Database Is One-Stop Resource on Kids' Medications

When adults are advised by their health care professional to use a medication, they expect to receive information—backed up by data from studies—on the correct and safe dose to take. For drugs used in children, this information may not be available because historically not all products are studied in children.

To fix this situation, Congress passed legislation to increase pediatric studies and incorporate the resulting information in labeling. This is a key point because medicines often affect children differently from the way they work in adults.

The Food and Drug Administration (FDA) has been working hard on this project. To make it easier for parents and health care professionals to find information on pediatric medications, the FDA created a database that covers medical products studied in children under recent pediatric legislation.

The Pediatric Labeling Information Database (*www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=labelingdatabase*) is a one-stop resource. You can search for information by the product's commercial or chemical name, or by the condition for which it was studied. FDA's Office of Pediatric Therapeutics (OPT), which focuses on safety, scientific, and ethical issues that arise in pediatric clinical trials or after products are approved for use in children, developed the tool in collaboration with another branch of the agency, the Center for Drug Evaluation and Research.

OPT also maintains a Safety Reporting page (*www.fda.gov/ScienceResearch/SpecialTopics/PediatricTherapeuticsResearch/ucm123229.htm*) with information on products that have been tied to safety problems that specifically relate to children. This page lists products that have been the subject of an adverse event report presented to FDA's Pediatric Advisory Committee, a group of outside experts that advises the agency on pediatric treatments, research and labeling. (An adverse event is any undesirable experience associated with a medical product.) The committee's recommendation is also given if further actions were necessary to ensure safe use of the product in children.

"We are excited to share this goldmine of information with parents," says Debbie Avant, R.Ph., the health communications specialist in OPT who helped develop and maintain

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A Label for Kids

Parents should always read medicine labeling carefully. For prescription medications and vaccines, there is a Pediatric Use section in the labeling that says if the medication has been studied for its effects on children. The labeling will also tell you what ages have been studied. (This labeling is the package insert with details about a prescription medication.)

Congress' efforts to increase the number of studies of prescription drugs used in children have allowed FDA to build a foundation for pediatric research and discover new things. For example, researchers have found that certain drugs produce more side effects for the nervous system in children than adults, says Dianne Murphy, M.D., OPT's director.

FDA is able to use information gathered from pediatric studies to make labeling changes specific to kids, and to share that news with the public. The database, which is updated regularly, currently contains more than 440 entries of pediatric information from the studies submitted in response to pediatric legislative initiatives. The labeling changes include:

- 84 drugs with new or enhanced pediatric safety data that hadn't been known before;
- 36 drugs with new dosing or dosing changes;
- 80 drugs with information stating that they were not found to be effective in children; and
- 339 drugs for which the approved use has been expanded to cover a new age group based on studies.

The easiest way for parents to use the database is to search by their child's condition to find all mentions of that condition in all of the labeling information within the database. If you know the name of the drug you want to find, sort the database's information by trade name.

Avant says parents should note that the database contains the version of the label at the time of the labeling change. It may not be updated with later changes if they don't affect children.

More Than Halfway There

OPT has also evaluated the amount of progress in the inclusion of pediatric information in drug labeling and has published a research letter in the Journal of the American Medical Association (*jama.jamanetwork.com/article.aspx?volume=307&issue=18&page=1914*) on May 9, 2012. They found that in 2009, more than 60% percent of the drugs used for both adults and children that were in the Physician's Desk Reference—a drug information resource for physicians and other health professionals—had specific information on pediatric use, compared to only 22 percent in 1975.

Critical information in the pediatric section of the labeling tells you if the product was studied in children but could not be shown to work. When a product has been studied in adults and cannot be shown to be effective, that information is not put in the label. However, Congress told FDA to put this information in labeling when a product had been studied in children and was not effective.

"There is still much work to be done, as we have only studied two thirds of the products that are already on the market," says Murphy. "And there is a steady stream of new products approved every year for children and adults."

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