

MISSOURI BOARD OF PHARMACY

NEWSLETTER



NOVEMBER 2015

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C-II PRESCRIBING FOR APRNS AND PAS

The Board has received several questions asking if advanced practice registered nurses (APRNs) or Physician Assistants (PAs) have authority to prescribe Schedule II hydrocodone combination products. In some instances, pharmacies have reportedly refused to fill any hydrocodone prescription written by an APRN or PA based on lack of authority.

On October 6, 2014, the DEA rescheduled hydrocodone combination products from Schedule III to Schedule II. Missouri law was amended in 2015 to authorize APRNs and PAs with a valid collaborative practice agreement to prescribe limited quantities of Schedule II medications containing hydrocodone.

Specifically, § 195.070.2, RSMO, provides:

2. An advanced practice registered nurse, as defined in section 335.016, but not a certified registered nurse anesthetist as defined in subdivision (8) of section 335.016, who holds a certificate of controlled substance prescriptive authority from the board of nursing under section 335.019 and who is delegated the authority to prescribe controlled substances under a collaborative practice arrangement under section 334.104 may prescribe any controlled substances listed in Schedules III, IV, and V of section 195.017, and [may have restricted authority in Schedule II. Prescriptions for Schedule II medications prescribed by an advanced practice registered nurse who has a certificate of controlled substance prescriptive authority are restricted to only those medications containing hydrocodone.](#) However, no such certified advanced practice registered nurse shall prescribe controlled substance for his or her own self or family. Schedule III narcotic controlled substance and Schedule II - hydrocodone prescriptions shall be limited to a one hundred twenty-hour supply without refill.

Section 334.747.2, RSMo, provides:

334.747. 1. A physician assistant with a certificate of controlled substance prescriptive authority as provided in this section may prescribe any controlled substance listed in Schedule III, IV, or V of section 195.017, and [may have restricted authority in Schedule II](#), when delegated the authority to prescribe controlled substances in a supervision agreement. . . [Prescriptions for Schedule II medications prescribed by a physician assistant with authority to prescribe delegated in a supervision agreement are restricted to only those medications containing hydrocodone.](#) Physician assistants shall not prescribe controlled substances for themselves or members of their families. Schedule III controlled substances and Schedule II - hydrocodone prescriptions shall be limited to a five-day supply without refill. Physician assistants who are authorized to prescribe controlled substances under this section shall register with the federal Drug Enforcement Administration and the state bureau of narcotics and dangerous drugs, and shall include the Drug Enforcement Administration registration number on prescriptions for controlled substances.

According to BNDD, APRNs or PAs must amend their DEA and BNDD registrations to add C-II authority before prescribing an allowed C-II hydrocodone product. Once their registrations are amended, APRNs and PAs may prescribe hydrocodone products unless otherwise restricted by their governing collaborative practice agreement. According to BNDD, this authority includes single ingredient products like Zohydro.

REMINDER: Prescriptions written by APRNs/PAs with valid C-II hydrocodone prescribing authority are limited to a 120-hour/5-day supply with no refills.



CONGRATULATIONS!



The Board would like to congratulate Inspector Frank VanFleet, R.Ph., on his upcoming retirement at the end of 2015. Frank began working for the Board in February 2000 and has served as an inspector in the Kansas City area for over 15 years. Prior to joining the Board, Frank worked as an inspector for the California Board of Pharmacy.

Best wishes Frank and thanks for your excellent service to the Board and Missouri's citizens!



Also, congratulations to inspectors Andi Miller and Dan Vandersand who recently celebrated 5 years of service with the Board.

PRESCRIPTION SECURITY PAPER

The Board has recently noticed an increase in questions related to security paper requirements for written prescriptions. Confusion apparently exists on when security paper is required. Board regulation 20 CSR 2220-2.085 requires that written prescriptions given to patients bearing an electronic signature must be on paper that has features to prevent copying or alteration. If the prescriber physically signs the prescription, the Board's requirement does not apply.

