

# FDA Recall Policies

from an FDA Center for Food Safety and Applied Nutrition Industry Affairs Staff brochure, June 2002

Editor's Note: Pharmacies participating in the Wisconsin Pharmacy Quality Collaborative [see page 14] must be responsive to FDA drug safety alerts and Class I recalls and must participate in the FDA MedWatch program. The following documents explain FDA recall policies and the MedWatch program.

The recall of a defective or possibly harmful consumer product often is highly publicized in newspapers and on news broadcasts. This is especially true when a recall involves foods, drugs, cosmetics, medical devices, and other products regulated by FDA. Despite this publicity, FDA's role in recall activities is often misunderstood not only by consumers, but also by the news media, and occasionally even by the regulated industry. The following headlines, which appeared in two major daily newspapers, are good examples of that misunderstanding: "FDA Orders Peanut Butter Recall," and "FDA Orders 6,500 Cases of Red-Dyed Mints Recalled."

The headlines are wrong in indicating that the Agency can "order" these recalls. The Federal Food, Drug, and Cosmetic Act, (the law) does not generally authorize FDA to "order" a manufacturer to recall a food, cosmetic or supplement. The agency may request a product recall if the firm is not willing to remove dangerous products from the market without FDA's written request. It is only when a medical device, human tissue product, or infant formula pose a risk to human health that the law specifically authorizes FDA to prescribe a recall and to rule on the scope and extent of the same.\*


The manufacturers or distributors of the product voluntarily carry out most recalls of products regulated by FDA. In some instances, a company discovers that one of its products is defective and recalls it entirely on its own. In others, FDA informs a company of findings that one of its products is defective and suggests or requests a recall. Usually, the company will comply.

If the firm does not recall the product, then FDA can seek legal action under the

FD&C Act. These include seizure of available product, and/or injunction of the firm, including a court request for recall of the product.

This cooperation between FDA and its regulated industries has proven over the years to be the quickest and most reliable method to remove potentially dangerous products from the market. This method has been successful because it is in the interest of FDA, as well as industry, to get unsafe and defective products out of consumer hands as soon as possible.

FDA guidelines for companies to follow when recalling defective products under the Agency's jurisdiction are published in Title 21 of the Code of Federal Regulations, Part 7. These guidelines make clear

 THE ENTIRE MEDWATCH PROGRAM IS EXPLAINED AT [WWW.FDA.GOV/MEDWATCH/INDEX.HTML](http://WWW.FDA.GOV/MEDWATCH/INDEX.HTML). THIS IS A VALUABLE WEB SITE FOR PRACTITIONERS WISHING TO PARTICIPATE IN THE PROGRAM.

that FDA expects these firms to take full responsibility for product recalls, including follow-up checks to assure that recalls are successful. Under the guidelines, companies are expected to notify FDA when recalls are started, to make progress reports to FDA on recalls and to undertake recalls when asked to do so by the Agency.

The guidelines also call on manufacturers and distributors to develop contingency plans for product recalls that can be put into effect if, and when needed. FDA's role under the guidelines is to monitor company recalls and assess the adequacy of a firm's action. After a recall is completed, FDA makes sure that the product is destroyed or suitably reconditioned and investigates why the product was defective.

Generally, FDA accepts reports and other necessary recall information sub-

mitted by e-mail. In many cases, this has become routine for some firms and FDA district offices. However, FDA maintains the prerogative for investigational visits and other in-person communications where the agency considers it appropriate.

The guidelines categorize all recalls into one of three classes according to the level of hazard involved.

- **Class I** recalls are for dangerous or defective products that predictably could cause serious health problems or death. Examples of products that could fall into this category are a food found to contain botulinal toxin, food with undeclared allergens, a label mix-up on a life saving drug or a defective artificial heart valve.
- **Class II** recalls are for products that might cause a temporary health problem, or pose only a slight threat of a serious nature. One example is a drug that is under-strength but that is not used to treat life-threatening situations.
- **Class III** recalls are for products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing regulations. Examples might be a container defect (plastic material delaminating or a lid that does not seal); off-taste, color, or leaks in a bottled drink; and lack of English labeling in a retail food.

