Federal update

From the FDA

Asthma inhalers recalled

Approximately 82,000 inhalers of beclomethasone dipropionate (Vanceril) are being recalled by the manufacturer as these inhalers may not contain its active ingredient.

The Food and Drug Administration (FDA) approved Schering/Key Pharmaceuticals’ recall plan. The problem was discovered on November 20 during a routine inspection at the Kenilworth, NJ, facility.

The prescription inhalers, which contain an aerosol propellant and chemical stabilizers but no medicine, are not harmful; however, patients using the faulty inhaler may have breathing problems.

Patients are being advised to return the inhaler for an exchange or refund. Pharmacies and drug distributors with unsold boxes should also return them to the manufacturer.

The products affected by the recall are Vanceril 84 µg Double Strength Inhalation Aerosol Convenience Packs, with lot numbers 9-DMT-157, 9-DMT-158, 9-DMT-160, 9-DMT-161, and 9-DMT-163. All have July 2000 expiration dates.

For information, call 800-621-9760.

FDA approves Keppra

The Food and Drug Administration (FDA) approved levetiracetam (Keppra) to control partial-onset seizures in patients who have epilepsy.

Levetiracetam is not metabolized through the liver, making it unlikely to cause interactions with other medications. In clinical trials of more than 1300 patients, no serious blood- or liver-related side effects were seen.

Patients who added levetiracetam to other epilepsy medications had 17% to 30% fewer partial-onset seizures than patients who took standard medicine.

Levetiracetam may cause dizziness and sleepiness. It will be available by prescription in spring 2000.

Breast scanning system receives second FDA regulatory approval

The TranScan TS2000 electrical impedance breast scanning system recently received premarket approval.

The TS2000 is a real-time, noninvasive, radiation-free imaging device for breast examination, based on the “mapping” of local electrical impedance properties of breast systems. It utilizes the inherent differences in capacitance and conductivity between neoplastic tissue and surrounding normal tissues.

It is intended to be used as an adjunct to mammography in patients with equivocal mammographic findings characterized by the criteria of ACR BI-RAD 3 or 4, except for cases with clear mammographic or nonmammographic indications for biopsy.

First drug device combined treatment for certain precancerous skin lesions approved

The FDA approved aminolevulinic acid hydrochloride (Levulan Kerastick) for topical solution, 20%, to be used in conjunction with photodynamic therapy for treatment of actinic keratoses (AKs) of the face or scalp.

Aminolevulinic acid is a two-stage treatment process that involves the topical application of aminolevulinic acid by a physician directly to the individual AK lesions, followed 14 to 18 hours later by photodynamic therapy. Photocactivation of treated AKs is accomplished with blue light irradiation utilizing a special light source designed to provide a uniform distribution of blue light to the affected face or scalp areas.

The dosage form was designed to treat individual AK lesions, reducing skin irritation of unaffected, nonlesional skin. It is not currently indicated for the treatment of AKs of the back and arms.

In controlled clinical trials, the most common adverse effect was a stinging or burning sensation during light treatment.

New drug approved to reduce stroke risk

The FDA has approved a new drug that combines aspirin and dipyridamole into one pill to reduce the risk of stroke for patients who have already had transient ischemic attacks or completed ischemic strokes due to blood clots in the brain.

Clinical trial of the drug included 6602 patients who had an ischemic stroke (76%) or transient ischemic attack (24%) within three months prior to entry. The results showed the combination reduced the risk of stroke by 36.8% and the cumulative risk of stroke and death by 24.2% compared with placebo.

The study also compared the use of the combination to the single use of each active ingredient, and results showed the combination was more favorable for reducing risk of stroke than each active ingredient alone.

The new drug, which will be marketed as Aggrenox, is contraindicated for patients with hypersensitivity to dipyridamole, aspirin, or any of the product’s other components. Adverse effects associated with
the use of the drug include headache, abdominal pain, dizziness, and nausea.

From the CDC

CDC urges caution to reduce workplace needlestick injuries

The Centers for Disease Control and Prevention (CDC) along with the National Institute for Occupational Safety and Health (NIOSH), are recommending that employers adopt strategic measures to protect healthcare workers from job-related injuries caused by needles in syringes, intravenous delivery systems, and related medical devices.

Every year, it is estimated that 600,000 to 800,000 occupational needlestick injuries occur. These can lead to serious or potentially fatal infections with blood-borne pathogens such as hepatitis B virus, hepatitis C virus, or human immunodeficiency virus (HIV).

NIOSH recommendations for work-related needlestick injuries are outlined in a new bulletin, “NIOSH Alert: Preventing Needlestick Injuries in Health Care Settings.”

The Alert suggests examples of devices that may reduce the risk of needlesticks, but advises that no one device will be appropriate or effective for every workplace. Examples of such devices include but are not limited to:
- Needless devices, such as connectors for intravenous delivery systems that use blunt or valved ends, rather than needles for attaching one length of IV tubing to another;
- Devices in which safety features are an integral part of the design, such as sheaths and shields over needles;
- Devices that operate passively without requiring user activation, such as an IV connector with a permanent rigid housing over the needle;
- Devices designed so that the user can easily tell whether the safety feature is activated, such as a visually obvious needle cover or the audible sound of a protective sheath being engaged;
- Devices in which the safety feature cannot be deactivated and remains protective through disposal;
- Devices that perform reliably, are easy to use and practical, and are safe and effective for patient care.

Copies of “NIOSH Alert: Preventing Needlestick Injuries in Health Care Settings,” HHS (NIOSH) Publication No. 2000-108, are available at no charge from the NIOSH by calling 800-35-NIOSH (800-356-4674). It is also available online at www.cdc.gov/niosh.

Influenza is hitting 37 states

Influenza cases have been reported in 37 states, almost three times the number of states reporting influenza cases 1 month ago, reports the CDC.

Scattered influenza cases were reported by health officials in 35 other states. Ten states reported no influenza, and three states did not report, the CDC says.

CDC officials recommend that people at high risk, including those 65 years of age and older and those with certain chronic conditions, receive the vaccine.
diseases, get flu vaccinations every year beginning in October.

**Pet reptiles pose health hazard**

Pet reptiles and amphibians are responsible for an estimated 93,000 cases of infection with *Salmonella* annually, according to the CDC.

Families and pet store owners are often unaware of the risks, and few states have enacted laws that require individuals purchasing reptiles to be educated about *Salmonella*, the CDC said.

Those with poorly functioning immune systems are most at risk for *Salmonella* infections, and they are also most at risk for having serious complications from these infections.

The CDC recommends these precautions for those already owning a pet reptile:

- Always wash hands thoroughly after handling a reptile or reptile cage.
- Do not allow reptiles in the kitchen or other food preparation areas.
- Do not wash reptiles, their cages, or their dishes in the kitchen sink. If the bathtub is used, clean and disinfect it with bleach.
- Do not let reptiles roam about the home.
- For those expecting a new infant, remove the reptile from the home before the infant arrives.
- Keep reptiles away from children younger than 5 years and individuals with poorly functioning immune systems.

The report can be found in the November 12 issue of *Morbidity and Mortality Weekly Report*.

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