The Board is not aware of any Drug Enforcement Administration or Missouri Bureau of Narcotics and Dangerous Drugs requirement for security paper for controlled substance prescriptions. However, Centers for Medicare & Medicaid Services (CMS) requires all written prescriptions given to Medicaid beneficiaries to be on tamper-resistant paper. For more information, visit the CMS web page on [Tamper Resistant Prescriptions](#).

BNDD SCHEDULING UPDATE

Previously, federal law classified lofupane, sold under the brand name of DaTscan, as a Schedule II drug. The DEA decontrolled the drug in September 2015 and the product is no longer a controlled substance. BNDD has received inquiries from pharmacists and hospitals about Missouri's scheduling of lofupane. According to BNDD, lofupane will remain a Schedule II drug in Missouri until BNDD is able to update Missouri's controlled substance listings. Questions regarding the rescheduling should be forwarded to BNDD.

COMPLIANCE NOTES FROM THE FIELD:

- A Missouri pharmacy recently reported a controlled substance loss after diversion by a technician. An investigation found technicians were able to check-in controlled substance orders by themselves in a backroom that wasn't monitored. Additionally, keys to the C-II cabinet were routinely kept in plain view on top of the cabinet. All pharmacies must maintain effective security to deter theft and diversion of controlled substances. Check your pharmacy's procedures to make sure controlled substances are adequately monitored and stored at all times.
- A pharmacist failed to report that a pharmacy technician was terminated for stealing merchandise, donuts and chocolate milk. The pharmacist-in-charge indicated he did not know a report had to be filed since the conduct "had nothing to do with the pharmacy."

Pharmacies are required to report the termination or discipline of any Board licensee or registrant for conduct that would be



grounds for discipline under § 338.055.2, RSMo. Stealing, theft or diversion by a technician, intern or a pharmacist should be reported to the Board- even if the items/funds were not stolen or diverted from the actual pharmacy. Technician actions must be reported within fifteen (15) days of the action. [See 20 CSR 2220-2.010(1)(P)]. Technician discipline/actions reports should be submitted on the Board's website at <https://renew.pr.mo.gov/pharmacists-tdtf.asp>

- Only prescriptions that were not received by the patient can be returned to stock;
- Third party payor claims must be reversed, if applicable;
- Drugs must be maintained in the patient container. The medication may never be poured back into a stock bottle;
- The prescription container must be labeled to show the dispensing date, prescription number and drug name; and
- The drug expiration date must be the lesser of one (1) year from the dispensing date or the manufacturer's original expiration date, if known.

INSPECTION TIPS:

Errors Involving Return to Stock Prescriptions

The Board continues to receive reports of prescription errors involving return to stock (RTS) prescriptions. RTS prescriptions are prescription vials that have been prepared but not received or picked up by the patient and are eventually put back in the pharmacy's inventory. Board regulations require that RTS prescriptions must remain in the prescription container. 20 CSR 2220-3.040(3). The Board has received reports of two types of errors related to RTS prescriptions: (1) the wrong drug/strength being dispensed to the patient or (2) a patient receiving confidential information related to another patient.

Errors involving the wrong drug are usually the result of a mix-up during the drug selection process. Recent examples include different strengths or drugs being mixed in the same vial. In some instances, the completely wrong strength or drug was dispensed. Using a drug from a RTS vial can be outside of the normal dispensing process and some of the normal verification steps may be different (i.e., using bar code scanning to catch errors). In a recent instance, the pharmacist was unaware that a technician used an RTS vial.

The second type of error is a violation of patient confidentiality when a patient receives prescription information related to another patient. Examples include patients receiving a prescription vial that has two different labels on it when a RTS label is not removed. In some instances, patients have peeled off their label to find another patient's full label underneath. The Board has also received reports of patients receiving an extra vial with their prescription when a RTS vial inadvertently gets packaged with the patient's prescription.

Pharmacists should use extra care when RTS vials are used in the dispensing process to make sure prescriptions are dispensed properly. Pharmacies should also review their procedures to minimize the chance of errors. Some recommendations include having the verifying pharmacist view the RTS vial during final product verification, notifying the verifying pharmacist when a RTS vial is used or marking RTS vials when they are placed back into inventory so they are clearly identifiable from an active prescription being dispensed.

