



Alabama State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Fifty-Year Pharmacists

The Alabama State Board of Pharmacy wishes to congratulate the following Alabama pharmacists who have completed 50 years in the practice of pharmacy. Thank you for your service and dedication to the pharmacy profession.

Elmer Barfield	Roberta Compton
Arthur Ennis	James Hoven
Theodore Jennings	Gerald Jones
James Grisham	Jerry Newman
Larry Presley	Garry Ray
Eric Smith	Reginald Teed
Robert Thomas	Larry Reese
Larry Smitherman	Dixie Stephenson
Robert Moulton	James Scott
Ronald Smith	Lowell Barron
Douglas Fowler	Kenneth Glover
Claude Hobbs	Benjamin Lewis
Andrew Thrash	Omer Warhurst
William Young	

Because of an oversight in the February 2015 *Newsletter*, the following pharmacist was omitted from the list congratulating the pharmacists who had completed 50 years in the practice of pharmacy.

.....
 Charles C. Thomas

Thank you for your 51 years of service and dedication to the pharmacy profession. The Board apologizes for the oversight.

Unapproved Prescription Drugs

The prescribing and dispensing of marketed unapproved drugs has continued throughout the years. Manufacturers of these products have not received appropriate approval from Food and Drug Administration (FDA) and/or do not conform to the monograph for over-the-counter (OTC) drugs. Not only is this action illegal, but it also poses a significant risk to the

public health due to the lack of proven safety and efficacy of the products. Many health care providers are unaware of the unapproved status of these drugs and are continuing to prescribe them because the drugs' labels do not disclose the lack of FDA approval.

In order to determine if a drug product has FDA approval, you can search the publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"). The "Orange Book" identifies drug products approved on the basis of safety and effectiveness by FDA. The most common way to search is by proprietary name or active ingredient. Products are listed as either prescription, OTC, or discontinued products. If a product is FDA-approved, the resulting list will provide approved products by dosage form, route, and name of applicant. The "Orange Book" also lists the drug product's therapeutic equivalency to the brand name product. If the product is not FDA-approved, the results will show, "No matching records found."

All drugs approved between 1938 and 1962 have had to be reviewed for effectiveness. However, drugs approved before 1938 were "grandfathered" and allowed to remain on the market without further FDA approval. These drugs are called Drug Efficacy Study Implementation (DESI) drugs and do not appear in the "Orange Book" because they are not found to be therapeutically equivalent to approved products.

Companies or manufacturers wishing to obtain approval of their product can submit a new drug application (NDA) or an abbreviated new drug application (ANDA). The NDA is quite extensive, covering a new product's chemistry, pharmacology, medical, biopharmaceutics, and statistics in order to meet FDA's requirements for marketing. An ANDA contains data for the approval of a generic drug product, such as demonstrating bioequivalence to the innovator drug. An ANDA is not required to provide preclinical and clinical data in order to receive approval. Although a drug may contain a combination of products that are currently approved by FDA, the combination product is considered a new drug and will also need to undergo the FDA approval process. For OTC drug products, FDA reviews the active

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Discontinue Use of Chen Shwezin Sterile Drug Products, FDA Warns

In October 2015, the United States Food and Drug Administration (FDA) issued a statement alerting health care providers and patients not to use drug products intended to be sterile that were made and distributed by Chen Shwezin, Inc, dba Park Compounding Pharmacy of Westlake Village, CA, because of lack of sterility assurance. Following an FDA inspection during which investigators observed unsanitary conditions, including poor sterile production practices, FDA recommended that Park Compounding Pharmacy cease sterile operations and recall all of its non-expired sterile drug products. However, the company had refused to recall its products, according to an FDA safety alert.

At this time, FDA has not received reports of any adverse events associated with the use of products from Park Compounding Pharmacy. FDA recommends that health care providers check their medical supplies, quarantine any sterile drug products from Park Compounding Pharmacy, and not administer them to patients.

More information is available in the FDA safety alert, available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm465582.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 the final article of a three-part series on seven persistent safety gaffes of 2014.

