FDA Safety Page

How FDA reviews drug names

Editors' note: *According to a 1999 Institute of Medicine report, approximately 7,000 deaths occur yearly due to medication errors. To help save lives, the Food & Drug Administration has agreed to share information on its drug error prevention activities with* Drug Topics *through this new quarterly column. What follows is the first installment of this column.*

The Food & Drug Administration has received approximately 18,000 reports of actual or potential medication errors since 1992 and continues to improve the process by which these errors are assessed. Over the past nine years, the FDA has increased the safe use of drug products by minimizing user errors attributed to nomenclature, labeling, and/or packaging of drug products. The group in charge of these activities is the Office of Postmarketing Drug Risk Assessment (OPDRA) under the FDA's Center for Drug Evaluation & Research (CDER). Ten clinical pharmacists and a physician make up OPDRA's medication error staff.

The name review process

Since October 1999, OPDRA has reviewed approximately 400 proposed proprietary names for drug products. Proprietary names undergo a multifactorial review designed to improve consistency and minimize risk with soundalike and lookalike names. The process includes:

- *Expert panel review*. An expert panel meets weekly to exchange opinions on the safety of a new proprietary name. The panel comprises OPDRA medication error prevention staff and representatives from the Division of Drug Marketing & Advertising Communications (DDMAC), who rely on their clinical, regulatory, and professional experiences to decide on the acceptability of a proprietary name.
- *Handwriting and verbal analyses*. These are conducted within FDA to determine the degree of confusion in visual appearance or pronunciation between the proposed proprietary name and names of other U.S. drugs. FDA health professionals (nurses, pharmacists, and physicians) are requested to interpret both written inpatient and outpatient prescriptions and verbal orders in an attempt to simulate the Rx ordering process.
- *Computer-assisted analysis*. Currently, OPDRA utilizes existing FDA databases to identify potential soundalike and/or look-alike proprietary names. In the future, OPDRA plans to use validated computer software that will improve the ability to detect similarities in spelling and sound among proprietary names.
- *Labeling and packaging analysis*. OPDRA provides a safety assessment of the container labels, carton and package insert labeling, and proposed packaging of each product to identify areas of potential improvement.
- *Overall risk evaluation*. This final phase of the name review process weighs the results of each phase of the review as well as additional risk factors such as overlapping strengths, dosage forms, dosing recommendations, indications for use, storage, labeling, and packaging, and important lessons learned from the agency's post-marketing experience.

How can you help?

Pharmacists and other health professionals can assist the FDA in minimizing medication errors by reporting any actual or potential medication errors to MedWatch, the FDA's medical product reporting and safety information program launched in June 1993. All identification of reporter, institution, and patient are kept confidential and are protected from disclosure by the Freedom of Information Act.

Medication errors can easily be reported to MedWatch via telephone (1-800-FDA-1088), Web site (**http://fda.gov/medwatch**), and fax (1-800-FDA-0178). In addition, a standardized MedWatch adverse event reporting form (FDA form 3500) is available to aid in submitting voluntary reports of medication errors. You should provide a complete description of the error; level of staff (e.g., pharmacist, nurse, physician) involved; medication involved; patient outcome; setting of the incident (e.g., inpatient, outpatient); relevant patient information (e.g., age and gender); date of event; manufacturer of the drug; dosage form and strength; and size of container. Finally, you will need to check both "Product Problem and/or Adverse Event" and "other" on the form.

We also encourage you to include your suggestions for preventing errors. With your contributions to increased reporting and the new processes implemented by OPDRA, the agency can provide effective intervention strategies that will minimize the risks associated with medication errors.

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MEDWATCH

To report a problem with an FDA-regulated product, please call 1-800-FDA-1088.