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Kentucky Board of Pharmacy

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Drug Manufacturer and Wholesaler Renewal Deadline September 30, 2007

Drug manufacturer and wholesaler permits expire on September 30, 2007. A drug manufacturer or wholesaler may renew and pay the fee online. Renewal applications will not be mailed out; however, a renewal form may be printed from the Kentucky Board of Pharmacy's Web site at *www.pharmacy.ky.gov*. If you have any questions concerning the renewal process please contact the Board office. A drug manufacturer or wholesaler application with a United States post office box address only will **not** be accepted and will be returned. All incomplete applications will be returned. Remember, the deadline is September 30, 2007.

Board Meeting and Retreat 2007

The Friday, November 16, 2007 Board meeting will be held at the Board office beginning at 9 AM.

The Board will host a Board Retreat on Saturday and Sunday, November 17 and November 18, 2007, at the Marriott Resort in Lexington, KY. The agenda will be set at the September 12, 2007 Board meeting. If you have a suggested item for the agenda, please forward it to the Board office, or if you have questions, please contact the Board office. All pharmacists and individuals are invited to attend.

Pharmacist Interns

201 Kentucky Administrative Regulation (KAR) 2:040 establishes the standards for training, qualifications, and registration of pharmacist interns. An applicant for registration as a pharmacist intern shall register with the Board by filing an "Application for Registration as a Pharmacist Intern." Prior to registration, an applicant shall have been accepted by a college or school of pharmacy approved by the Board and submitted proof of acceptance by a college or school of pharmacy approved by the Board.

An applicant for examination for licensure as a pharmacist shall have completed 1,500 hours in an internship. Credit for an internship shall be awarded for hours worked in a pharmacy or in related research during the time the pharmacist intern is completing the academic coursework. Credit for an internship shall be limited to 48 hours per week if the pharmacist intern is not actively enrolled in a college or school of pharmacy and shall be limited to 20 hours per week if the pharmacist intern is actively enrolled in a college or school of pharmacy (the maximum credit allowed for this enrolled time shall be 500 hours).

Credit shall be given for the following forms of internship: (1) completion of an academic experience program; (2) work performed in a pharmacy under the supervision of a preceptor; or (3) work or research related to the practice of pharmacy that was performed under the supervision of a preceptor for a government body, college or university, pharmacy business, or other entity if the pharmacist intern has **received prior approval by the Board** (the maximum allowed for this time shall be 400 hours).

Within ten (10) days of beginning an internship, a pharmacist intern shall submit a **"Pharmacist Preceptor's Affidavit." On or before October 1 of each year of an internship, a pharmacist intern shall submit an "Internship Report."**

A preceptor shall be a pharmacist who has been licensed by the Board for at least one (1) year and is a community-based faculty member of the College of Pharmacy of the University of Kentucky or meets the standards established by the College of Pharmacy of the University of Kentucky for a community-based faculty member. A preceptor shall be actively engaged in the practice of pharmacy in the location where the pharmacist intern performs his or her other internship. The preceptor shall supervise only one (1) pharmacist intern for the purpose of obtaining credit for the practice of pharmacy experience, unless the pharmacist is supervising interns as a faculty member at a school or college of pharmacy approved by the Board during an academic experience program. To become a preceptor a pharmacist should request this in writing (there is no cost) and if the pharmacist meets the qualification(s) above then he or she will become a preceptor in Kentucky.

If a student is enrolled in a college or school of pharmacy in another state and will be completing an academic experience program in Kentucky, then that student must be enrolled in Kentucky as a pharmacist intern and the pharmacist must be enrolled as a preceptor.

If an individual has graduated from a college or school of pharmacy from outside the state of Kentucky and will be applying for licensure as a pharmacist in Kentucky, then he or she must register as a pharmacist intern if he or she wishes to practice as a pharmacist intern until successfully passing the Kentucky pharmacist licensure examination or that individual can only perform pharmacy technician duties.

Each applicant for pharmacist intern, preceptor, or employer should review Regulation 201 KAR 2:040 regarding pharmacist interns and the requirements. 201 KAR 2:040 is available on the Board's Web site at *www.pharmacy.ky.gov.* If you have any questions, please contact the Board's office at your convenience.

