

MISSOURI BOARD OF PHARMACY

NEWSLETTER



MAY 2015

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BOARD UPDATES

The Board welcomes a new Board member:



Christina M. Lindsay, PharmD.

Kansas City, Missouri
Original Appointment:
2-19-15
Current Term Expires:
12-3-19

Ms. Lindsay is a 2007 doctorate of pharmacy graduate of the University of Missouri-Kansas City School of Pharmacy. She is a licensed pharmacist in Missouri, Kansas, and Nebraska. Ms. Lindsay started her pharmacy career with CVS/pharmacy as a pharmacy student in 2003 and then went on to serve as a Pharmacy Manager, and currently as a District Pharmacy Supervisor. During her role as a District Pharmacy Supervisor, she also served as pharmacy management preceptor for the surrounding pharmacy schools.

BOARD OF PHARMACY

3605 Missouri Boulevard or P.O. Box 625
Jefferson City, MO 65102-0625
573.751.0091 Telephone | 573.526.3464 Fax
MissouriBOP@pr.mo.gov | pr.mo.gov/pharmacists

Missouri Board of Pharmacy Pharmacist Licensing FAQ
(This FAQ provides general information for Missouri pharmacist applicants. This document addresses the most common pharmacist licensure questions and does not contain all licensing requirements. Applicants should consult 20 CSR 220, Chapter 7, for applicable licensing requirements.)

Non-Missouri Pharmacy Students/Graduates
How that I've graduated, how do I get licensed as a Missouri pharmacist?
To be licensed as a Missouri pharmacist, applicants must:
• File a Missouri Pharmacist Examination Application with the Board.
• Pay the application fee.
• Submit fingerprints and undergo a criminal history background check (institutions are in the applicant's control).
• Take and pass the North American Pharmacist Licensure Examination (NAPLEX), and
• Take and pass the Multistate Pharmacy Jurisprudence Examination (MPJE) for Missouri. The Board has received pharmacist licenses from students who have completed their courses but have not officially graduated. You do not apply for a Missouri pharmacist license until you have your pharmacy school diploma.
Application should I submit?
Missouri Pharmacist Examination Application (MPEX) and MPJE. New graduates who are transferring from another state should file a Missouri Pharmacist Examination Application (MPEX) and Missouri Pharmacist Licensure Transfer Application.
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Missouri Intern Pharmacist Guide for Missouri Pharmacy School Students
How do I register to take the NAPLEX and MPJE?
The NAPLEX and MPJE are administered by the National Association of Boards of Pharmacy (NABP).
• Register online with www.nabp.net (you will be charged by credit card).
• Call for e-mail: exam@nabp.net that you need.

Missouri Board of Pharmacy
Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO 65102
Telephone: (573) 751-0091
Email: exam@pr.mo.gov
Website: pr.mo.gov/pharmacists
April 2015

NEW BOARD RESOURCES

Visit the Board's website to view these new Board brochures:

- Missouri Intern Brochure (STLCoP & UMKC Students)
- Missouri Intern Brochure (Non-Missouri Students)
- New-Graduate Pharmacist Licensing FAQ



FISCAL YEAR 2014:

The Board's FY 2014 Annual Report has been released. Copies of the Annual Report are available online at pr.mo.gov/pharmacists-annual-reports.asp. Here are a few interesting FY 14 statistics:

- 34,673 licensees, registrants and permit holders at the end of FY 14
- 18,691 pharmacy technicians
- 9,954 licensed pharmacists (current & new)
- 5,992 incoming telephone calls handled by the Board office
- 1,500 in-state pharmacies
- 921 non-resident pharmacies
- 653 complaints received/opened by the Board
- 91 Board disciplinary actions (excludes tax suspensions)
- 86 Missouri counties with ≤ 10 pharmacies
- 58 pharmacy technicians disqualified/conditionally registered
- 8 pharmacist licenses suspended/probated
- 2 pharmacist licenses revoked

PHARMACY/DRUG DISTRIBUTOR RENEWALS:

Pharmacy and Drug Distributor renewals will be mailed in July. Renewals will be mailed to the official mailing address designated with the Board. Avoid renewal delays! Update your Board mailing address now. Note: An official Pharmacy Change of Location Application or a Drug Distributor Change of Location Application must be filed if the pharmacy's/distributorship's physical address has changed.

