobutanol which is present as an analgesic or as an analgesic and a preservative in a quantity not more than 3.0 percent, and such drug contains one or more other active ingredients and is for parenteral use only.

CROSS REFERENCE: For the Spanish-language version of the required labeling statement, see §201.16(b) of this chapter.

[39 FR 11736, Mar. 29, 1974, as amended at 40 FR 13496, Mar. 27, 1975]

Subpart C—Exemptions

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

The prescription-dispensing requirements of section 503(b)(1)(A) of the act are not necessary for the protection of the public health with respect to the following drugs subject to section 502(d):

(a) The following exempt narcotic preparations:

(1) Pharmaceutical preparations containing not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(2) Pharmaceutical preparations containing not more than 16.2 milligrams (¼ grain) morphine, or any of its salts, per 29.5729 cubic centimeters (1 fluid ounce) or per 28.3 grams (1 avoirdupois ounce);

(3) Pharmaceutical preparations containing not more than 64.8 milligrams (1 grain) codeine, or any of its salts, per 29.5729 cubic centimeters (1 fluid ounce) or per 28.3 grams (1 avoirdupois ounce);

(4) Pharmaceutical preparations containing not more than 32.4 milligrams (½ grain) dihydrocodeine, or any of its salts, per 29.5729 cubic centimeters (1 fluid ounce) or per 28.3 grams (1 avoirdupois ounce);

(5) Pharmaceutical preparations containing not more than 16.2 milligrams (¼ grain) ethylmorphine, or any of its salts, per 29.5729 cubic centimeters (1 fluid ounce) or per 28.3 grams (1 avoirdupois ounce);

Provided, That the preparations described in this paragraph contain one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the preparation valuable medicinal qualities other than those possessed by the narcotic drug alone.

(b) Drugs containing chlorobutanol, intended for external use only.

(c) Epinephrine solution, 1 percent, preserved with chlorobutanol and intended for use solely as a spray.

(d) Combination drugs listed in part 329 as exempted from section 511 of the act.

[39 FR 11736, Mar. 29, 1974, as amended at 55 FR 11581, Mar. 29, 1990]

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

Subpart A—General Provisions

Sec.