As a reminder, Board regulation 20 CSR 2220-3.040 requires the following for RTS prescriptions:

GOLD CERTIFICATES:

The following pharmacists will receive gold certificates in honor of maintaining a pharmacist license with the Board for 50 years. Congratulations to those who have served the public for 50 years as a pharmacist!



Beisner, Gerald H
Collins, Robert W
Cushman, Sam M
Fitzpatrick, William
Gaffney, William E
Greim, Larry E
Hagen, Donald L
Hiner, William L
Hodson, Larry E
McDermott, Larry C
Mikesic, Paula A
Schachter, Willard
Sievers, William F, Jr
Sisson, Albert E, II
Underwood, George

FROM THE DEPARTMENT OF INSURANCE:

Get Free Help during Medicare's Annual Enrollment Period (October 15 to December 7)

Medicare can be very complex for individuals who are enrolling or for those who may be assisting a loved one. Medicare's Annual Enrollment Period, October 15-December 7, is in



progress. To help beneficiaries make good choices, the Missouri Department of Insurance, Financial Institutions and Professional Registration offers the CLAIM program.

CLAIM, which is Missouri's State Health Insurance Assistance Program or SHIP, has been serving Missourians since 1993, and exists solely to provide Medicare beneficiaries with free, unbiased counseling for their Medicare questions and issues. The program is funded from a federal grant and state funds.

CLAIM can help with questions about Medicare and the decisions a Medicare beneficiary needs to make during Medicare's Annual Enrollment Period. CLAIM can also assist with questions about Part D (prescription drug) enrollment and changes, billing, appeals and grievances, and can provide counseling for low-income assistance.

CLAIM has a network of more than 300 trained volunteer counselors across the state. To make arrangements to talk to a counselor or for more information, visit missouricclaim.org or call 1-800-390-3330. You may also submit questions to CLAIM using their online form at www.missouricclaim.org/about/contact.

CLAIM has many outreach events and presentations around the state. Check their calendar at www.missouricclaim.org/events to see if there is an event in your area.



DHSS NEEDS YOUR INPUT

The Missouri Department of Health & Senior Services' (DHSS) Bureau of Immunizations is conducting a very important research study about vaccine awareness in Missouri.

As our trusted partner, we would like to request your participation in an in-depth interview in the upcoming weeks with a third-party research group. This short phone interview will last between 15 and 30 minutes.

Your input is very valuable to DHSS. Your participation in these interviews will help DHSS better understand:

- How DHSS can better support Missouri pharmacists with vaccine information and programs;
- How pharmacists approach the topic of vaccines with customers; and
- Pharmacists' knowledge about the ShowMeVax registry.

Your comments will be completely confidential and will not be attributed to you in any way. DHSS is looking for your candid responses.

If you are interested in participating, please contact Patty Olsen at polsen@vandivergroup.com or call 314-991-4641, Ext. 121 to set up your interview time.

DISCIPLINARY ACTIONS:

PHARMACISTS:

Bruce D. Ballard, #028642, Raymore, MO. Probation for two (2) years. Violation of discipline involving dispensing errors. Section 338.055.2(5), (6), (13), and (15), RSMo.

Ashley I. Fredrick-Schreiner, #2009021440, Montgomery City, MO. Probation for two (2) years. As pharmacist-in-charge, created controlled substance prescriptions not authorized by a physician; dispensed controlled substance prescription to an unknown person without a valid, patient specific prescription; and failed to supervise pharmacy personnel to assure full compliance with state/federal law/regulations. Section 338.055.2(5), (6), (13), and (15), RSMo.

Amanda L. Law, #2009025376, Addison, TX. Probation for five (5) years effective 5/1/2016. Ingested a controlled substance obtained from employer without a valid prescription; pled guilty to felony possession of a controlled substance, then withdrew guilty plea following completion of drug court. Section 338.055.2(2), (5), (13), (15), and (17), RSMo.

