Chapter 246-883 WAC
PHARMACEUTICAL—SALES REQUIRING PRESCRIPTIONS

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WAC

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WAC 246-883-020 Identification of legend drugs for purposes of chapter 69.41 RCW. (1) In accordance with chapter 69.41 RCW, the board of pharmacy finds that those drugs which have been determined by the Food and Drug Administration, under the Federal Food, Drug and Cosmetic Act, to require a prescription under federal law should also be classified as legend drugs under state law because of their toxicity or potential for harmful effect, the methods of their use and the collateral safeguards necessary to their use, indicate that they are only safe for use under the supervision of a practitioner.

(2) For the purposes of chapter 69.41 RCW, legend drugs are drugs which have been designated as legend drugs under federal law and are listed as such in the 2009 edition of the *Drug Topics Red Book*. Copies of the list of legend drugs as contained in the *Drug Topics Red Book* are available for public inspection at the headquarters office of the State Board of Pharmacy, 310 Israel Road S.E., P.O. Box 47863, Olympia, Washington 98504-7863. To obtain copies of this list from the department, interested persons must submit a written request, indicating which format they wish to receive, and payment of the actual cost of the text or CD, including shipping and handling charges from the publisher. Requestors may also contact the publisher directly to obtain copies. The department takes no responsibility for periodic updates or online access. Arrangements for periodic updates or online access must be made directly with the publisher.

(3) There may be changes in the marketing status of drugs after the publication of the above reference. Upon application of a manufacturer or distributor, the board may grant authority for the over the counter distribution of certain drugs which had been designated as legend drugs in this reference. These determinations will be made after public hearing and will be published as an amendment to this chapter.

[Statutory Authority: RCW 18.64.005 and 69.41.075. WSR 10-02-081, § 246-883-020, filed 1/5/10, effective 2/5/10. Statutory Authority: RCW 69.41.075 and 18.64.005(7). WSR 02-14-049, § 246-883-020, filed 6/27/02, effective 7/28/02. Statutory Authority: RCW 69.41.075, 18.64.005. WSR 00-06-078, § 246-883-020, filed 3/1/00, effective 4/1/00. Statutory Authority: RCW 69.41.075. WSR 96-21-041, § 246-883-020, filed 10/11/96, effective 11/11/96. Statutory Authority: RCW 18.64.005. WSR 92-09-070 (Order 264B), § 246-883-020, filed 4/14/92, effective 5/15/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-883-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.44.075 [69.41.075]. WSR 85-18-091 (Order 196), § 360-32-050, filed 9/4/85. Statutory Authority: RCW 18.64.005 and 69.41.075. WSR 83-20-053 (Order 176), § 360-32-050, filed 9/29/83. Statutory Authority: RCW 69.41.075. WSR 81-10-025 (Order 160), § 360-32-050, filed 4/28/81. Statutory Authority: 1979 1st ex. s. c 139.

WSR 79-09-138 (Order 149, Resolution No. 9/79), § 360-32-050, filed 9/5/79.]

WAC 246-883-025 Introductory trade or stock packages. Introductory trade or stock packages may be distributed by registered drug manufacturers to licensed pharmacies under the following conditions:

(1) The package shall be invoiced by the drug manufacturer as a no charge sale.

(2) The product shall be distributed by the manufacturer to the pharmacy by mail or common carrier.

(3) The drug's package shall not be marked as a sample or with any other labeling that is inconsistent with the claim that the manufacturer intended the package for sale.

(4) The manufacturer shall be limited to distributing one introductory package of each dosage strength of a product on a one-time basis to a pharmacy in order to familiarize and assure that a company's new product will be available in pharmacies. The quantity shall not be larger than one hundred solid dosage units or sixteen liquid ounces.

[Statutory Authority: RCW 18.64.005. WSR 92-09-072 (Order 266B), § 246-883-025, filed 4/14/92, effective 5/15/92.]