RULE REVIEW:

The Board is currently considering changes to the following rules:

- 20 CSR 2220-2.200 (Sterile Compounding): The Board is considering a comprehensive rule revision to incorporate major provisions of USP Chapter 797.
- 20 CSR 2220-2.090 (Pharmacist-In-Charge): Rule language is being updated to clarify PIC responsibilities
- 20 CSR 2220-6.050 (Class J: Shared Services): The Board is considering language that would authorize dispensing of medication between pharmacies for on site patient administration without a Class J license.

Have suggestions/comments? Potential changes will be discussed during the July Board meeting. Comments can also be e-mailed to: MissouriBOP@pr.mo.gov.

MARK YOUR CALENDAR:

- July 14-15, 2015- Board Meeting ♦ Columbia, Missouri
- July 16, 2015- "Lunch with the Chief" webinar
- October 13, 2015- "Lunch with the Chief" webinar

INSPECTION TIPS

- Is your Notification of Intent current? Pharmacists immunizing by protocol or administering medication by prescription order must have a current Notification of Intent on file with the Board. Notifications of Intent must be filed annually. Check your Notification of Intent status and filing date online at <https://renew.pr.mo.gov/pharmacy-licensee-search.asp>.



Unsanitary Reconstitute Unit

- What does your pharmacy's Reconstitute or Fillmaster look like? An unsanitary unit is a common inspection finding. Pharmacists should routinely check the pharmacy for compliance and make sure all equipment has been properly cleaned.



DISCIPLINARY ACTIONS:

PHARMACISTS:

Carmen K. Broadbent, #2003026181, Springfield, MO. Three (3) years probation. As pharmacist-in-charge, verified and dispensed unauthorized prescriptions, misbranding by unauthorized distribution of a legend drug, and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.

Mary V. Drake, #042911, Godfrey, IL. Sixty (60) days suspension—credit given for suspension served under Illinois disciplinary order, followed by five (5) years probation. Disciplinary action in Illinois relating to diversion of controlled substances from employer for personal use. Section 338.055.2(5), (6), (13), and (15), RSMo.

Tre'Von Elam, #2012031705, Dallas, TX. Public Censure. Administered Boostrix vaccinations without a valid, patient specific prescription. Section 338.055.2(5), (6), (13), and (15), RSMo.

Jana L. Ellis, #2008033118, Little Rock, AR. Voluntary Surrender of license, cannot reapply for seven (7) years. Disciplinary action in another state regarding forged controlled substance prescriptions and dispensed them to herself, diversion of controlled substances. Section 338.055.2(5), (8), (13), (15), and (17), RSMo.

Hillary A. Jackson, #2012013212, Sedalia, MO. Administrative Hearing Commission granted temporary authority to suspend for one (1) year due to misappropriation of controlled substances from employer for personal use, created and filled controlled substance prescriptions not authorized by her healthcare providers for herself, consumed controlled substance without a prescription while working as a pharmacist. Section 338.055.4 and .5, RSMo.

Lynn A. Morris, #028332, Nixa, MO. Three (3) years probation. Allowed employees to obtain non-controlled medications by creating prescriptions under the name of a doctor without the doctor's authorization or without being physically examined by the doctor; dispensed prescriptions without doctor authorization; misbranding; and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.

Megan R. Quick, #2012014981, Ozark, MO. Suspension for fourteen (14) days. Practiced with an expired license. Section 338.055.2(5), (12), (13), and (15), RSMo.

