



Alabama State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

“Take-Back” Prescription Disposal Programs – DEA Response

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The Controlled Substance Act and its implementing regulations establish a closed system of distribution for controlled substances, which requires those individuals or firms desiring to handle controlled substances to be registered with Drug Enforcement Administration (DEA). This closed system facilitates an accurate accounting of all controlled substances from their manufacture through and including their disposition. This closed system reduces the potential for diversion of controlled substances from these registrants because of the audit trail and the ability of this system to detect excessive, suspicious, and unusual orders or shipments. The ultimate user is a nonregistrant, and there is no provision in the Controlled Substance Act to allow a DEA registered pharmacy to acquire controlled substances from a nonregistrant.

§34-23-51. Application for License; Qualifications of Applicants; Examination of Applicants; License by Reciprocity

No applicant shall be granted reciprocal licensure unless all evidence and supporting documents of licensure in the state from which the applicant is reciprocating are approved as meeting the requirements for reciprocity of the National Association of Boards of Pharmacy.

680-X-2-.17. Reciprocity

- (1) The Board may issue a license without examination to an applicant who furnishes satisfactory proof that he/she has been licensed to practice pharmacy by examination in another state, that **under like conditions** grants reciprocal licensure without examination to pharmacists duly licensed by examination in this state.

Statutory Authority: §34-23-92 Code of Alabama 1975

Alabama Reciprocates with Florida

Alabama and Florida licensed pharmacists are now able to reciprocate licensure if their original licensure was issued by a national examination. Due to previous regulatory restrictions in Florida, an Alabama pharmacist was unable to reciprocate to Florida or a Florida pharmacist to Alabama.

680-X-2-.16. Practical Training Programs Standards

- (2) The minimum externship/internship required for licensure shall be fifteen hundred (1500) hours. This may be obtained through a college-structured program or through a non-structured program, all under the supervision of a registered preceptor. Four hundred (400) hours of the minimum total requirement must be obtained after completing the requirements of the

third professional year. The four hundred (400) hours must be completed in a **traditional pharmacy setting**, so that the emphasis is on the distribution of medicines, prescriptions, and medical supplies. An extern/intern must be employed a minimum of fifteen (15) hours a week and no more than forty (40) hours of externship/internship may be allowed for credit in any one calendar week.

- (3) An applicant for licensure, lacking the minimum 1500 hours in the manner stated, may be admitted to the examination only if all requirements are met other than the requirement of practical pharmacy training. Those applicants, so admitted, who pass the examination administered by the Board shall be required to file affidavits attesting to the prescribed practical training program prior to being issued a license to practice pharmacy.
- (4) Practical training externship/internship report, along with a preceptor affidavit, must be submitted for the records within ten (10) days after termination of a training period or at the end of each sixteen-week period, which ever occurs first.
- (5) Externship/Internship registration shall be limited to those persons who are actively engaged in meeting the academic or practical experience requirements for licensure examination. In order to be considered enrolled in a school of pharmacy, a person shall not be absent from school for more than two (2) consecutive semesters or three (3) consecutive quarters. Any person, working as an extern/intern, must obtain a permit from the Board before assuming duties in a pharmacy. In order to be favorably considered for an extern/intern permit, a person must have completed two (2) academic years in pre-pharmacy and be attending classes in the first professional year of an approved school of pharmacy.
- (6) Externship/Internship may be acquired only under the supervision of a preceptor who may supervise no more than three (3) externs/interns at any one time.
- (7) The term supervision shall mean that at the site where externship/internship is being obtained, the preceptor shall be in personal contact with and actually giving professional instructions to the extern/intern during the entire period of such externship/internship. At all times, a person, who is serving an externship/internship, must be under the immediate direct supervision of a registered pharmacist on the premises.
- (8) All candidates for licensure, who are working either as externs or interns, shall report their place of employment and/or practice site to the Board of Pharmacy within ten (10) days of such employment. Any change in such employment or practice site shall be reported to the Board within ten (10) days of the change.

Statutory Authority: §34-23-92, Code of Alabama 1975

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Study Fuels Concerns over Foreign Drugs Bought Online

According to study results published in the May 2008 issue of *Annals of Pharmacotherapy*, many prescription medications purchased from foreign pharmacies through Internet drug outlets differ significantly from the versions approved by the Food and Drug Administration (FDA). "These findings have implications for safety and effectiveness that should be considered by clinicians to potentially safeguard patients who choose to purchase foreign-manufactured drugs via the Internet," the study authors say.

The study evaluated 20 simvastatin tablets and capsules, including the US innovator product and 19 generic samples obtained from international Internet drug outlets. Tablet samples were tested according to United States Pharmacopeia (USP) guidelines where applicable, using high-performance liquid chromatography, disintegration, dissolution, weight variation, hardness, and assessment of physical characteristics.

