

February 2008



NEWS

Colorado State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

1560 Broadway, Suite 1300, Denver, CO 80202-5143

Contacting Your Inspector

The contact information for the three Colorado State Board of Pharmacy inspectors has changed. To contact them directly, please note the following:

Billie Marseilles..... Phone: 303/726-3873
E-mail: billie.marseilles@dora.state.co.us

Mark O'Neill..... Phone: 303/594-2562
E-mail: mark.o'neill@dora.state.co.us

Sue Martin..... Phone: 303/548-7264
E-mail: susan.martin@dora.state.co.us

The mailing address and fax number for the inspectors remain the same:

Colorado State Board of Pharmacy
1560 Broadway Suite 1300
Denver, CO 80202
Fax: 303/894-7692

Disciplinary Actions July 1, 2007 through December 31, 2007 and those Previously Unreported

The following disciplinary actions include the registrant/licensee, the license/registration number, effective date, and action.

A.F. Hauser; WHO 7306; Effective August 22, 2007; Stipulation.

Kirk Agthe; 14605; Effective September 21, 2007; Voluntary Relinquishment.

Mary E. Aronson; 12577; Effective October 22, 2007; Letter of Admonition.

Bryan L. Bacon; IN 2003423; Effective July 13, 2007; Stipulation.

Thomas W. Bader; 9321; Effective October 19, 2007; Summary Suspension. Effective December 18, 2007; Voluntary Relinquishment.

Dennis Ray Bledsoe; 10971; Effective July 11, 2007; Stipulation.

Scott E. Brierton; 13440; Effective August 3, 2007; Stipulation.

James M. Brown; 14511; Effective September 18, 2007; Stipulation.

Lynda Jo Budman; 15314; Effective September 26, 2007; Stipulation.

Byram Healthcare Centers; DRU 3415 (lapsed), WHI Applicant (withdrawn); Effective March 22, 2007; Cease and Desist Order.

The Chemins Company, Inc; MFR 1015; Effective June 21, 2007; Stipulation.

College Pharmacy; PDO 24-38; Effective October 19, 2007 through October 23, 2007; Summary Suspension (lifted). Effective December 18, 2007; Stipulation.

Rodney J. Diffendaffer; 14639; Effective July 23, 2007; Suspension.

Tara L. Diffendaffer; 14749; Effective September 6, 2007; Stipulation.

Discount Pet Drugs & Supplies; Not Licensed; Effective November 16, 2007; Cease and Desist Order.

Foothills Family Pharmacy; PDO 567; Effective August 13, 2007; Stipulation.

Kit C. Frisk; 14867; Effective September 18, 2007; Stipulation.

Ami S. Hackman; 14747; Effective July 6, 2007; Voluntary Cessation of Practice.

Dana E. Hessel; 13016; Effective September 26, 2006; Letter of Admonition.

Hogan's Pharmacy; Not Licensed; Effective September 25, 2007; Cease and Desist Order.

Dustin J. Holthus; 17079; Effective July 24, 2007; Letter of Admonition.

Hospira Worldwide; WHI 6048; Effective September 4, 2007; Stipulation.

Donald E. Kriest; 16764; Effective July 24, 2007; Letter of Admonition.

Demar Lewis, III; 13773; Effective August 1, 2007; Summary Suspension.

Loveland Community Health Center Pharmacy; PDO 82-103; Effective December 10, 2007; Stipulation.

Kevin A. Levulis; 13200; Effective December 13, 2007; Summary Suspension.

Dolores Ann Lovin; 9412; Effective October 22, 2007; Letter of Admonition.

Salem R. Montez; 15006; Effective August 27, 2007; Letter of Admonition.

James E. Neering; 10490; Effective July 24, 2007; Letter of Admonition.

NuCare Pharmaceuticals, Inc; WHO 7134; Effective October 9, 2007; Stipulation.

Feliks Obertman; 17891; Effective October 5, 2007; Stipulation.

Pamela Patrick-Curley; 12106; Effective September 26, 2007; Letter of Admonition.

S-A-J Distributors; Not Licensed; Effective November 19, 2007; Cease and Desist Order.

Kory M. L. Scharringhausen; 17593; Effective May 18, 2007; Letter of Admonition.

Madhavi Sloat; 14825; Effective November 13, 2007; Stipulation.

Oliver Stanford; 14507; Effective August 3, 2007 through August 30, 2007; Suspension.

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NABP Testifies in Support of Proposed BTC Drug Class

NABP testified at the Food and Drug Administration (FDA) meeting November 14, 2007, stating its support for the proposed creation of a behind-the-counter (BTC) class of drugs. The meeting was held to solicit input on the public health benefits of certain medications being available BTC without a prescription but only after intervention by a pharmacist.