WAC 246-883-030 Ephedrine prescription restrictions. (1) The board of pharmacy, pursuant to RCW 69.41.075, hereby identifies ephedrine, or any of its salts in a solid or aqueous form normally intended for oral administration, in any quantity, as a legend drug subject to the restrictions of RCW 69.41.030.

(2) The following products containing ephedrine or its salts in the amount of 25 mg. or less per solid dosage unit or per 5 ml. of liquid forms in combination with other ingredients in therapeutic amounts are exempt from subsection (1) of this section:

	TRADE NAME	EPHEDRINE CONTENT
1.	AMESAC capsule (Russ)	25 mg. ephedrine HCL
2.	AZMA AID tablet (Various, eg Purepac)	24 mg. ephedrine HCL
3.	BRONC-EASE PLUS (Natur-Pharma)	25 mg. ephedrine HCL
4.	BRONCHODILATOR AND EXPECTORANT (PDK Labs)	25 mg. ephedrine HCL
5.	BRONITIN tablet (Whitehall)	24 mg. ephedrine HCL
6.	BRONKAID tablet (Breon)	24 mg. ephedrine sulfate
7.	BRONKOLIXER (Sterling Winthrop)	12 mg. ephedrine
8.	BRONKOTABS tablet (Breon)	24 mg. ephedrine sulfate
9.	EFEDRON nasal jelly (Hyrex)	0.6% ephedrine HCL in 20 g.
10.	MINI THINS asthma relief (BDI Pharmaceuticals)	25 mg. ephedrine
11.	PAZO HEMORRHOID suppositor (Bristol-Meyers)	3.86 mg. ephedrine sulfate
12.	PAZO HEMORRHOID ointment (Bristol-Meyers)	0.2% ephedrine sulfate

	TRADE NAME	EPHEDRINE CONTENT
13.	PRIMATENE tablet (Whitehall)	24 mg. ephedrine HCL
14.	PRIMATENE M tablet (Whitehall)	24 mg. ephedrine HCL
15.	PRIMATENE P tablet (Whitehall)	24 mg. ephedrine HCL
16.	QUELIDRINE (Abbott)	5 mg. ephedrine HCL
17.	TEDRAL tablet (Parke-Davis)	24 mg. ephedrine HCL
18.	THEODRINE tablet (Rugby)	25 mg. ephedrine HCL
19.	VATRONOL nose drops (Vicks Health Care)	0.5% ephedrine sulfate

(3) Ma Huang or other botanical products of genus ephedra used in their natural state and containing 25 mg. or less of ephedrine per recommended dosage as a preparation for human consumption are not legend drugs for the purposes of this section.

(4) Any reformulation of listed products which increases the ephedrine content to more than 25 mg. of ephedrine per solid dosage unit or per 5 ml. of liquid forms shall negate the exemption. The manufacturers of listed products shall notify the board of any reformulation which increases the ephedrine content to more than 25 mg. of ephedrine per solid dosage unit or per 5 ml. of liquid forms prior to distributing that product in the state of Washington.

(5) Manufacturers of products containing 25 mg. or less of ephedrine per solid dosage unit or per 5 ml. of liquid forms in combination with other ingredients in therapeutic amounts may gain exemption from subsection (1) of this section if, prior to the distributing of any such product in the state of Washington, the manufacturer:

(a) Provides the board with the formulation of any such product;

(b) Provides the board samples of all dosage forms in which the product is to be marketed in the packaging in which the product is to be marketed; and

(c) Receives the board's approval to market such product.

[Statutory Authority: RCW 18.64.005. WSR 94-08-100, § 246-883-030, filed 4/6/94, effective 5/7/94; WSR 93-05-046 (Order 333B), § 246-883-030, filed 2/17/93, effective 3/20/93. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-883-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-042 (Order 165), § 360-32-055, filed 3/2/82. Statutory Authority: RCW 69.41.075. WSR 81-10-025 (Order 160), § 360-32-055, filed 4/28/81. Statutory Authority: 1979 1st ex. s. c 139. WSR 79-09-138 (Order 149, Resolution No. 9/79), § 360-32-055, filed 9/5/79.]

