

201 KAR 2:115. Controlled release tablets, capsules and injectables.

RELATES TO: KRS Chapter 217

STATUTORY AUTHORITY: KRS 217.814(7), (8), 217.819(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.819 directs the Kentucky Board of Pharmacy to prepare a nonequivalent drug product formulary of drugs which should not be interchanged by pharmacists. In conformance with the publication cited, "Approved Prescription Drug Products with Therapeutic Equivalence Evaluations," this administrative regulation lists controlled release tablets, capsules and injectables as noninterchangeable.

Section 1. The following are determined to be noninterchangeable: controlled release tablets, capsules and injectables - these dosage forms are subject to bioavailability and bioequivalence difference, primarily because different manufacturers developing controlled release products for the same active ingredient do not employ the same approach to formulating their controlled release products. Approved controlled release products for which bioequivalence data are available and considered as meeting necessary bioequivalence requirements are exempted from this administrative regulation. (9 Ky.R. 285; Am. 688; eff. 1-6-83.)