6) Compounded Pain Creams: High Profit Margin and Danger

Some compounding pharmacies have been heavily marketing compounded pain creams directly to consumers via unsolicited calls, suggesting that the creams are more effective and safer than oral or injectable pain medications. Many of the creams contain drugs that can cause central nervous system depression or adverse cardiac effects, and most have not been

FDA-approved for use in combination with each other or for topical use. Patients are charged per ingredient, with many creams containing numerous, expensive medications. Toxicity from the creams has been reported to poison control centers, including cases of accidental child exposures and intentional use for multiple family members. Patients are often unaware of the dangers with using the creams, which include unsafe packaging in containers without child-resistant closures. ISMP is specifically concerned about some statements that may be unproven, such as the products' safe use with children. Compounded pain creams need prominent warnings on labels that describe the potential for toxicity, and physicians and pharmacists who prescribe and dispense the creams must provide patients with instructions about possible adverse effects, safe storage, and proper use. ISMP believes regulatory or licensing oversight is necessary.

7) Clear Care: Still Causing Severe Eye Injuries Five Years Later

Since early 2010, ISMP has received scores of reports of painful eye injuries from patients using CLEAR CARE® Cleaning & Disinfecting Solution for contact lenses by Alcon (formerly CIBA VISION), a Novartis company, and similar store-brand products. Hundreds more can be found on Internet listservs. Located on store shelves near other lens disinfectants and solutions, these disinfecting products differ from other commonly used solutions in that they must be used with a special lens case in order to neutralize the 3% hydrogen peroxide component of the solution over at least six hours before putting the lenses back into the eyes. However, many patients have inadvertently used the solution to soak their lenses in a standard lens case, or thought the solution was saline and instilled it directly into their eyes. This has caused severe eye burning, leading many to seek out emergency medical care for corneal burns. In 2012, Alcon made a label enhancement to warn customers to use the special lens case, but the label change has been ineffective. Neither the company nor FDA's Medical Devices division have been persuaded to make effective label improvements before permanent eye injury or blindness occurs. If the labeling and packaging cannot be improved to reduce the harm being reported, perhaps these products should be pulled from the market or available only behind the pharmacy counter.

Risk of Dose Confusion and Medication Errors With Avycaz, FDA Cautions

Confusion about the drug strength displayed on the vial and carton labels has led to some dosing errors with the intravenous antibacterial drug Avycaz™ (ceftazidime and avibactam), warned FDA in September 2015. The agency explained that Avycaz was initially approved with the vial and carton labels displaying the individual strengths of the two active ingredients (2 g/0.5 g); however, the product is dosed based on the sum of the active ingredients (2.5 g). To prevent medication errors, FDA revised the labels to indicate that each



vial contains Avycaz 2.5 g, equivalent to ceftazidime 2 g and avibactam 0.5 g, according to an FDA safety alert.

As of September 2015, FDA had received reports of three medication error cases related to confusion on how the strength was displayed on the Avycaz vial and carton labels. Two cases stated that the errors occurred during preparation of the dose in the pharmacy. The third case described concern about the potential for confusion because the strength displayed for Avycaz differs from how the strength is displayed for other beta-lactam/beta-lactamase drugs. Based on the information provided in the reports, FDA is aware that at least one of the patients received a higher-than-intended dose of Avycaz. As of September 2015, no adverse events were reported.

More details are included in the FDA safety alert, available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463595.htm.

US Compounding, Inc, Recalls All Lots of Sterile Compounded Products

In September 2015, US Compounding, Inc, of Conway, AR, issued a voluntary recall of all lots of sterile products aseptically compounded and packaged by the company, and that remain within expiry, because of a lack of sterility assurance. The affected sterile products were distributed nationwide to patients, providers, hospitals, and clinics between March 14, 2015, and September 9, 2015. The recall does not apply to any nonsterile compounded medications prepared by US Compounding. Providers are advised to discontinue use of the products, quarantine any unused product, and contact US Compounding to arrange the return of any unused sterile compounded products using the information provided in the FDA press release, available at www.fda.gov/Safety/Recalls/ucm464071.htm.

The company issued this recall out of an abundance of caution. Providers who have dispensed any sterile product distributed by US Compounding should contact patients to whom product was dispensed and notify them of this recall. A list of all sterile compounded products that have been recalled is provided on FDA's website at www.fda.gov/Safety/Recalls/ucm464072.htm.

FDA Investigates the Risks of Using Pain Medicine Tramadol in Young Patients

As of September 2015, FDA is investigating the use of the pain medicine tramadol in young patients because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in patients treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. Tramadol is not FDA-approved for use in patients aged 17 years or younger; however, data show it is being used "off-label" in the pediatric population, according to the safety alert on FDA's website, available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463499.htm.