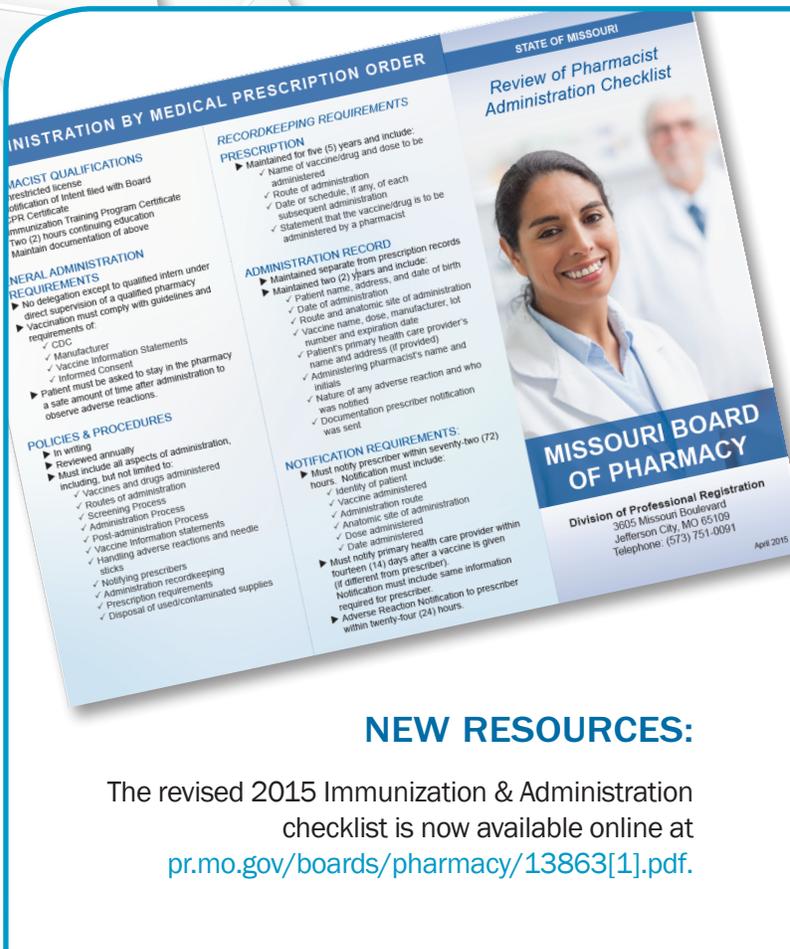
Jason R. Sten, #2013023618, Kansas City, MO. Public Censure. Administered vaccines without a signed protocol. Section 338.055.2(5), (6), (13), and (15), RSMo.

William E. Taylor, #2011019651, Nixa, MO. Two (2) years probation. As pharmacist-in-charge, verified and dispensed unauthorized prescriptions, misbranding by unauthorized

distribution of a legend drug, and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.

Frances M. Thexton, #041887, Warrensburg, MO. Suspension for fourteen (14) days, followed by one (1) year probation. Misappropriated controlled substance from her mother's prescription; practiced while suspended for failure to file/pay Missouri taxes. Section 338.055.2(4), (5), (6), (7), (13), (15), and (17), RSMo.

Timothy E. Thompson, #2011032868, Rogersville, MO. Revoked and cannot reapply for seven (7) years. Violation of discipline, removed controlled substances from employer pharmacy without a valid prescription and for which he did not pay; did not provide employer copy of Settlement Agreement. Section 338.055.2(5), (6), (13), and (15), RSMo.



NEW RESOURCES:

The revised 2015 Immunization & Administration checklist is now available online at [pr.mo.gov/boards/pharmacy/13863\[1\].pdf](http://pr.mo.gov/boards/pharmacy/13863[1].pdf).



PHARMACIES:

ExelleRx, Inc., #2003015952, Memphis, TN. Probation until September 13, 2016. Disciplinary action in another state regarding company's civil consent decree with the United States Government related to its dispensing approximately 7,000 Schedule II controlled substances to hospice patients prior to obtaining the physician's authorized signature. Section 338.055.2(5), (8), and (13), RSMo.

Family Pharmacy, #003475, Ozark, MO. Three (3) years probation. Pharmacists verified and dispensed prescriptions under the name of a doctor not lawfully authorized by the doctor; employees obtained non-controlled medications by creating prescriptions under the name of a doctor without the doctor's authorization or without being physically examined by the doctor; misbranding; and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.

Family Pharmacy #5, #2007028926, Rogersville, MO. Three (3) years probation. Pharmacists verified and dispensed prescriptions under the name of a doctor not lawfully authorized by the doctor; employees obtained non-controlled medications by creating prescriptions under the name of a doctor without the doctor's authorization or without being physically examined by the doctor; misbranding; and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.