Internet Pharmacy Web Sites/Faxes

The Board office has received many questions and concerns from pharmacies and pharmacists in Kentucky regarding the receipt of faxes and seeing questionable Internet pharmacy Web sites. Once the Board receives this information, it is determined whether or not the pharmacy is permitted by Kentucky. If the pharmacy and/or Web site is not licensed by the Board, then it is turned over to the Kentucky Bureau of Investigation (KBI). The KBI will follow up with an investigation, and through cooperation with carriers can, and does, seize packages sent

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FDA Issues Guidance on Glycerin Testing to Prevent DEG Poisoning

Spurred to action by repeated instances of diethylene glycol (DEG) poisoning, Food and Drug Administration (FDA) recently issued a guidance for industry entitled "Testing of Glycerin for Diethylene Glycol." This guidance provides recommendations on testing that will help pharmaceutical manufacturers, repackers, and other suppliers of glycerin, and pharmacists who engage in drug compounding, to avoid the use of glycerin that is contaminated with DEG and prevent incidents of DEG poisoning.

DEG contamination of glycerin can be detected by using specific analytical test procedures described in the United States Pharmacopeia monograph for glycerin, which quantifies the amount of DEG present at a detection level of 0.1%, as recommended by the interagency Diethylene Glycol Contamination Prevention Workshop of 1997. The guidance is available on the FDA Web site at *www.fda.gov/cder/guidance/7654fnl.htm.* FDA is accepting electronic comments on the guidance at *www.fda.gov/dockets/ecomments.*

Improperly Compounded Colchicine Blamed for Recent Deaths

Compounded colchicine that was 10 times as potent as labeled was responsible for two recent deaths in Oregon and Washington, the *Portland Tribune* reported on April 27, 2007. State officials are investigating the drug's role in a third death, also in Oregon. The drug was sent to a Portland, OR, clinic by ApothéCure, Inc, a Dallas, TX-based compounding pharmacy that distributes its drugs throughout the country. The two patients who died had received injections of colchicine as a treatment for back pain. Lab tests revealed that the colchicine administered in the two deaths had a potency of 4 mg/ml, rather than the 0.5 mg/ml stated on labels. According to Gary A. Schnabel, executive director of the Oregon State Board of Pharmacy, ApothéCure, a licensed Texas pharmacy, may be operating as a manufacturer. Both the Oregon Board and the Texas State Board of Pharmacy have opened investigations into the incident. The Texas Board advised ApothéCure to stop making colchicine; the company agreed, the *Portland Tribune* reported. On May 2, FDA announced the recall of all strengths, sizes, and lots of injectable colchicine compounded and sold by ApothéCure within the last year. The FDA MedWatch Safety summary on this issue is available at *www.fda.gov/medwatch/safety/2007/safety07.htm#Colchicine.*

New Podcasts Provide Emerging Drug Safety Information

FDA recently supplemented its print- and Web-based public health advisories with the launch of an audio broadcast service providing emerging drug safety information. The broadcasts, commonly known as podcasts, can be transmitted to personal computers and personal audio players. The service is part of FDA's ongoing effort to broaden and speed its communications on the safety of marketed medications when unexpected adverse events are reported to FDA. Since FDA launched the service in February 2007, broadcasts have addressed the potential hazards of local anesthetics used in hair removal; the voluntary market withdrawals of drugs to treat the symptoms of Parkinson's disease and irritable bowel syndrome; and serious adverse events associated with agents that reduce the need for blood transfusions in cancer patients. The broadcasts are available on the FDA Web site at *www.fda.gov/cder/drug/podcast/default.htm.*

Prevent Tragedies Caused by Syringe Tip Caps

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Over the past several years, there have been a number of reports where children have swallowed or choked on hypodermic syringe caps that were overlooked by parents and left on the syringes administering the medication. In 2001, a 5-month-old child asphyxiated when a cap from a Becton Dickinson 3 ml hypodermic syringe ejected into his throat during medication administration. In this case, a pediatrician provided the parents with the hypodermic syringe (without the needle) to administer Vantin® (cefpodoxime) suspension. With the cap intact, the father inserted the syringe into the Vantin, pulled back the plunger, and the medication flowed into the syringe. To him, the cap appeared to be part of the syringe. When he placed the syringe containing the medication into the baby's mouth, the cap flew off and became lodged in his airway. The baby was taken to the hospital where a procedure was performed to remove the cap; however, he did not survive.

Despite these reports, the mother of a 9-month-old child recently notified the Institute for Safe Medication Practices about a near fatal experience involving her child. Her community pharmacist gave her a parenteral syringe (without the needle) to help her accurately measure and administer an oral rehydration liquid for her daughter. Unfortunately, the pharmacist's good intention resulted in patient harm. The mother was unaware that the syringe tip held a small, translucent cap; however, despite this, she was able to withdraw the oral liquid. Then as she administered the liquid, the cap on the end of the syringe ejected and became lodged in the child's throat, causing airway obstruction. Fortunately, the child recovered.