Several international samples analyzed were not comparable to the US product in one or more aspects of quality assurance testing, and significant variability was found among foreign-made tablets themselves. Five samples failed to meet USP standards for dissolution, and two for content uniformity. Among all samples, variability was observed in hardness, weight, and physical characterization.

Testing Medication Names Prior to Marketing



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with 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 Medi-*

cation Errors Reporting Program. ISMP address: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Medication names that look-alike and sound-alike, confusing or absent drug labeling, and non-distinct or ambiguous drug packaging significantly contributes to medication errors. This is not a new problem. These conditions have led to serious drug mix-ups and deaths. Research has identified that one of the most frequent causes of pharmacy drug dispensing errors (29%) is failure to accurately identify drugs, most prominently due to look-and sound-alike drug names (Leape et al. JAMA, July 5, 1995).

In addition, many medications are packaged in bottles with similar shapes and similar labels, making it easy to confuse one drug with another.

MedMARX data reports there are 1,470 different drugs implicated in medication errors due to brand and/or generic names that looked or sounded alike. From this data, USP has compiled a list of 3,170 pairs of names that look and/or sound alike.

FDA is also concerned about drug naming confusion and its subsequent potential error effects. On June 5-6, 2008, FDA hosted a public workshop to discuss a concept paper (www.fda.gov/cder/drug/MedErrors/meeting_names.pdf) about a pilot program to address look- and sound-alike brand names. The pilot, called for in the FDA Amendments Act of 2007, would allow drug companies (or outside contractors) to voluntarily evaluate proposed brand names and submit the data for review to FDA. Currently, FDA's Division of Medication Error Prevention screens drug names using its own safety testing methods, in consultation with other divisions responsible for product approval.

The concept paper outlines the types of studies that should be conducted, including simulations of real-world conditions with practicing clinicians who evaluate handwritten, electronic, and oral prescribing scenarios to detect name similarities and other potential confusion with laboratory and medical terms or abbreviations. Dosage form, strength, and frequency also should be considered, as well as the clinical environment where it will be used. Based on discussions during the June meeting and submitted comments, FDA will revise the concept paper and present testing methods to the pharmaceutical industry.

It is hoped that testing drug names prior to marketing will decrease the number of look-and sound-alike medication names. ISMP receives numerous reports of



errors and potential errors caused by look-and-sound-alike medications every year. ISMP, through its wholly owned for-profit subsidiary Med-E.R.R.S., Inc[®], has been reviewing drug names and packaging for pharmaceutical manufacturers for more than 10 years.

If you are a pharmacist or other health care practitioner who is interested in medication safety and error prevention, you can make a difference! Med-E.R.R.S. is looking for pharmacists from all practice settings to help test labeling, packaging, and nomenclature in the pre-marketing phase for pharmaceutical companies. The process is fun, simple, and easy and a small honorarium is paid for your participation.

For more information or to sign up, go to www.med-errs.com and click on "Become a Reviewer."

Coalition Looks to Pharmacies, Regulators to Reduce Diversion

A recent report by the Coalition Against Insurance Fraud looks to pharmacies and pharmacy regulators, among others, to cut down on the prevalence of prescription drug diversion, particularly of controlled substance analgesics.

The report, "Prescription for Peril: How Insurance Fraud Finances Theft and Abuse of Addictive Prescription Drugs," calls on the pharmacy profession to provide additional training on prescription drug abuse and diversion in pharmacy education curricula and continuing professional education, and to exert closer point-of-sale scrutiny of certain prescriptions and patients. For instance, the report suggests diversion could be reduced significantly if pharmacies asked for photo identification in connection with controlled substance prescriptions, similar to regulations in place for pseudoephedrine-containing products.

The coalition also recommends wider adoption of prescription monitoring programs to maintain state-wide records of narcotic prescriptions, allowing closer monitoring by prescribers and dispensers. In addition, the coalition calls on lawmakers and licensing boards to "swiftly and decisively penalize the small fraction of prescribers and dispensers who facilitate drug diversion and abuse."

FDA Encourages Pharmacists to Use Patient Safety News

FDA Patient Safety News is a monthly video news program produced by FDA targeted to pharmacists and other health care professionals. The program provides the

latest information on recalled and counterfeit products, important safety alerts, preventing medical errors and mitigating risks from the use of medical products, including drugs, devices, vaccines, and diagnostic products.

The videos can be watched online or downloaded free of charge. Pharmacists can view the entire program or individual segments, and FDA encourages further use and distribution of the video or text of the program, as there are no copyright restrictions. The video and demonstrations can also be used in staff-development programs or in other teaching environments.

Pharmacists can search for video segments on topics of interest, get additional information about topics, e-mail segments to others, report problems with medical products to FDA, and sign up to be notified about each month's program. The show is also broadcast on several medical satellite networks: VHA, GE TiP-TV, HSTN, LTCN, and HNN. These networks presently reach over 4,000 hospitals and long-term care facilities across the US.

