

**SUBSTITUTION OF EXTENDED RELEASE METHYLPHENIDATE PRODUCTS.** As pharmacists are aware, in recent weeks the Food and Drug Administration (FDA) changed the Orange Book equivalency rating of extended release methylphenidate products manufactured by Mallinkrodt and Kudco from “AB” to “BX” due to concerns about bioavailability equivalency with Janssen Pharmaceuticals’ Concerta product. More details concerning FDA’s action, the reasons for it, and the consequences are found here:  
<http://www.fda.gov/drugs/drugsafety/ucm422569.htm>

Note further that Janssen Pharmaceuticals manufactures an “authorized generic” of Concerta, which is marketed by Actavis under licensing agreement. Actavis’ product is not marketed under the Concerta name, but it is identical to Janssen’s Concerta. FDA’s Orange Book rating change does not apply to the Actavis product.

Board staff have received questions as a result of the FDA action:

1. If a provider prescribes Concerta and authorizes generic substitution, what may I substitute? As noted above, the Actavis marketed generic is the only AB-rated equivalent product to Concerta.
2. What if the provider prescribes Concerta, authorizes generic substitution, and the patient was previously stabilized on a Mallinkrodt or Kudco product? A pharmacist may seek a verbal authorization/clarification from the prescriber that a patient already taking, and stabilized on, a Mallinkrodt or Kudco product should continue to receive that product. Clinical discussion and documentation of any such approval is critical, however, for at least two reasons: (a) the product is a Schedule II controlled substance; and (b) FDA’s decision to redesignate these products as “BX” rated to Concerta stems from bioavailability concerns. Note further that the FDA’s statement (linked above) warns that the Mallinkrodt and Kudco products may be withdrawn from the market if the companies do not or cannot confirm the bioequivalence of their products to Concerta within six (6) months.
3. What if the provider prescribes Concerta, authorizes generic substitution, and the patient has never taken an extended release methylphenidate product? Again, the Actavis marketed generic is the only AB-rated equivalent product to Concerta. As noted in the answer to question #2, a pharmacist could seek a verbal authorization from the prescriber to dispense the Mallinkrodt or Kudco product. But this approach is not recommended due to FDA’s bioavailability concerns with these products and the possibility that they will not be available at all within six (6) months.
4. What if the provider prescribes Concerta, authorizes generic substitution, and the patient has previously taken the brand Concerta product? Again, the Actavis marketed generic is the only AB-rated equivalent product to Concerta. As noted in the answer to question #2, a pharmacist could seek a verbal authorization from the prescriber to dispense the Mallinkrodt or Kudco product. But this approach is not recommended due to FDA’s bioavailability concerns with these products and the possibility that they will not be available at all within six (6) months.