Although parenteral syringes are not designed for oral administration, health care practitioners may provide them to patients or caregivers to measure oral liquids without realizing how dangerous this practice may be. Some syringe

manufacturers place the small, translucent caps on parenteral syringes packaged without needles as a protective cover. However, practitioners may not realize the cap is there or may not inform patients or caregivers of the need for its removal prior to use. The danger arises due to the fact that the cap does not provide a good seal. Subsequently, medications can be drawn into many of these syringes without removing the caps. If not removed before administration, the force of pushing the plunger can eject the cap and cause it to lodge in a child's trachea.

Safe practice recommendations: Consider the following strategies to help protect your patients from tragedies caused by syringe tip caps.

- **Increase awareness.** Share this and previous errors with staff to illustrate why parenteral syringes should never be used for oral liquid medications. Show staff a video from FDA and ISMP highlighting this issue (access the video link at: *www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=3#6*).
- **Product availability.** Ensure that **oral** syringes (without caps) or other appropriate measuring devices are readily available for distribution or purchase at your practice site. Verify that the dosage can be accurately measured using the oral syringe. It may be necessary to keep a few different sizes on hand to ensure proper measurement of smaller doses.
- **Limit access.** If parenteral syringes must be stocked for use with injectable products, purchase syringes that are not packaged with the translucent caps to minimize the likelihood of this error.
- **Warning labels.** Add warning labels that state, "not for use with oral liquids" to boxes or storage bins containing parenteral syringes.
- **Educate patients and caregivers.** Provide education to patients and caregivers regarding proper use of an oral syringe (or other measuring device). Demonstrate how to measure and administer the dose and inform them about how to clean the device, if it is to be reused. Several years ago, Becton Dickinson voluntarily elected to package parenteral syringes without the small caps in response to this serious issue. However, since some manufacturers still include a cap on parenteral syringes, the danger of asphyxiation with the cap is still present. We have again contacted FDA to alert them about this problem. They have stated that they will be following up with each syringe manufacturer with the goal to get the syringe caps removed. At the very minimum, we believe that the packaging of parenteral syringes should be required to clearly state, "not for oral use" or "not for use with oral liquids."

New FDA Web Page Warns Against Buying Isotretinoin Online

FDA has launched a special Web page to warn consumers about the dangers of buying isotretinoin online. Improperly used, isotretinoin can cause severe side effects, including birth defects and serious mental health problems. The Web page, *www.fda.gov/buyonline/accutane*, is positioned as a search result on Internet search engines when consumers initiate an online search for the drug under any one of its four names (isotretinoin is sold under the brand name of Accutane® and in generic versions called Amnesteem™, Claravis™, and Sotret®). The Web page warns that the drug "should only be taken under the close supervision" of a physician and a pharmacist, and provides links to related information, including ways to check that drugs purchased online come from legitimate pharmacies.

To reduce risks, FDA and the manufacturers of isotretinoin have implemented a strict distribution program called iPLEDGE to ensure that women using isotretinoin do not become pregnant, and that women who are pregnant do not use isotretinoin. Isotretinoin is available only at pharmacies that are registered for this distribution program. Additionally, the distribution program is designed to prevent the sale of isotretinoin over the Internet. Dispensing must comply with the agency's risk management requirements.

Tampering Results in Misbranding of Ziagen as Combivir

GlaxoSmithKline and FDA warned health care professionals of an apparent third-party tampering that resulted in the misbranding of Ziagen® as Combivir® and employed counterfeit labels for Combivir tablets. Two 60-count misbranded bottles of Combivir tablets contained 300 mg tablets of Ziagen.

The counterfeit labels identified are Lot No. 6ZP9760 with expiration dates of April 2010 and April 2009. The incident appears to be isolated and limited in scope to one pharmacy in California.

Pharmacists are advised to immediately examine the contents of each bottle of Combivir in their pharmacies to confirm that the bottles contain the correct medication. If a bottle contains anything other than Combivir tablets, pharmacists are advised to notify the manufacturer.

The letter from GlaxoSmithKline and FDA, containing photos of actual Combivir and Ziagen tablets, is posted on the FDA Web site at *www.fda.gov/medwatch/safety/2007/Ziagen_Dear_RPh_03-29-2007.pdf*.