A long-time advocate of this measure, NABP passed a resolution in 1993 advocating a third class of drugs that would be dispensed without a prescription only by licensed health care professionals authorized to prescribe and/or dispense prescription drugs. Continuing its support of this concept, NABP passed a resolution in 1995 stating that medications being converted from prescription-only to over-the-counter status that pose serious risks and require patient education for effective use should be placed in a special class requiring sale only by licensed health care professionals after counseling the patients on proper use.

More information is available in the *Federal Register* (Docket No. 2007N-0356).

A Rose by Any Other Name . . . Might Be Safer



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 and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Edition by visiting www.ismp.org. 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.

What's in a name? Well, if the name is referring to a pharmaceutical compound getting ready to go to market, a lot goes into that name.

In order for a drug manufacturer to test its drug chemicals in animals, it must submit three possible generic names to the United States Adopted Names (USAN) Council, the organization responsible for assigning generic drug names. USAN Council selects a generic drug name, based on safety, consistency, and logic and then refers this name to the World Health Organization to check for similar generic names being used in other countries.

There is a method to this naming madness. For instance, drug name "stems" group therapeutically-related drugs. An example would be the stem *-vastatin* for drugs that lower cholesterol, and is used in the generic names of atorvastatin (Lipitor®) and lovastatin (Mevacor®). Another example of the use of stems is *-mab* used in anticancer drugs. MAB stands for 'monoclonal antibodies' and is used in the generic drug names alemtuzumab and cetuximab. The stem gives clues about what a drug is used for; however, drug names that share a common stem can contribute to medication errors because they may sound or look alike. This is especially problematic if the products share common dosage forms and other similarities.

Additionally, USAN Council guidelines call for generic names to be simple to pronounce with only one way to say it and have no more than four syllables. Yet, the names mentioned in the preceding paragraph are difficult to pronounce and some have five syllables.

After a drug has completed phase-I clinical trials, the manufacturer submits potential brand names to FDA as well as the US Patent and Trademark Office.

Drug manufacturers often work with drug naming companies to help them develop unique brand names. A report in the January-February 2004 issue of the *Journal of the American Pharmacists Association* stated that there are more than 9,000 generic drug names and 33,000 trademarked brand names in use in the US. Although the drug names may be unique, more and more often they are leading to miscommunications and are resulting in errors.

According to USP-ISMP Medication Errors Reporting Program (MERP) data, 25% of the errors reported relate to the products generic or brand name. To help combat this problem, in 1990 FDA established the Labeling and Nomenclature Committee (LNC) to review proposed trade names. The LCN, which has evolved into the Division of Medication Errors and Technical Support of the Office of Surveillance and Epidemiology, formerly the Office of Drug Safety, has been actively reviewing drug names.

Although prescribers and consumers would like drug names to give an indication of the intent of the drug in the name itself, FDA prohibits trade names associated with the product's intended use and will not approve names that imply efficacy. Yet there are many exceptions to this "intended" rule. A drug such as Celebrex® (pain treatment) connotes "celebration" and Halcion® (sleep aid) conjures up images of restfulness (halcyon). Perhaps naming drugs for their intended purpose would decrease the number of medication errors associated with confusing and sound-alike/look-alike drugs. Until prescribers conform to writing the indication or purpose on the actual prescription, the drug name itself may give a clue to the patient as to what is being prescribed. The patient may read the prescription before handing it to the pharmacist and question why he or she is being prescribed "Oncocure" when he or she does not have cancer.

Studies estimate that anywhere from 7,000 to 20,000 people die or are injured each year in the United States because of drug name confusion. What can pharmacists do? Go to the Med-E.R.R.S.® Web site www.med-errs.com and register to become a drug name reviewer. Although not required, many drug companies seek the consultant advice of Med-E.R.R.S. to test their potential generic and brand names before submitting these names to FDA. Med-E.R.R.S., Inc, a wholly owned subsidiary of ISMP, assists pharmaceutical and health care technology companies in evaluating the safety of their products and services. Med-E.R.R.S., Inc has tested more than 600 names for over 35 pharmaceutical companies in 2006. Med-E.R.R.S. integrates knowledge and experience with the input of clinicians in the field to systematically analyze potential trademarks, packaging, and technology.

Med-E.R.R.S. pharmacist reviewers participate in online surveys to review names of potential drugs handwritten by a number of "prescribers" to determine if any of the tested names look like medical terms or other current drugs on the market. They are also asked to review the potential drug names to compare if the potential name sounds like another drug or like another medical term.