FDA is evaluating all available information and will communicate final conclusions and recommendations to the public

when the review is complete. Health care providers are encouraged to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Decreased Potency Reported in Drugs Stored in Becton-Dickinson Syringes

In September 2015, FDA expanded its alert regarding compounded or repackaged drugs stored in Becton-Dickinson (BD) general use syringes to include certain additional syringe sizes including 1 mL, 10 mL, 20 mL, and 30 mL BD syringes, and BD oral syringes. FDA's original alert applied to compounded or repackaged drugs that have been stored in 3 mL and 5 mL BD syringes. The agency expanded the alert based on BD reports that an interaction with the rubber stopper in certain lots of these syringes can cause some drugs stored in these syringes to lose potency if filled and not used immediately. BD reports that the following drugs in particular can be affected by the stoppers, but it does not know whether other drugs can be affected: fentanyl, rocuronium, neostigmine, morphine, midazolam, methadone, atropine, hydromorphone, cisatracurium, and remifentanyl. This safety alert does not pertain to BD prefilled, prefillable, heparin flush, saline flush, or insulin syringes, indicates BD in an alert notice. Further, BD's alert notice also has a search tool to assist customers in determining if their lots are affected. FDA advises hospital pharmacies and staff to contact any outsourcers to determine if affected lots of BD syringes were used for compounded or repackaged products. Hospital pharmacies and staff should not administer compounded or repackaged drugs that have been stored in any of these syringes unless there is no suitable alternative available. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program.

More details are included in the FDA Safety Alert, available at www.fda.gov/Drugs/DrugSafety/ucm458952.htm.

MediStat Pharmacy Issues Recall of Sterile Drug Products

MediStat Pharmacy, a 503B outsourcing facility in Foley, AL, has initiated a national recall of all sterile injectable products distributed between November 1, 2014, and September 3, 2015. The recall is based on the identification of various pathogens within the compounding environment. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from MediStat, and not administer them to patients. FDA has received reports of several adverse events that are potentially associated with the drug products made by MediStat. MediStat voluntarily ceased sterile compounding operations in September 2015. FDA asks health care providers and patients to report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting program.

More details are included in an FDA press release, available at www.fda.gov/Safety/Recalls/ucm461939.htm.

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ingredients and labeling for over 80 therapeutic classes of drugs instead of individual drug products. An OTC drug monograph is developed for each category and published in the *Federal Register*. New OTC products that conform to the final monograph for that particular category may be marketed without further FDA review.

In June 2006, FDA launched the Unapproved Drugs Initiative, which seeks to remove these unapproved products from the market using a risk-based enforcement program. The program will concentrate its resources on products that pose the highest threat to public health without imposing undue burdens on consumers or unnecessarily disrupting the market. FDA has developed a Compliance Policy Guide (CPG) for marketed unapproved drugs, which was last revised in September 2011. The CPG provides notice that any illegally marketed product is subject to FDA enforcement at any time. The CPG also outlines the steps manufacturers can make to approve a drug product, the specific enforcement actions that will be taken based on the classification of the product (DESI, OTC, etc), and the charges that can be made by FDA for those illegally marketing the drug products.

For more information regarding unapproved drugs and for the full CPG, visit www.fda.gov/Drugs. All of the information gathered for this article can be referenced on FDA's website at www.fda.gov.

2016-2017 Technician Renewal

As of January 26, 2016, the Board office has 800 technician renewals that have been placed on **administrative hold** pending proof of United States citizenship. These registrations have been renewed, but are **not** current or in good standing. Proof of US citizenship must be received and verified by the Board office before the status can be changed to active.

Please ask your technician to provide you with his or her original 2016-2017 registration.

Board Members for Calendar Year 2016

- ◆ Dr Tim Martin, President
- ◆ Buddy Bunch, Vice President

- ◆ David Darby, Treasurer
- ◆ Donna Yeatman, Member
- ◆ Ralph Sorrell, Member
- ◆ Dr Susan P. Alverson, Executive Secretary

Board Meeting Schedule 2016

- ◆ February 16-17, 2016
- ◆ March 15-16, 2016
- ◆ April 19-20, 2016
- ◆ May 24-25, 2016
- ◆ June 21-22, 2016
- ◆ July 19-20, 2016
- ◆ August 23-24, 2016
- ◆ September 20-21, 2016
- ◆ October 11-12, 2016
- ◆ November 15-16, 2016
- ◆ December 13-14, 2016

Reminder

Please notify the Board, in writing, of any change of address or employment by visiting its website, www.albop.com; click on "Verification/Addr/Employment Change" and enter the appropriate information.

Do You Know a Pharmacist or Technician Who Needs Help?

Call the Alabama State Board of Pharmacy Wellness Program help line at 205/981-2273. All calls are confidential.

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