WAC 246-899-040 Manufacturers, wholesalers, distributors, pharmacy location, requirement that drug products offered for sale comply with 21 U.S.C. 355—Immediate suspension and subsequent revocation of licenses authorized for violation. (1) In order to provide for enforcement of RCW 69.41.100 through 69.41.180 and to protect the public health and safety when generic drugs are substituted for brand name drugs pursuant to RCW 69.41.110 through 69.41.180 drug products which are offered for sale by, or stored at the premises of, any manufacturer, distributor, wholesaler or pharmacy location must have an approved new drug application (NDA) or abbreviated new drug application (ANDA) designation by the Federal Food and Drug Administration pursuant to 21 U.S.C. 355 unless they are exempt from the requirements for such a designation.

(2) In order to provide for enforcement of RCW 69.41.100 through 69.41.180 and to protect the public health and safety drug products offered for sale by, or stored at the premises of, a manufacturer, wholesaler, distributor or pharmacy location which do not have the required NDA or ANDA, or exemption therefrom referenced in subsection (1) of this section, are hereby declared to be contraband and subject to surrender to and destruction by the Washington state board of pharmacy. This surrender and destruction shall take place as specified below.

(3) The board shall publish in its newsletter the source from which the current list compiled by the Federal Food and Drug Administration of generic drugs which do not have an NDA or ANDA and are not exempt from such a requirement and are therefore contraband as provided in subsection (2) of this section may be obtained. The board shall also respond to both written and telephone inquiries from any source regarding the status of any generic drug.

(4) Whenever it is made to appear to the board that a manufacturer, wholesaler, distributor or pharmacy location within he [the] state of Washington is in possession of a stock of drugs which are contraband as defined in subsection (2) of this section, a representative of the board shall confirm with the Federal Food and Drug Administration, by telephone, that the particular drug or drugs involved do not have the required NDA or ANDA and that they are not exempt from this requirement. Upon receipt of this confirmation, the board shall direct such of its investigative personnel as it deem necessary to proceed to the premises of the manufacturer, wholesaler, distributor or pharmacy location and to then inform the owner, or person in charge, of the contraband status of the drugs in question.

(5) The pharmacy board investigative personnel shall offer the owner, or person in charge, of the premises at which the drug products are being kept the opportunity to immediately voluntarily surrender to the board all stocks of the drug products whether kept at the premises of the manufacturer, wholesaler, distributor, or pharmacy location, or at any separate storage facility under the control of the manufacturer, wholesaler, distributor or retailer, which are contraband under subsection (2) of this section. A receipt shall be given to the owner, or person in charge, for all drug products voluntarily surrendered.

(6) All drug products voluntarily surrendered pursuant to subsection (5) of this section shall be destroyed by the board of pharmacy unless they are ordered returned to the manufacturer, wholesaler, distributor or pharmacy location by order of a court of competent jurisdiction. No destruction of any drug products surrendered will be ac-

complished until thirty days after the date of their surrender to the board.

(7) Retention, dispensing, promotion or advertisement, of any drug products by a manufacturer, wholesaler, distributor or pharmacy location, either at their business premises or at any separate storage facility after notification of their contraband status under subsection (2) of this section shall constitute a direct and immediate danger to the public health and safety and will be good and sufficient cause for the immediate summary suspension and subsequent revocation of any license issued by the board of pharmacy to the manufacturer, wholesaler, distributor or pharmacy location and will also constitute good and sufficient cause for revocation of any license issued by the board of pharmacy to the owner of any manufacturer, wholesaler, distributor or pharmacy location or any person in charge thereof who knowingly retains, dispenses, promotes or advertises, any drug products which are contraband under subsection (2) of this section after notification of their status.

[Statutory Authority: RCW 69.41.180. WSR 92-12-035 (Order 277B), § 246-899-040, 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 § 246-899-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 87-18-066 (Order 207), § 360-49-040, filed 9/2/87. Statutory Authority: RCW 69.41.180. WSR 80-14-012 (Order 157, Resolution No. 9/80), § 360-49-040, filed 9/22/80; WSR 80-02-113 (Order 153, Resolution No. 1/80), § 360-49-040, filed 1/28/80.]