# PRODUCT UPDATE

**Valerie Burger, RN, MA, MS, OCN®**
**Associate Editor**



## NEW PRODUCTS

### Pantoprazol Sodium Formulation Requires No Refrigeration

Protonix® (pantoprazol sodium) for injection, manufactured by Wyeth (Madison, NJ), no longer requires refrigeration. A new formulation of Protonix is available that can be stored at room temperature (20°C–25°C). Protonix is a proton pump inhibitor that suppresses gastric secretion production. It is a well-tolerated treatment for gastroesophageal reflux disease and Zollinger-Ellison syndrome. Zollinger-Ellison syndrome is caused by tumors usually found in the head of the pancreas and the upper small bowel. These tumors, called gastrinomas, produce the hormone gastrin; high levels of gastrin cause large amounts of stomach acid. Protonix is recommended to be administered as an admixture and can be kept at room temperature, once prepared, for as many as 22 hours. For more information, visit www.wyeth.com.

### Fast-Track Approval Is Granted to Pancreatic Cancer Drug

The U.S. Food and Drug Administration (FDA) has provided fast-track designation status for Virulizin®, a new antitumor agent aimed at treating pancreatic cancer. Lorus Therapeutics Inc., a biopharmaceutical company in Toronto, Canada, presented Virulizin at the American Society of Clinical Oncology annual meeting in May. Fast-track designation is a system that allows drugs or devices to go through the approval process more quickly and often is granted because options are needed in an underserved treatment population. For a drug to receive fast-track designation by the FDA, the manufacturer must prove that it is intended to treat life-threatening illnesses that have limited treatment options. This allows items to move rather quickly through the otherwise lengthy process.

Virulizin also has received orphan drug status in the United States, which allows for drugs to undergo an accelerated review process and drug market exclusivity. Virulizin is an anticancer drug that stimulates the immune system to attack cancer cells rather than attacking the cells directly. This could result in fewer systemic side effects. For more information, visit www.lorusthera.com.

### VeinViewer Imaging System Makes Veins Easier to Access

Luminetx, a technology company in Memphis, TN, has developed a device that will map and project a patient's veins, allowing a practitioner to more accurately locate them for venous access. The VeinViewer Imaging System has an application for patients with hard-to-find veins who need venipuncture. A clinical trial was performed and showed increased success rates in the ability to perform venipuncture on patients who previously had been rejected as blood donors because of their difficult-to-access veins.

The VeinViewer has received FDA clearance and is expected to be on the market in 2006. The product is much like a worklight that can be placed over the vein area. The device uses infrared light to image red blood cells that then are processed by a computer and projected back onto patients' skin, providing a map of their veins. For more information, visit www.luminetx.com.

### American Cancer Society Offers E-Card Reminders

The American Cancer Society's (ACS's) new e-cards allow users to send a check-up reminder to someone they care about. Log on to ACS's Web site and choose from several different types of e-cards: ask someone to support you in Making Strides or Relay for Life, send someone a reminder for a check-up, ask someone to support or join you in quitting smoking, or send a Daffodil Days card. Users can create a special message or use a standard reminder. To send the cards, visit www.cancer.org/docroot/ECD/ECD_0.asp.

### Safety Handle Debuts at Annual Nursing Meeting

DeRoyal (Powell, TN), maker of orthopedic soft supplies and acute care products, introduced a retractable and reusable safety scalpel handle at the recent Association of Perioperative Registered Nurses' annual meeting. The Canica-Safety™ Handle has integrated features that allow for touchless retraction and ejection of scalpel blades. The blade can be retracted into the handle before passing the scalpel to other team members, thereby reducing the risk of a sharps injury. Contaminated blades can be discharged from the handle with a slider activation mechanism so the soiled blade does not need to be touched prior to disposal in a sharps container. The safety handle is reusable after sterilization and fits most conventional scalpel blades. For additional DeRoyal product information, call 800-DeRoyal (800-337-6925) or visit www.deroyal.com.