Family Pharmacy, #2002026762, Springfield, MO. Three (3) years probation. Pharmacists verified and dispensed prescriptions under the name of a doctor not lawfully authorized by the doctor; employees obtained non-controlled medications by creating prescriptions under the name of a doctor without the doctor's authorization or without being physically examined by the doctor; misbranding; and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.

John Hollis Pharmacy, #2015001161, Nashville, TN. Three (3) years probation. Prior disciplinary action against president/owner's Tennessee pharmacist license due to alcohol and drug abuse. Section 338.055.2(8), RSMo.

Precision Pharmacy, #2009033432, Bakersfield, CA. Probation until 2/10/17. Disciplinary action in other states regarding multiple sterile compounding violations, acting as a manufacturer/wholesaler without a license, and various labeling and recordkeeping violations. Section 338.055.2(5), (8), and (13), RSMo.

United Scripts LTC LLC, #2012030984, Maryland Heights, MO. Public censure. Failure to provide adequate security/effective controls to detect and prevent drug diversion; failure to maintain accurate controlled substance records. Section 338.055.2(6) and (15), RSMo.

VERIFY TECHNICIAN LICENSURE STATUS

Pharmacy technician registration will end on May 31. Technicians not renewed by May 31, are not authorized to work. Licensees should check the Board's Web site on June 1, to ensure your technicians have been validly renewed.

Be sure to also check the following lists which also contain information on pharmacy technicians prohibited or restricted from working:

- **Employment Disqualification List:** Includes technicians that are prohibited from working as a Missouri pharmacy technician.
- **Conditional Registration List:** Identifies individuals with restricted technician registrations. Conditionally registered technicians are authorized to work in Missouri subject to the terms and conditions designated by the Board. An abbreviated listing of technician conditional terms/conditions may be found on the back of the technician's conditional registration.
- **"HB 600" List:** Includes technicians/pharmacists that have been suspended for tax purposes. Individuals on the HB 600 list are prohibited from working as a technician until removed from the list.

The technician lists are available on the Board's Website and are frequently updated. Licensees should establish procedures for regularly checking the technician listings to ensure pharmacy staff are authorized to work. The Board also sends out electronic alerts (e-alerts) when names are added to the list. Sign up for e-alerts here or on the Board's Web site.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY® NATIONAL PHARMACY COMPLIANCE NEWS - 2ND QUARTER 2015

FDA'S NEW DATABASE SIMPLIFIES SEARCHING FOR GUIDANCE DOCUMENTS

Food and Drug Administration (FDA) has released a new database that houses most FDA guidance documents for regulatory professionals. The guidance documents for nearly all FDA-regulated professions and industries are available in a searchable database that allows users to enter keywords that update automatically as they are typed. Search results may also be narrowed by product, date, document type, and other terms. The database also indicates whether there is an open comment period and the deadline for submitting



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comments. The database can be accessed at www.fda.gov/RegulatoryInformation/Guidances/default.htm.

2014-2015 TARGETED MEDICATION SAFETY BEST PRACTICES FOR HOSPITALS

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.

The purpose of the Targeted Medication Safety Best Practices (TMSBP) for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices on specific medication safety issues that continue to cause fatal and harmful errors in patients despite repeated warnings in ISMP publications. These best practices are realistic practices, already adopted by many organizations, upon which hospitals can focus their medication safety efforts. The best practices are applicable to all types of hospitals including, but not limited to, critical access hospitals, cancer hospitals, and children's hospitals. They may also be applicable to other health care settings, as well as non-inpatient areas of hospitals and hospital systems. These best practices have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the ISMP Medication Safety Alert! are referenced after each best practice.

RECURRENT ISSUE OF SERIOUS HARM

Oral methotrexate for non-oncological indications administered daily instead of weekly or twice weekly is a recurrent issue and one of the six TMSBPs.

ISMP has published this error in seven ISMP Medication Safety Alert! issues from 1996 to 2013. Although dosed daily for oncology purposes, it is used weekly or twice weekly to treat a variety of autoimmune diseases (eg, psoriasis, severe rheumatoid arthritis). Error reports point to inadvertent ordering and/or entering as daily instead of weekly or twice weekly, and lack of patient education/ understanding of medication dosing schedule. To minimize the risk of error, Best Practice 2 calls for hospitals to:

- a) Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.
- b) Provide patient education by a pharmacist for all weekly oral methotrexate discharge orders.

