



## PIC Question of the Week: 10/04/04

Q: What does a “**ZB**” designation mean in relation to therapeutic equivalency codes?

A: Pharmacists must dispense therapeutically equivalent products. Under the Drug Price Competition and Patent Term Restoration Act of 1984, manufacturers seeking approval to market a generic drug product must submit data demonstrating that the drug product is bioequivalent to the pioneer (innovator) drug. A key point underlying the 1984 law is that bioequivalent drug products are therapeutically equivalent, and therefore, interchangeable. This is sanctioned by the FDA and the listing of these products can be found in the “Orange Book.” Drug products which the FDA considers to be therapeutically equivalent and have adequate evidence supporting these bioequivalences are designated “**AB**.”

“Z” codes are used by the Defense Medical Logistics Standard Support Program. They are not part of the FDA “Orange Book” system. A “**ZA**” code indicates a pharmaceutical entity that has been evaluated by the FDA, but the particular labeled product has not been evaluated. A “**ZB**” code is assigned to all nonprescription pharmaceuticals and legend pharmaceutical entities that have not been evaluated in the “Orange Book.” If one should encounter a “**ZB**” rating, do not dispense that particular pharmaceutical because no equivalence data is available.

Reference: [druginfo@cder.fda.gov](mailto:druginfo@cder.fda.gov) (accessed 12/18/03)

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