

## **902 KAR 55:045. Exempt prescription products.**

RELATES TO: KRS 218A.020-218A.250, 21 C.F.R. 1308.31-1308.32

STATUTORY AUTHORITY: KRS 218A.020

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.020(3) provides that if a controlled substance is designated, rescheduled, or deleted as a controlled substance under federal law and notice is given to the Cabinet for Health and Family Services, the Cabinet for Health and Family Services may similarly control the substance under KRS Chapter 218A by administrative regulation. This administrative regulation exempts prescription products from the licensing, distribution, recordkeeping, and reporting provisions of KRS Chapter 218A if the products have received approval as an exempt prescription product pursuant to 21 C.F.R. 1308.32.

Section 1. Exempt Prescription Products. (1) Except as provided by subsection (2) of this section, the Cabinet for Health and Family Services exempts prescription products from the licensing, distribution, recordkeeping, and reporting provisions of KRS 218A.150 – 218A.172, 218A.180, 218A.200, and 218A.202 if the products have received approval as exempt prescription products pursuant to 21 C.F.R. 1308.32.

(2) All products containing butalbital shall:

(a) Be reported to the Kentucky All-Schedule Prescription Electronic Reporting System in accordance with the requirements established in 902 KAR 55:110; and

(b) Not be exempt from the licensing, distribution, and recordkeeping provisions of KRS 218A.150 – 218A.172, 218A.180, and 218A.200. (6 Ky.R. 377; eff. 2-6-1980; Recodified from 901 KAR 1:041, 4-14-1982; Am. 11 Ky.R. 1680; eff. 6-4-1985; 18 Ky.R. 1472; eff. 2-7-1992; 19 Ky.R. 1666; 2251; eff. 3-17-1993; 20 Ky.R. 864; eff. 12-6-1993; 21 Ky.R. 1394; eff. 1-9-1995; 23 Ky.R. 4228; eff. 7-16-1997; 25 Ky.R. 629; 1631; eff. 1-19-1999; 26 Ky.R. 903; 1171; eff. 12-15-1999; 40 Ky.R. 2635; 41 Ky.R. 290; eff. 9-17-2014.)