To further national efforts to manage drug name confusion, ISMP hosted an invitational summit on October 9-10, 2007, in Philadelphia. This meeting brought together a full range of pharmacy professionals



and representatives from standard-setting organizations, regulatory agencies, the pharmaceutical industry, and the payer community. During the meeting, the attendees discussed post-marketing strategies to identify and reduce name confusion and ways to improve upon their scope and effectiveness. ISMP believes that the health care industry can significantly reduce the risk to patients from otherwise preventable product mix-ups due to look-alike and sound-alike names. A report from the summit will be available online soon.

So a rose by any other name may smell as sweet, but Reminyl® renamed Razadyne™, (see *ISMP Medication Safety Alert!® Community/Ambulatory Edition*, Volume 4, issue 5, May 2005, **Reminyl®/Amaryl® Your Reports at Work.**) may “smell” safer, and therefore “sweeter.” Sweeter, that is until recently when MERP started receiving errors involving confusion between Razadyne and Rozerem™. Stay tuned.

FDA Study Suggests Consumers are Seeking Meds Online to Avoid Rx Rules

FDA recently announced the results of a year-long investigation, which suggest that consumers are buying drugs online to avoid the need for prescriptions from their physicians.

The investigation, comprising surveys conducted from September 2006 to August 2007 in international mail and courier facilities across the country, found 88% of the 2,069 drug packages examined appeared to be prescription medicines available in the US. More than half (53%) of the products sampled have FDA-approved generic versions, likely sold at lower costs, according to earlier studies that have shown generics in the US to be generally less expensive than comparable drugs in Canada or Western Europe. Other products included dietary supplements, foreign products with “illegible or incomprehensible” labeling, and medications not available in the US.

FDA warns that products from unregulated Internet drug sellers may contain the wrong ingredients or toxic substances. Earlier this year, FDA learned that 24 apparently related Web sites operating outside the US may be involved in the distribution of counterfeit prescription drugs.

FDA Posts Drug Safety Newsletter, Labeling Changes

FDA released the first issue of its new *Drug Safety Newsletter* in late 2007. The quarterly online newsletter provides information for health care professionals about the findings of selected post-marketing drug safety reviews, emerging drug safety issues, and recently approved new drugs.

The newsletter is available on the FDA Web site at www.fda.gov/cder/dsn/default.htm and will be sent electronically to *Drug Safety Newsletter* and/or MedWatch subscribers.

FDA also provides monthly updates on medication labeling changes, such as boxed warnings, contraindications, warnings, precautions, adverse reactions, and patient package insert/medication guide sections. The Safety-Related Drug Labeling Changes page is accessible at www.fda.gov/medwatch/safety.htm.

NABP Awards DMEPOS Accreditations Representing Over 11,000 Pharmacies

NABP accredited several independent pharmacies and chains, representing over 11,000 pharmacies, through its durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation program during fourth quarter 2007.

The DMEPOS program ensures that pharmacies supplying DMEPOS products meet the Centers for Medicare and Medicaid Services’ (CMS) quality and accreditation standards. Those pharmacies that are accredited through the program are doing their part to ensure that Medicare beneficiaries receive the appropriate products, services, and patient care associated with DMEPOS.

A full listing of pharmacies accredited through the NABP DMEPOS program is available under Accreditation Programs on the NABP Web site, www.nabp.net.

FDA Acts to Ensure Thyroid Drug Potency until Expiration

FDA is tightening the potency specifications for levothyroxine sodium to ensure the medication retains its potency over its entire shelf life. FDA is taking this action in response to concerns that the potency of the drug may deteriorate prior to its expiration date.

The revised potency specifications require levothyroxine sodium drug products to maintain 95% to 105% potency until their expiration date. Previously, these products were allowed a potency range of 90% to 110%. FDA has given manufacturers and marketers two years to comply with the revised specification.

More information is available on the FDA Web site at www.fda.gov/cder/drug/infopage/levothyroxine/default.htm.

FDA Reform Law Provides for Establishment of Tracking Standards

President Bush signed HR 3580, the Food and Drug Administration Amendments Act of 2007, into law on September 27, 2007. Among other provisions, the law reauthorizes and expands the Prescription Drug User Fee Act and the Medical Device User Fee and Modernization Act.

The legislation expands FDA authority to regulate marketed drugs, establish a surveillance system to monitor and assess the safety profile of drugs on the market, reauthorize and modify programs that evaluate the use of drugs and devices by children, and expand federal databases that track information on certain clinical trials.

The law also requires the US Department of Health and Human Services to establish a standardized numerical identifier that must be applied to prescription medications at the point of manufacture, and to develop standards to serve as guidelines in the implementation of track-and-trace and package-level identification technology to monitor prescription medications through the supply chain.