Brian Mitchell, #042307, Kennett, MO. Revoked, cannot reapply for five (5) years. Pled guilty to felony knowingly and willfully executing a scheme to defraud a health care benefit program while on discipline with the Board. Section 338.065, RSMo.

Clinton Z. Ross, #2001028180, St. Louis, MO. Suspension for one (1) year followed by Probation for five (5) years. Pled guilty to two counts of stealing a controlled substance, illegally removed controlled substances from employers. Section 338.055.2(5), (13), and (15), and Section 338.065, RSMo.

Julie Ann Schrock, #2008027487, St. Louis, MO. Probation for five (5) years to begin when renews license. Removed and dispensed controlled substances to herself from pharmacies without valid prescriptions; misbranding. Section 338.055.2(1), (5), (13), (15), and (17), RSMo.

PHARMACIES:

Care Pharmacy, LLC, #2011012258, Creve Coeur, MO. Revoked and cannot reapply for seven (7) years. Technician dispensing without a pharmacist on duty; dispensing controlled substances without a written prescription, and prescription error. Section 338.055.2(5) for incompetency, misconduct dishonesty and misrepresentation, (6), (13), and (15), RSMo.



Ferguson Drug, #15803, Powered by Walgreens, #2009008023, Willow Springs, MO. Censure of permit. Possessed and dispensed controlled substances without a valid BNDD license. Section 338.055.2(15), RSMo.

Medicine Shoppe Pharmacy, #2008019033, St. Louis, MO. Probation for three (3) years. Inspection violations including CII safe unlocked and CIII-Vs not dispersed through inventory, overfilled stock bottles, failure to timely complete controlled substance inventory, failure to provide patient counseling, labeling errors, failure to maintain distribution records, adulteration of drug products, failure to use gloves when handling tablets, and return to stock violations. Section 338.055.2(5), (6), (13), and (15), RSMo.

Mitchell Pharmacy, #2005035753, Kennett, MO. Revoked, cannot reapply for seven (7) years. Pled guilty to felony knowingly and willfully executing a scheme to defraud a health care benefit program while on discipline with the Board. Section 338.065, RSMo.

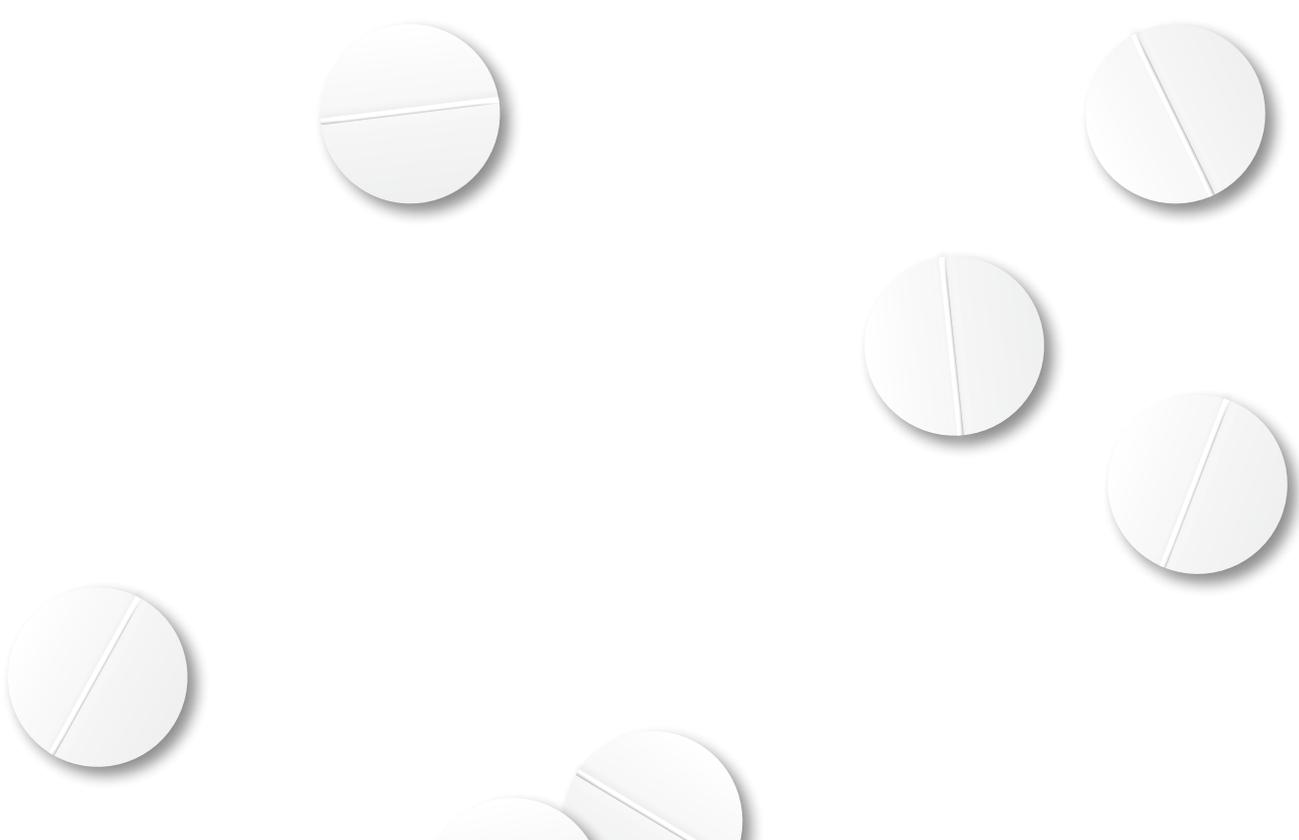
Rogers Pharmacy, #005685, St. Joseph, MO. Censure of permit. Created prescriptions that were never filled by the