WAC 246-883-040 Regulated steroids. The board finds that the following drugs shall be classified as steroids for the purposes of RCW 69.41.310. The drugs designated shall include the following and any synthetic derivatives or any isomer, ester, salt, or derivative of the following that act in the same manner on the human body from the attached list:

(1) Anabolicum

(2) Anadrol

(3) Anatrofin

(4) Anavar

(5) Androxon
(6) Andriol
(7) Android
(8) bolandiol
(9) bolasterone
(10) boldenone
(11) boldenone undecylenate
(12) bolenol
(13) Bolfortan
(14) bolmantalate
(15) Cheque
(16) chlorotestosterone
(17) clostebol
(18) Deca Durabolin
(19) dehydrochlormethyl-testosterone
(20) Delatestyl
(21) Dianabol
(22) Dihydrolone
(23) dihydrotestosterone
(24) dimethazine
(25) Drive
(26) Drolban
(27) drostanolone
(28) Durabolin
(29) Durateston
(30) Equipoise
(31) Esiclene
(32) ethylestrenol
(33) Exoboline
(34) Finaject
(35) Fluoxymesterone
(36) formebolone
(37) Halotestin
(38) Halostein
(39) Hombreol
(40) Iontanyl
(41) Laurabolin
(42) Lipodex
(43) Maxibolin
(44) mesterolone
(45) metanabol
(46) methenolone acetate
(47) methenolone enanthate
(48) methandienone
(49) methandranone
(50) methandriol
(51) methandrostenolone
(52) methyltestosterone
(53) mibolerone
(54) Myagen
(55) Nandrolin
(56) nandrolone
(57) nandrolone decanoate
(58) nandrolone cyclotate
(59) nandrolone phenpropionate
(60) Nelavar
(61) Nerobol

(62) Nilevar
(63) nisterime acetate
(64) Norbolethone
(65) Nor-Diethylin
(66) norethandrolone
(67) Normethazine
(68) Omnifin
(69) oxandrolone
(70) oxymesterone
(71) oxymetholone
(72) Parabolan
(73) Permastril
(74) pizotyline
(75) Primobolone/Primobolan depot
(76) Primotestin/Primotestin depot
(77) Proviron
(78) Quinalone
(79) Quinbolone
(80) Restandol
(81) silandrone
(82) Sostanon
(83) Spectriol
(84) stanolone
(85) stanozolol
(86) stenbolone acetate
(87) Stromba
(88) Sustanon
(89) Tes-10
(90) Tes-20
(91) Tes-30
(92) Teslac
(93) testolactone
(94) testosterone
(95) testosterone cypionate
(96) testosterone enanthate
(97) testosterone ketolaurate
(98) testosterone phenylacetate
(99) testosterone propionate
(100) testosterone undecanoate
(101) Thiomucase
(102) tibolone
(103) trenbolone
(104) trenbolone acetate
(105) trestolone acetate
(106) Trophobolene
(107) Winstrol

[Statutory Authority: RCW 18.64.005 and 69.41.075. WSR 92-12-035 (Order 277B), § 246-883-040, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-883-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 89-22-048, § 360-32-060, filed 10/30/89, effective 11/30/89.]

WAC 246-883-050 Theophylline prescription restrictions. The board of pharmacy, pursuant to RCW 69.41.075, hereby identifies theo-

phylline, or any of its salts in a solid or liquid form normally intended for oral administration in any quantity, as a legend drug subject to the restrictions of RCW 69.41.030. Provided, products containing 130 mg or less of theophylline per solid dosage unit or 130 mg or less per 5 ml of liquid forms, shall not be considered a legend drug and where the product contains other recognized therapeutic ingredients, may be sold or distributed without a prescription. Products with theophylline as the only active ingredient are identified as legend drugs.

[Statutory Authority: RCW 18.64.005. WSR 92-09-070 (Order 264B), § 246-883-050, filed 4/14/92, effective 5/15/92.]