FDA Issues Halt on Manufacture, Distribution of Unapproved Suppository Drugs

FDA notified health care professionals and consumers that companies must stop manufacturing and distributing unapproved suppository drug products containing trimethobenzamide hydrochloride.

These products, used to treat nausea and vomiting in adults and children, have been marketed under various names, including Tigan®, Tebamide™, T-Gen, Trimazide, and Trimethobenz. Drugs containing trimethobenzamide in suppository form lack evidence of effectiveness. This action does not affect oral capsules and injectable products containing trimethobenzamide that have been approved by FDA.

FDA urges consumers currently using trimethobenzamide suppositories or who have questions or concerns to contact their health care professionals. Alternative products approved to effectively treat nausea and vomiting are available in a variety of forms.

The MedWatch safety summary and a link to the full press release are available at *www.fda.gov/medwatch/safety/2007/safety07.htm#trimethobenzamide*.

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by these pharmacies into Kentucky. Please continue to send the Board office any information regarding Internet pharmacies or faxes. If you have further questions, please contact the Board office.

Board Newsletter

At its July 11, 2007 meeting, the Board voted to allow the Kentucky *Newsletter* to be sent via an e-mail link beginning in 2008. Therefore, around the first of March 2008 each pharmacist will receive an e-mail from the Board with a link to the Web page where the Kentucky *Newsletter* can be found. If you wish to continue to receive the *Newsletter* by mail, please notify the Board in writing. If you have further questions, please contact the Board office at your convenience.

Methadone Leading Cause of Overdose Victims in Kentucky

Submitted by the Commonwealth of Kentucky Office of Drug Control Policy (ODCP) Communications Office – Contact Stacy Floyd at 502/564-8220

Overdose due to methadone is on the rise in Kentucky. The 2006 Office of the State Medical Examiner's Annual Report indicates 197 deaths related to the misuse of the prescription drug methadone. Methadone was the prescription drug that was most frequently detected in the blood of fatal overdose victims.

The numbers reflect the total cases undergoing autopsies by the Kentucky Medical Examiner's Office in 2006. Methadone was detected in 41% of the 484 overdose death cases in Kentucky.

"Prescription drug overdoses in general, and methadone overdoses in particular, claim a large number of lives each year in the Commonwealth. These tragic deaths of Kentuckians are unnecessary and preventable," said Kentucky Chief Medical Examiner Dr Tracey Corey. "Regional and local medical societies and health departments may help reduce this tragic loss of life by making patients and physicians aware of the possibilities of accidental fatal overdose associated with the use of prescription narcotics, especially when used in concert with other prescription drugs."

Figures from the Kentucky All Schedule Prescription Electronic Reporting (KASPER) system, supplied by Dave Sallengs, RPh, branch manager of Drug Enforcement and Professional Practices in the Office of Inspector General of the Cabinet for Health and Family Services, show neither the number of prescriptions filled in Kentucky for methadone, nor the number of dosage units prescribed have changed significantly from 2003 through 2006.

"Since methadone has a shorter duration in the body than other controlled substance pain relievers the daily dosage is higher," stated Sallengs. "This could lead to a perception by patients that they could use increased dosages without concern about overdose. More patient education by prescribers and pharmacists when methadone is prescribed could help diminish the incidence of these overdoses."

"It is important to get the message out and warn the citizens of Kentucky about the misuse of methadone. I urge all members of law enforcement, hospitals, poison control centers, and emergency medical technicians to continue educating themselves on the effects and symptoms associated with methadone abuse," said Kentucky ODCP Executive Director Laurie Dudgeon. "The seriousness of methadone overdose and its possible consequences cannot be overemphasized."

A recent federal government study found that nationwide methadone-related deaths climbed to more than 3,800 in 2004 from about 780 in 1999.

Facts on Methadone

- Methadone is commonly prescribed for treating patients suffering from chronic pain, and medical professionals describe methadone as an effective tool for pain management.
- Methadone used to treat pain can be prescribed by a medical professional licensed to prescribe controlled substances in Kentucky.
- Prescriptions written for methadone are reported by dispensers to the KASPER system as well as prescriptions filled for methadone by pharmacies.
- In Kentucky, methadone is also used to treat the addiction of narcotics/opiates by clinics licensed to do so. It is the most used drug for the treatment and maintenance of narcotic addiction.

ODCP plans to conduct training sessions concerning methadone to educate the general public as well as health care professionals.

The *Kentucky Board of Pharmacy News* is published by the Kentucky Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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