pharmacy for controlled and non-controlled substances, inaccurate records. Section 338.055.2(4), (5), (6), (13), and (15), RSMo.

Stephens Health Services, #2011008719, Bolivar, MO. Censure of permit. Technicians working unsupervised, failure to take controlled substance inventory after change of pharmacist-in-charge, improper refrigeration/temperature controls, med pak violations, failure to maintain power of attorney forms, non-compliance emergency CII dispensing, unauthorized acceptance of controlled substance returns from long-term care facilities, alteration of CII prescriptions without prescriber authorization, compounding violations, and reuse/repackaging violations. Section 338.055.(5), (6), (10), (13), (15), and (16), RSMo.

DRUG DISTRIBUTORS:

Goetze-Niemer Co., Inc, #900044, Kansas City, MO. Probation for eighteen (18) months. Repeat violation of products stored outside of the manufacturer's recommended temperature range. Section 338.055.2(5), (6), (13), and (15), RSMo.





NATIONAL ASSOCIATION OF BOARDS OF PHARMACY® NATIONAL PHARMACY COMPLIANCE NEWS - 4TH QUARTER 2015

FDA ISSUES WARNING ABOUT NAME CONFUSION FOR BRINTELLIX AND BRILINTA

Due to similar brand names, there have been incidents where the antidepressant Brintellix® (vortioxetine) and the anti-blood clotting medication Brilinta® (ticagrelor) have been confused, resulting in prescribing and dispensing errors, warns Food and Drug Administration (FDA). The agency notes that no reports indicate that a patient has ingested the wrong medication; however, reports of prescribing and dispensing errors continue. FDA recommends that health care providers include the generic name of the medication in addition to the brand name, as well as the indication for use when prescribing these medications. Patients are advised to check their prescriptions to ensure that the correct medication was dispensed. More information is available in an FDA safety alert at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456569.htm.

SEVEN PERSISTENT SAFETY GAFFES IN COMMUNITY/AMBULATORY SETTINGS THAT NEED TO BE RESOLVED!

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes 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, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.

This is part two of a three-part series on seven persistent safety gaffes of 2014.