### New Nasopharynx Applicator Set Delivers Brachytherapy to Throat

Varian Medical Systems in Charlottesville, NC, has developed the Nasopharynx Applicator Set, designed for the delivery of brachytherapy to the upper-throat area. The Nasopharynx Applicator Set has received FDA clearance. The new applicator is compatible with computed tomography and magnetic resonance imaging. It comprises two soft and transparent mold probes with two very soft guidance tubes. It also features an expandable balloon for easy fixation. For more information, visit www.varian.com.

## FDA ANNOUCEMENTS

### Pazdur to Head Office of Oncology Drug Products

The FDA has announced that Richard Pazdur, MD, will be the leader of the newly established Office of Oncology Drug Products. Pazdur has been charged to develop and lead a comprehensive oncology program. The Office of Oncology Drug Products consolidates all oncology activities across all FDA centers and will ensure collaboration among the FDA, the National Cancer Institute, and other cancer organizations.

Pazdur has experience heading the Division of Oncology Drug Products in the FDA, as well as extensive experience as a cancer researcher, practicing clinical oncologist, and tenured professor. For more information, visit www.fda.gov/bbs/topics/news/2005/NEW01175.html.

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*Mention of specific products and opinions related to those products do not indicate or imply endorsement by the* Oncology Nursing Forum *or the Oncology Nursing Society.*

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## FDA Announces New Drug Safety Oversight Board

Health and Human Services Secretary Mike Leaveitt has announced the creation of the new Drug Safety Oversight Board. This board will oversee important safety issues, including development and implementation of center-wide drug safety policies.

The FDA plans to initiate three new methods of communication to improve the flow of information about potential drug safety issues to physicians and the public. The Drug Watch Web page will supply information about possible serious side effects and other safety risks associated with drugs. Healthcare Professional International Sheets will be one-page summary sheets that cover potential safety issues based on adverse events reports. Patient Information Sheets will be consumer-friendly drug sheets that will provide new information that may affect how a medication is prescribed and offer advice on how to use it. For more information, visit www.hhs.gov/news/press/2005pres/20050215.html.

# RECALL ALERTS

Kingswood Laboratories in Indianapolis, IN, has initiated a nationwide recall of **Moi-Stir Oral Swabsticks.** Some of these swab sticks have been found to contain two types of mold, *Aspergillus* and *Penicillium*. Patients with cancer who have compromised immune systems could have serious consequences from using a contaminated swab. Consumers who have any of the recalled swabs should stop using them immediately. For more information or questions, contact Lynn Meng, RN, MSN, quality assurance manager, at 800-968-7772.

Able Laboratories in Cranbury, NJ, is conducting a nationwide recall of **all of its manufactured drugs** because of concerns about production and quality standards. Able Laboratories has stopped all drug production, and the FDA is evaluating the situation. A list of affected drugs is available at www.fda.gov, and phone inquiries can be directed to Able Laboratories at 800-982-2253.

WelchAllyn Company in Skaneateles, NY, has announced a recall of the **Automated External Defibrillator 597 AED20™.** The machines in question were manufactured in Buffalo Grove, IL, from February–July 2004. A short could occur when the machine is impacted, and the machine will fail to analyze a patient's electrocardiogram. Machines will be repaired at no cost. For more information, contact the company at 800-462-0777.

McNeil Consumer and Specialty Pharmaceuticals in Fort Washington, PA, is voluntarily recalling all lots and flavors of **Children's Tylenol® Meltaways** 80 mg in bottles and blisters, **Children's Tylenol SoftChews** 80 mg in blisters, and **Junior Tylenol Meltaways** 160 mg in blisters. The blister pack design was intended to provide flexibility in dosing but may cause confusion, leading to improper dosing and even overdosing. Taking more than the recommended dose of acetaminophen (the active ingredient in Tylenol) can result in liver damage. For more information, contact McNeil's Consumer Relationship Center at 877-895-3665 or visit www.tylenol.com.