Question: Does the best practice of a weekly frequency default for oral methotrexate apply to a specialty cancer hospital?

Answer: The intent of this best practice is to reduce errors when methotrexate is prescribed as a weekly regimen for non-oncologic or oncologic indications. Even when used for oncologic purposes, oral methotrexate is sometimes prescribed as a weekly regimen, not daily. Thus, this best practice applies to all patient care settings, including specialty cancer hospitals.

Teaching Points (Both Verbal and Written)

- Explain the weekly dosing schedule.
- Explain that taking extra doses is dangerous.
- Have the patient repeat back the instructions.
- Provide the patient with the free ISMP high-alert medication consumer leaflet on methotrexate (found at www.ismp.org/AHRQ/default.asp).

To read all of the best practices, visit www.ismp.org/Tools/BestPractices/default.asp.

ACPE RELEASES UPDATED DEFINITION OF CPE AND GUIDANCE ON CPD

The Accreditation Council for Pharmacy Education (ACPE) has released two documents that provide guidance and support for continuing pharmacy education (CPE) and continuing professional development (CPD). The two documents, approved by the ACPE board of directors, are described below.



NATIONAL ASSOCIATION OF BOARDS OF PHARMACY® NATIONAL PHARMACY COMPLIANCE NEWS - 2ND QUARTER 2015 CONTINUED....

- The revised Definition of Continuing Education for the Profession of Pharmacy defines the quality of CPE required by ACPE and the competencies required for CPE activity content. The Definition document will assist providers of CPE in planning activities that will be applicable to the professional development of pharmacists and certified pharmacy technicians.
- The Guidance on Continuing Professional Development (CPD) for the Profession of Pharmacy incorporates feedback from a broad survey of the pharmacy profession that was conducted in July 2014. The Guidance document provides details on the learning activities that may contribute to the professional development of both pharmacists and pharmacy technicians beyond CPE, and also “provides a process for pharmacists and pharmacy technicians to meet and maintain defined competencies in areas relevant to their respective professional responsibilities.”

Additional information, including links to the documents, is available in a press release on the ACPE website at www.acpe-accredit.org/pdf/ACPEAdvancesCPE-CPDforPharmacists.pdf.

HOSPIRA ISSUES RECALL FOR MULTIPLE LOTS OF KETOROLAC TROMETHAMINE INJECTION DUE TO POTENTIAL CONTAMINATION

Hospira, Inc, of Lake Forest, IL, has issued a voluntary recall of ketorolac tromethamine injection, USP in the United States and Singapore due to potential particulate matter. The presence of particulate was confirmed through a customer report of visible floating particulate that was identified as calcium-ketorolac crystals. If injected, medications contaminated with particulate matter may cause localized inflammation, allergic reaction, granuloma formation, or microembolic effects. Multiple lots are impacted by this recall and are listed in a press release posted to the FDA website at www.fda.gov/Safety/Recalls/ucm433857.htm. The lots were distributed from February 2013 to December 2014 in the US. To date, there have been no cases of adverse events associated with this medication. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

FDA WARNS OF COUNTERFEIT CIALIS TABLETS ENTERING THE US

Potentially dangerous, counterfeit versions of Cialis® 20 mg tablets were intercepted in the mail before reaching a US consumer, warns FDA. Laboratory analysis of the counterfeit product showed that it contained multiple active ingredients that could lead to adverse effects or harm if used, indicates an FDA Drug Safety Announcement. The agency reminds US consumers to only buy prescription medications from state-licensed pharmacies located in the US. FDA notes that it cannot confirm that the manufacturing, quality, storage, and handling of products ordered from unlicensed websites follow US standards because the products are from an unknown source.

To help consumers identify these counterfeit medications, FDA provides guidelines in the safety announcement. For example, these counterfeits list “AUSR81137” on the front of the bottle and lack a National Drug Code number. Other possible identifiers include misspellings and unusual colors on the label, and a manufacturer listed as “112 Wharf Road, WEST RYDE, NSW 2114” on the side of the bottle.

