

# Reporting Drug Quality Problems

**W**ould you know what to do if your medication didn't seem right? What if it were discolored, chipped, or labeled with the incorrect product name? These are examples of drug quality problems that should be reported to the Food and Drug Administration's (FDA) Drug Quality Reporting System (DQRS).

FDA created the system in 1971 to minimize consumer exposure to unsafe, ineffective, and poor quality drugs. Reporting drug quality problems is voluntary, but essential.

"One DQRS report can lead to a drug recall," says Jay Schmid, DQRS Team Leader in FDA's Division of Compliance Risk Management and Surveillance. Drug quality reports help identify trends and can lead to several types of FDA actions:

- drug recalls
- drug safety alerts
- product label changes
- seizure of products
- repackaging or reformulation of products

## Types of Quality Problems

Here are some of the primary reasons for DQRS reports:

- suspected mislabeled drugs
- inaccurate or unreadable product labels/labeling (including the package insert)
- packaging that is torn or punctured

- *Suspected mislabeled drugs*
- *Inaccurate or unreadable product labels/labeling (including the package insert)*
- *Packaging that is torn or punctured*
- *Sterile containers or vials that are punctured or leaking*
- *Packaging or product mix-ups*
- *Abnormal odor or taste*
- *Other quality problems*



FDA receives drug quality reports through its MedWatch program at [www.fda.gov/Safety/MedWatch/default.htm](http://www.fda.gov/Safety/MedWatch/default.htm)

## We encourage consumers to contact their pharmacists first if they have drug quality concerns ...

- sterile containers or vials that are punctured or leaking
- packaging or product mix-ups
- abnormal odor or taste
- capsule leakage
- chipped, cracked, or splitting tablets
- tablet or capsule discolorations
- broken, cracked, or chipped syringes
- suspected product contamination
- sterile syringes with floating objects or growth
- vials with foreign floating objects or growth
- container closure defects
- leaking vials

"We review and triage reports as soon as we get them," says Capt. Juliette Johnson, DQRS program manager at FDA. The reports can fall into three priority classifications depending on the severity of the problem. Reports are classified as

- **Priority 1**  
Imminent or serious health hazard
- **Priority 2**  
Potentially significant manufacturing problem
- **Priority 3**  
Routine follow-up

Priority 1 and 2 reports are sent to the appropriate FDA offices and divisions for immediate follow-up recommendations and investigation. "Not all reports need an immediate follow-up," says Johnson.

### Tips for Reporting

Consumers or health care professionals can report drug quality problems. "We encourage consumers to contact their pharmacists first if they have drug quality concerns or complaints," says Johnson. "This allows for a screening process. Pharmacists

can provide essential information regarding the product and the product labeling."

**Report through MedWatch.** FDA receives drug quality reports through its MedWatch program. The MedWatch FDA Form 3500 is used for product quality reports. This form is also used to report adverse events (unexpected side effects) that occur while using FDA-regulated products such as prescription and over-the-counter drugs, medical devices, and special nutritional products such as dietary supplements.

**Be assured that reporting is confidential and secure.** Your information is confidential. Health care professionals are sometimes afraid to make the reports, according to Johnson. "If an adverse event is possibly associated with product quality, health care professionals sometimes worry that they will be singled out," Johnson says. "But if a reporter chooses not to have his or her identity disclosed, the reporter will remain anonymous; their name and contact information will not be released to anyone outside of FDA without their permission."

**Fill out forms completely.** It's important to fill the MedWatch form out completely as possible with regard to suspect product information and contact information. In 2008, the DQRS staff received 6,263 reports, but was not able to conduct adequate follow-up on one-third of those reports due to a lack of information. In many of those cases, the manufacturer's name or the National Drug Code (NDC) number listed on the product label was missing.

Drug products are identified and reported using the NDC number. It is a unique 11-digit, 3-segment num-

ber assigned to each medication. The number identifies the labeler or vendor, product, and trade package size. In other cases, contact information such as the phone number or email address was listed incorrectly or was not provided.

### How to Report

Consumers or health care professionals can use any of these methods to report problems:

**Online** - Use FDA Form 3500 at FDA's MedWatch Web page ([www.fda.gov/Safety/MedWatch/default.htm](http://www.fda.gov/Safety/MedWatch/default.htm)). FDA encourages online reporting because it is the quickest and most direct route.

**Mail** - Download the pre-addressed, postage-paid FDA Form 3500 at [www.fda.gov/medwatch/getforms.htm](http://www.fda.gov/medwatch/getforms.htm) or call 1-800-FDA-1088 to request the form.

**Fax** - Get the form (as above) and fax it to 1-800-FDA-0178.

**Phone** - Call 1-800-FDA-1088. [FDA](http://www.fda.gov)

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This article appears on FDA's Consumer Updates page ([www.fda.gov/ForConsumers/ConsumerUpdates/default.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/default.htm)), which features the latest on all FDA-regulated products.

### For More Information

Your Guide to Reporting Problems to FDA  
[www.fda.gov/ForConsumers/ConsumerUpdates/ucm095859.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm095859.htm)

Drug Quality Reporting System Web page  
[www.fda.gov/AboutFDA/CentersOffices/CDER/ucm082071.htm](http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm082071.htm)