3) Vaccine Errors: Repetitive Errors Reported in the Last Decade

How often do DTaP (diphtheria and tetanus toxoids, and

acellular pertussis) and Tdap (tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis) vaccine mix-ups need to occur before regulatory action is taken to prevent confusion? Whatever the number, we can say that health care providers have probably met that threshold! Yet, vaccine errors like this continue to occur at an alarming rate (based on those reported to ISMP alone). Vaccine mix-ups occur often because of age-dependent formulations of the same vaccine, similar vaccine abbreviations, similar vaccine containers and labels, and storage near each other. Confusion between the diluent and vaccine has led to administration of the diluent alone or use of the wrong diluent. With an unfortunate rise in parents choosing not to vaccinate their children or themselves, health care providers cannot continue to make errors when vaccinating those who choose to be immunized; the impact on both individual and community immunity may be far-reaching.

4) Wrong Patient Errors: Not Opening the Bag at the Point of Sale

Community pharmacies are vulnerable to dispensing correctly filled prescriptions to the wrong patient at the point of sale, a risk that is well substantiated in the literature. This error is not influenced by the attributes of a specific medication; thus, dispensing any prescription medication to the wrong patient at the point of sale carries a similar level of risk. Based on an

ISMP study, the error happens frequently at an estimated rate of 1.22 per 1,000 prescriptions. Among approximately 56,000 community pharmacies in the United States, this error rate suggests that 332,755 prescriptions will be dispensed to the wrong patient each month, or about six every month per pharmacy. One of the most effective ways to prevent this error is to open the bag of filled prescriptions at the point of sale to verify that the medications are for the correct patient. According to the ISMP study, this simple step reduces the risk of error by 56%, yet few pharmacies follow this practice.

5) Disrespectful Behavior: A History of Tolerance in Health Care

Bullying, incivility, and other forms of disrespectful behavior are still rampant in health care and allowed to exist. Health care providers tolerate the behavior, remain silent, or make excuses in an attempt to minimize the profound devastation that disrespectful behavior causes. An ISMP survey conducted in 2003 clearly demonstrated the scope of disrespectful behavior among many levels of interdisciplinary staff, and an ISMP survey conducted a decade later



demonstrates little progress. Disrespect diminishes a person's ability to think clearly, make sound judgments, speak up regarding questions, or avoid at-risk behaviors. Disrespectful behaviors also underlie a resistance to collaborate with others, follow procedures that promote safe practices, or implement new safety practices. While a culture of disrespect is harmful on many levels, its effect on patient safety makes it a matter of national urgency.

FDA ADVISES CAUTION AGAINST CODEINE FOR TREATING COLDS IN YOUNG PATIENTS

FDA is evaluating the safety of using medicines containing codeine to treat patients under 18 years old for coughs and colds because of the possibility of severe side effects. Codeine, an opioid, may cause slowed or difficult breathing in children, especially for those who already suffer from breathing problems, the agency notes. FDA recommends that health care providers use caution when prescribing or recommending codeine for patients under 18 years old, and that parents and caregivers be alert for signs of shallow or noisy breathing, confusion, or unusual sleepiness. FDA is also considering a European Medicines Agency recommendation made in April to not give children under 12 codeine for coughs and colds, and to not use codeine for patients 12 to 18 years old who have asthma or other chronic breathing problems. More information is provided in an FDA safety alert available at <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm>.

DAYTRANA PATCH MAY CAUSE PERMANENT SKIN COLOR CHANGES, FDA WARNS

In June 2015, FDA warned health care providers and consumers that Daytrana®, a methylphenidate transdermal system prescribed for treating attention deficit hyperactivity disorder, may cause permanent loss of skin color in the affected area. FDA has added a new warning to the drug label to describe this skin condition, known as chemical leukoderma. Chemical leukoderma is a skin condition that causes the skin to lose color as a result of repeated exposure to specific chemical compounds, according to an FDA safety alert. The condition is not physically harmful, but it is disfiguring.

FDA advises patients and caregivers to watch for new areas of lighter skin, especially under the drug patch, and to immediately report any changes to their health care providers. Patients should not stop using the Daytrana patch without consulting a health care provider. FDA also

recommends that providers for patients who experience these skin color changes consider alternative treatments. More details are included in the FDA safety alert available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm452595.htm.