To date, FDA is not aware of any adverse events associated with these counterfeit medications; however, consumers are encouraged to talk to a health care provider about their condition and options for treatment if a counterfeit product was received.

The National Association of Boards of Pharmacy® (NABP®) has reviewed more than 10,900 websites selling prescription drugs to patients in the US and found that nearly 97% are operating out of compliance with pharmacy laws and practice standards established to protect the public health. To help consumers in the US find the safest sources for purchasing medications online, NABP developed the Verified Internet Pharmacy Practice Sites® (VIPPS®) program. NABP encourages consumers to look for the VIPPS Seal and to check NABP's list of accredited sites on the AWARDX® Prescription Drug Safety Program website. In addition, consumers may soon watch for pharmacy sites using the newly launched .pharmacy Top-Level Domain; sites in the domain (with a website address ending in .pharmacy) will be reviewed by NABP and approved only if they are legitimate online pharmacies or pharmacy resources adhering to applicable pharmacy laws and best practices.

Additional details on the counterfeit Cialis are available in a Drug Safety Announcement posted to the FDA website at www.fda.gov/Drugs/DrugSafety/ucm431071.htm. More



NATIONAL ASSOCIATION OF BOARDS OF PHARMACY® NATIONAL PHARMACY COMPLIANCE NEWS - 2ND QUARTER 2015 CONTINUED....

information on VIPPS and other NABP programs is available in the Programs section of the NABP website, www.nabp.net.

NEW FDA DRUG INFO ROUNDS TRAINING VIDEOS REVIEW DRUG DISPOSAL AND REMS

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. The latest Drug Info Rounds videos are as follows.

- In “Disposal of Unused Medicines,” pharmacists discuss how consumers can safely dispose of expired or unused medications to prevent abuse or misuse and accidental poisoning.
- In “REMS,” pharmacists discuss the many components of Risk Evaluation and Mitigation Strategies (REMS) and how they can help manage a drug product with known or potential serious risks.

Drug Info Rounds is developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

FDA ISSUES NEW DRUG LABELING RULES TO BENEFIT PREGNANT, BREASTFEEDING WOMEN

FDA announced new prescription drug labeling requirements that will clarify how medications might affect women who are pregnant or breastfeeding and men and women of reproductive potential. The final “Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling Rule” removes the previously used pregnancy letter categories – A, B, C, D, and X – and places information into three main categories:

- **Pregnancy:** Labor and delivery guidelines now fall under this category, which also now includes information for pregnancy exposure registries. Such registries track data on the effects of certain approved medications on pregnant and breastfeeding women.
- **Lactation:** Previously labeled “Nursing Mothers,”

this category provides information such as how much drug is secreted through breast milk and the potential effects on a breastfed infant.

- **Females and Males of Reproductive Potential:** This is a new category that includes information on how a certain medication might affect pregnancy testing, contraception, and infertility.

The new labeling changes go into effect on June 30, 2015. Over-the-counter medication labels will not be affected. The new rules are available for download through the Federal Register at <https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-28241.pdf>.

FDA APPROVES ZOHYDRO ER WITH ABUSE-DETERRENT PROPERTIES

In February 2015, FDA approved a new formulation of Zohydro® ER with abuse-deterrent properties. The new formulation uses a technology that allows the drug to maintain its release properties when used as intended, according to a press release from Zogenix. The abuse-deterrent system, known as BeadTek, incorporates “pharmaceutical excipients” that create a viscous gel when the medication is crushed and dissolved in a liquid or solvent, thus making the product more difficult to abuse through methods that involve crushing, breaking, or dissolving the drug. In early 2014, Zohydro ER became the first extended-release, single-ingredient hydrocodone product to receive approval for use in the US. Approval of the drug came under criticism, with some organizations arguing that the potential for addiction, abuse, and misuse could outweigh therapeutic benefits, in part because the drug lacked abuse-deterrent properties. Zogenix indicates that transition to the new abuse-deterrent formulation will take place in second quarter 2015.

Additional information on the new formulation is provided in a press release available on the Zogenix website at <http://ir.zogenix.com/phoenix.zhtml?c=220862&p=irol-newsArticle&cat=news&id=2012326>.