2008 Survey of Pharmacy Law Now Available

The NABP 2008 *Survey of Pharmacy Law* CD-ROM is now available. The *Survey* consists of four sections including organizational law, licensing law, drug law, and census data. New topics include whether or not states recognize Verified Internet Pharmacy Practice Sites™ accreditation and if the boards of pharmacy require compliance with United States Pharmacopeia Chapter 797, “Pharmaceutical Compounding – Sterile Preparations.”

To order the *Survey*, visit www.nabp.net and download an order form; the cost is \$20.

The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from Purdue Pharma LP. For more information on the *Survey*, please contact NABP via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

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- Walgreen Pharmacy #2857**; PDO 7-45; Effective June 26, 2007; Stipulation.
- Walgreen Pharmacy #4610**; PDO 7-55; Effective September 5, 2007; Stipulation.
- Westcare, Inc**; PDO 37-30; Effective December 7, 2007; Stipulation.
- Fu-Hing Nick Yu**; 10885; Effective September 26, 2007; Letter of Admonition.
- Ted J. Zbacnik**; 15900; Effective August 2, 2007; Stipulation.

More information regarding the above disciplinary actions may be obtained from the following Web site: www.dora.state.co.us/doraimages/.

Electronic Newsletters

Beginning in August 2008, the Board's *Newsletter* will only be available electronically. *Newsletters* will no longer be mailed. You will be able to access the *Newsletter* from the Board's Web site, www.dora.state.co.us/pharmacy. If you wish to be notified when a *Newsletter* is available, please sign up for e-mail notification on the Board's Web site, www.dora.state.co.us/pharmacy. Click on E-Mail Notification Service under News and Hot Topics. *Newsletters* are published in February and August each year.

Emerging Contaminants – Linking Science to Effective Action

The Institute for Environmental Solutions (IES) is tackling the complex challenge of tracing pharmaceutical-related contaminants in wastewater. The goal of the IES Emerging Contaminants project (Linking Science to Effective Action) is to determine the environmental and human health impacts of trace contaminants, and what can and should be done to prevent or mitigate them. By addressing environmental issues with a scientific approach, we can prevent unwanted side effects, and provide opportunities to optimize environmental improvements. Absent this approach, millions of dollars could be wasted implementing potentially ineffective or counterproductive pollution control strategies.

Designing effective mitigation strategies requires an understanding of the sources of pharmaceutical, personal care, and related pollutants – which we do not have. Many entities have tried programs to take back unused prescription drugs. As yet, no data exist to justify these costly programs or to indicate a measurable environmental or human health benefit. The IES Emerging Contaminants project involves pilot research, testing, and evaluation programs, guided by a broad-based stakeholder advisory group, to determine and examine

the effectiveness of a range of contaminant mitigation strategies, such as pharmaceutical take-back programs.

In the meantime, concerned health professionals and citizens ask for recommendations regarding the best way to dispose of unused drugs. The historical practice of flushing drugs down the toilet is clearly a bad idea, as it injects contamination directly into the water system. Alternatives such as sequestering drugs in coffee grounds, kitty litter, or glue have not been tested to determine their effectiveness. The best current science-based recommendation for consumers and health professionals is to dispose of unwanted drugs in such a way as to minimize the possibility of reuse and to minimize contact with wastewater.

IES welcomes the participation of interested stakeholders in the Emerging Contaminants project. Please contact Carol Lyons, executive director, Carol@i4es.org or visit our Web site, www.i4es.org.

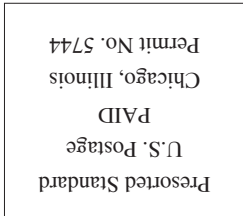
IES is a Denver-based nonprofit organization dedicated to delivering proactive, technically sound solutions to complex environmental and natural resource problems – without unwanted side effects.

Board Policies

Over the years, the Board has instituted various disciplinary, licensing, administrative, and miscellaneous policies pertaining to the practice of pharmacy. You are encouraged to periodically review those policies as they are a valuable tool in answering many of your questions that may not specifically be addressed in Board statutes or regulations. These policies can be both viewed and printed from the Board's official Web site, www.dora.state.co.us/pharmacy, under the selection, Statutes, Rules and Policies.

The *Colorado State Board of Pharmacy News* is published by the Colorado State 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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NATIONAL ASSOCIATION OF BOARDS OF PHARMACY FOUNDATION, INC.
 1600 FEELHANTHILL DRIVE
 MOUNT PROSPECT, IL 60056
 COLORADO STATE BOARD OF PHARMACY