FDA Expands NSAID Warning Labels Regarding Risks of Heart Attack, Stroke

The labels of certain non-steroidal anti-inflammatory drugs (NSAIDs) will soon contain more detailed information about the risk that the drugs may contribute to heart attack and stroke, reports FDA. Such warnings have been on prescription and over-the-counter NSAIDs since 2005, but the new requirements take into account new data showing that the risk of heart attack and stroke occurs even during the first few weeks of taking an NSAID. People who have cardiovascular and other heart problems are at even greater risk of adverse effects. An FDA alert available at www.fda.gov/ForConsumers/ConsumerUpdates/ucm453610.htm provides more details.

BAXTER INTERNATIONAL, INC, RECALLS THREE LOTS OF IV SOLUTIONS DUE TO PARTICULATE MATTER

In July 2015, Baxter International, Inc, voluntarily recalled two lots of intravenous (IV) solutions distributed to hospitals and other health offices because of the presence of particulate matter identified as an insect. The problem was identified before patient administration and no adverse health effects have been reported. The recall affects 0.9% sodium chloride injection, USP 50 mL and 100 mL, lot numbers P319921 and P327635, which were distributed to US customers between October 7, 2014, and July 14, 2015. Additional information is available in an FDA press release at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm455421.htm.

Baxter also voluntarily recalled one lot of IV solution to the hospital/user level because of the potential for leaking containers, particulate matter, and missing port protectors. This recall affects 0.9% sodium chloride injection, USP (AUTO-C) with lot number C964601 (National Drug Code 0338-0049-03; expiration date: April 30, 2016). This recalled lot was distributed to customers and distributors nationwide between January 22, 2015, and February 12, 2015. Leaking containers, particulate matter, and missing port protectors could result in contamination of the solution and, if not detected, could lead to a bloodstream infection or other serious adverse health consequences, explains FDA. The agency notes further that "injecting a product containing particulate matter, in the absence of in-line filtration, may result in blockage of blood vessels, which can result in stroke, heart attack or damage to other organs such as



the kidney or liver. There is also the possibility of allergic reactions, local irritation and inflammation in tissues and organs.” More information about this recall is available in an FDA safety alert at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456793.htm.

FDA WARNS AGAINST UNAPPROVED PRESCRIPTION EAR DROPS

FDA has ordered the manufacturers of certain prescription ear drops to stop making and distributing the products because they are not FDA-approved. The product labels do not disclose that they lack FDA approval, and health care providers may not be aware of the unapproved status, notes FDA. The agency took action against unapproved prescription otic drug products containing these ingredients:

- benzocaine;
- benzocaine and antipyrine;
- benzocaine, antipyrine, and zinc acetate;
- benzocaine, chloroxylenol, and hydrocortisone;
- chloroxylenol and pramoxine; and
- chloroxylenol, pramoxine, and hydrocortisone.

These drugs are frequently given to relieve ear swelling and pain in young children, and FDA took this action to protect

patients from the risks of taking unapproved drugs with no proven safety or effectiveness information. Further, such drugs may be contaminated or manufactured incorrectly, notes the agency. More information is provided in an FDA news release available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453348.htm.

ACINO PRODUCTS IN NEW JERSEY ORDERED TO STOP SELLING RECTACORT-HC AND GRX HICORT 25

Under the direction of FDA, a federal judge for the District of New Jersey has ordered Acino Products, LLC, of Hamilton, NJ, to stop selling and destroy certain unapproved and misbranded prescription drugs in its possession.

According to FDA, Acino has marketed unapproved hydrocortisone acetate 25 mg suppositories, under the brand names Rectacort-HC and GRx HiCort 25, for treatment of medical conditions including inflamed hemorrhoids, chronic ulcerative colitis, and other inflammatory conditions. The drugs have not been FDA-approved and also fail to carry adequate directions for use on their labels. Acino continued to market and sell the products despite several warnings from FDA investigators. The FDA news release is available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453466.htm.

