



PIC QUESTION OF THE WEEK: 2/27/06

Q: What are *Medication Guides* that are now being distributed by pharmacies?

A: The Food and Drug Administration (FDA) requires that pharmacies distribute *Medication Guides* to patients receiving certain prescription drug products that are considered to pose a “serious and significant public health concern.” A 1998 ruling provided the FDA authority to require these documents for 5-10 drug products each year. The *Guides* focus solely on serious adverse effects associated with certain medications and do not include comprehensive drug information. They apply primarily to human prescription drug products used in an ambulatory care setting without direct patient supervision by a healthcare professional. *Medication Guides* are required if the FDA determines that one or more of the following circumstances exist: patient labeling could help prevent serious adverse effects; the drug product has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risk(s) could affect a patient’s decision to use, or continue to use, the products; and/or the drug product is important to health and patient adherence to directions for use is crucial to the drug’s effectiveness. The manufacturer of the drug for which the FDA has chosen to require a *Guide* must obtain FDA approval of the *Guide* before providing them to distributors, packers, or authorized dispensers. *Medication Guides* are distinct from the patient-education leaflets or patient package inserts commonly distributed by pharmacies and must be provided with new AND refill prescriptions. See the references below for additional information on this topic. The FDA’s Center for Drug Evaluation and Research maintains an electronic link for all approved *Medication Guides*. *Guides* are currently required for all of the drugs in the accompanying table.

Medications with FDA-Mandated Medication Guides	
<ul style="list-style-type: none"> • abacavir sulfate and lamivudine (Epzicom) • abacavir sulfate (Ziagen) • abacavir sulfate, lamivudine, and zidovudine (Trizivir) • acitretin (Soriatane) • alosetron hydrochloride (Lotronex) • amiodarone (Cordarone) • Antidepressants in Children and Teenagers • atomoxetine hydrochloride (Strattera) • bosentan (Tracleer) • interferon alpha-2a, recombinant (Roferon-A) • interferon beta-1a (Rebif) • interferon alfacon-1 (Infergen) • interferon beta-1a (Avonex) • isotretinoin (Accutane, Amnesteem, Claravis, Sotret) • insulin human [rDNA origin] (Exubera) • lenolidamide (Revlimid) 	<ul style="list-style-type: none"> • Lindane Shampoo, Lindane Lotion • mefloquine hydrochloride (Lariam) • mifepristone (Mifeprex) • nevirapine (Viramune) • All Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) • peginterferon alfa-2a (Pegasys) • peginterferon alfa 2b (PEG-Intron) • pimecrolimus (Elidel Cream) • pramlintide acetate (Symlin) • ribavirin (Rebetol, Ribasphere, Ribavirin Copegus) • ribavirin and interferon alfa-2b combination (Rebeton) • sodium oxybate (Xyrem) • soltamox (tamoxifen citrate), • teriparatide (rDNA origin) (Forteo) • tacrolimus (Protopic Ointment) • tamoxifen (Nolvadex)

References:

- FDA. CFR Title 21, Part 208 Medication guides for prescription drug products. <http://www.fda.gov> (accessed 2006 Feb 22)
- CDER. Patient Labeling and Risk Communication. <http://www.fda.gov/cder/offices/ODS/labeling.htm> (accessed 2006 Feb 22)

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