**Section 790.180 FDA Drug Product Approval and Recommendation**

Drug products included shall have been approved and recommended for DPS use by the FDA and approved for listing in a publication of approved drug products distributed by the FDA for use in state programs. All products must have either a New Drug Application (NDA), Abbreviated New Drug Application (ANDA), or Antibiotic Form 5 or 6 Application approved by the FDA under the provisions of Sections 505 and 507 of the Federal Food, Drug and Cosmetic Act (21 U.S.C.A, 301 et seq.). All products have been certified by the FDA as safe and effective for their labeled use, meet current compendial and Good Manufacturing Practices (GMP) requirements, and have met the applicable bioavailability and bioequivalence criteria of the FDA.

(Source: Amended at 10 Ill. Reg. 8814, effective May 15, 1986)