FDA develops a strategy for each individual recall that sets forth how extensively it will check on a company's performance in recalling the product in question. For a Class I recall, for example, FDA would check to make sure that each defective product has been recalled or reconditioned. In contrast, for a Class III recall, the Agency may decide that it only needs to spot check to make sure the product is off the market.

Even though the firm recalling the product may issue a press release, FDA

seeks publicity about a recall only when it believes the public needs to be alerted about a serious hazard. For example, if a canned food product purchased by a consumer at a retail store were found by FDA to contain botulinal toxin, an effort would be made to retrieve all the cans in circulation, including those in the hands of consumers. As part of this effort, the Agency also could issue a public warning via the news media to alert as many consumers as possible to the potential hazard.

FDA also issues general information about new recalls it is monitoring through

*FDA Enforcement Reports*, a weekly publication available on FDA's Internet page, [www.fda.gov](http://www.fda.gov). For additional information on recalls, contact the FDA district office nearest you.

#### WHAT IS MEDWATCH?

FDA has the responsibility for assuring the safety and efficacy of all regulated marketed medical products.

MedWatch, The FDA Safety Information and Adverse Event Reporting Program, serves both health care professionals and the medical product-using public.

We provide important and timely clinical information about safety issues involving medical products, including prescription and over-the-counter drugs, biologics, medical and radiation-emitting devices, and special nutritional products (e.g., medical foods, dietary supplements and infant formulas).

Medical product safety alerts, recalls, withdrawals, and important labeling changes that may affect the health of all Americans are quickly disseminated to the medical community and the general public via this website and the MedWatch e-list. Select "Safety Information" to see reports, safety notifications and labeling changes posted to the website since 1996.

MedWatch allows health care professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense or use. Reporting can be done online, by phone or by submitting the MedWatch 3500 form by mail or fax. Select "How to Report" for more details. ●

\*Sec. 412, and Sec. 518, Food Drug and Cosmetic Act; Sec. 351 Public Health Service Act.

## Promoting Patient Safety in the Community Pharmacy

by Patrick Cory, PharmD

Ever since the Institute of Medicine published *To Err is Human; Building a Safer Health System* in 2000, drug safety has hit the mainstream. Several highly publicized drug withdrawals related to safety issues, such as the Vioxx withdrawal in 2004, served to intensify the interest and visibility. It is now common to see stories related to drug safety in the lay press and television news reports. Just this past March, ABC News *20/20* created a stir when it televised the results of an undercover pharmacy investigation focusing on errors. Third-party payers have also taken notice of the impact drug safety has on outcomes and cost of care. In fact, patient safety is one of the standards in the accreditation process for the National Committee for Quality Assurance (NCQA), a voluntary quality credentialing organization for managed care.

As with most things, community pharmacy can view the media attention on drug safety as either a threat or an opportunity. At a time when re-importation, mail order and even drug dispensing vending machines offer alternatives to the traditional dispensing model, reports such as the *20/20* report can easily be seen as a significant threat to the venerated position of the community pharmacist in the eyes of the public. On the other hand, this can also be seen as an opportunity to step forward and BE THE SOLUTION.

As part of the requirements for participating in the Wisconsin Pharmacy Quality Collaborative (WPQC) pilot, pharmacies must meet several quality criteria designed to reflect "best practices" for safety in everyday dispensing. Two of the criteria are specifically focused on pharmacists protecting patients by BEING THE SOLUTION for communication of critical safety information. For example, it is a requirement that pharmacies communicate significant new FDA safety information to their patients taking the drug in question. If pharmacists don't provide this information, who will? Another requires pharmacies to report relevant drug product issues and adverse effect information to the FDA via the MedWatch program. The FDA uses this information to track trends and flag previously unknown manufacturing issues or adverse effects.

If you were a patient, would you want to fill your prescriptions at a pharmacy certified by PSW to be proactively providing these services or at a pharmacy sticking with the status quo? If you were a third-party payer, would you want your membership to use pharmacies that were taking these extra steps to protect patients or to use a pharmacy sticking with the status quo?

I believe that these quality criteria will not only serve to protect patients from serious adverse drug reactions, but will also be a tremendous opportunity for community pharmacy to demonstrate its value to the public and payers alike. ●

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