



PIC QUESTION OF THE WEEK: 3/21/11

Q: What is the Food and Drug Administration's definition of *unapproved* drugs?

A: In June 2006, the Food and Drug Administration (FDA) announced a Compliance Initiative to remove *unapproved* drugs from the marketplace. Since this policy was enacted, as many as 550 products have been removed from pharmacy shelves. The FDA began regulating drug products for *safety* in 1938 with the federal Food, Drug, and Cosmetic Act (FDCA). In 1962, an additional law (Kefauver-Harris Amendment) was enacted requiring that drugs be both *safe AND effective*. Many drugs now being designated as *unapproved* were manufactured before these laws were enacted. This has led to confusion among healthcare professionals because many of these medications have been used for decades. This growing list now includes colchicine, over-the-counter and prescription cough and cold products, codeine and hydrocodone preparations and, most recently, formulations of sublingual nitroglycerin. A complete list of *unapproved* drugs can be accessed via the link below. In order to determine whether a product has been FDA-*approved*, the pharmacist should consult the compendium known as *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book). Be mindful that a product may have a National Drug Code (NDC) number, but still be considered *unapproved*. Another method for identifying FDA *approval* is by directly searching the NDC Directory. If the product has an "Application Number," this indicates it has been approved. If the drug is listed as "Other", **and lacks an application number**, the medication is considered *unapproved*. Although a specific product may be FDA-approved, each individual manufacturer of the product must obtain formal *approval* for safety, efficacy, and proper labeling. In May 2007, the FDA made a significant effort to remove *unapproved* extended-release guaifenesin products from the market. Adams Respiratory Therapeutics now distributes the only FDA-approved extended-release guaifenesin (Mucinex®, etc.) formulation. A similar situation that received considerable attention involved colchicine. Colchicine products never received formal FDA-approval and were recently removed from the market. The only approved colchicine product now available is Colcrys®. The FDA continues to review the approval status of available prescription medications and will undoubtedly declare more products to be *unapproved* in the near future.

References:

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