More information about the program and how to join the program mailing list is available on the FDA Web site at www.fda.gov/psn or by sending an e-mail to PSNews@cdrh.fda.gov.

Switch to HFA-Propelled Albuterol Inhalers Advised in Anticipation of CFC Ban

FDA recently issued a public health advisory alerting patients, caregivers, and health care professionals to switch to hydrofluoroalkane (HFA)-propelled albuterol inhalers because chlorofluorocarbon (CFC)-propelled inhalers will not be available in the United States after 2008. CFC-propelled albuterol inhalers are being phased out to comply with the Clean Air Act and an international environmental treaty, the Montreal Protocol on Substances that Deplete the Ozone Layer. Under this treaty, the US has agreed to phase out production and importation of ozone-depleting substances including CFCs. No CFC-propelled albuterol inhalers may be produced, marketed, or sold in the US after December 31. Three HFA-propelled albuterol inhalers have been approved by FDA: Proair[®] HFA Inhalation Aerosol, Proventil[®] HFA Inhalation Aerosol, and Ventolin[®] HFA Inhalation Aerosol. In addition, an HFA-propelled inhaler containing levalbuterol is available as Xopenex[®] HFA Inhalation Aerosol. More information is available on the FDA Web site at www.fda.gov/cder/mdi/albuterol.htm.

United States Pharmacopeia General Chapter 797

New standards for United States Pharmacopeia (USP) Chapter 797, "Pharmaceutical Compounding – Sterile Preparations" are in effect June 1, 2008, and include revisions of standards and conditions for improving patient safety. Refer to the USP Web site www.usp.org for a Chapter 797 guidebook.

Renewal Deadline for 2009-2010 is December 31, 2008

Online renewals for pharmacists, pharmacies, nonresident pharmacies, institutional pharmacies, manufacturers/wholesalers/distributors, and retail medical oxygen suppliers are available on the Board Web Site at www.albop.com at the same cost as a mail-in renewal. Failing to renew and to engage in any activity requiring a license and/or a controlled substance registration after the renewal date is subject to late fees and discipline.

680-X-3-.08 Annual Inventory of Controlled

Substances

- (1) Every pharmacy shall take an **initial inventory** of all controlled substances on hand and shall take a **new inventory** of all stocks of controlled substances on hand on **January 15th** or the alternative fixed date approved by the Board of each year, following the date the initial inventory was taken.
- (4) The inventory by a pharmacy must be taken either as of the **opening of business or as of the closing of business**. The pharmacy shall indicate on the inventory records whether the inventory was taken as of the opening of business or as of the close of business, the date the inventory was taken, followed by the person responsible for taking the inventory.
- (5) In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the pharmacy shall do as follows:
 - (a) If the substance is listed in Schedule II, an exact count or measure of the contents shall be made.
 - (b) If the substance is listed in Schedule II, IV or V, an estimated count or measure may be made of the contents unless the container hold more than 1000 tablets or capsules in which case an exact count of the contents must be made.

During a routine inspection, an inspector will ask to review inventory records. Keep the records accessible!

Amended Rule 680-X-2-.37 Continuing Education for Pharmacy Technicians

The Board amended this rule due to a typographical error. Paragraph (5) should have been §34-23-132 instead of §34-23-32.

FDA Amendments Act of 2007

For further information, refer to the Federal Register Vol. 73, No. 2 published January 3, 2008

Manufacturers of drug products, authorized dispensers, and pharmacies, will be required to provide a side effect statement with each prescription drug product, which **must read**:

"Call your doctor for medical advice about side effects. You may report side effects to Food and Drug Administration (FDA) at 1-800-FDA-1088."

- a. The side effects statement must be distributed with **new and refill** prescriptions.
- b. An authorized dispenser or pharmacy must choose one or more of the following options to distribute the side effects statement:
 - 1. distribute the side effects statement on a sticker attached to the unit package, vial, or container of the drug product;
 - 2. distribute the side effects statement on a preprinted pharmacy vial cap;
 - 3. distribute the side effects statement on a separate sheet of paper;
 - 4. distribute the side effects statement in a consumer medication information; or
 - 5. distribute the appropriate FDA-approved Medication Guide that contains the side effects statement.

Effective Date: January 1, 2008

Compliance Date: January 1, 2009

Special Notice about the Newsletter

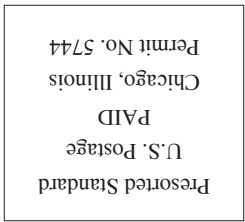
The *Alabama State Board of Pharmacy Newsletter* is an official method of notification to licensed pharmacists and pharmacy technicians registered by the Board. Board *Newsletters* serve in administrative hearings as proof of notification. Please read them carefully. We encourage you to keep them in the back of the *Alabama Pharmacy Law Book* for future reference.

Do You Know a Pharmacist or Technician Who Needs Help?

Call the Committee on Rehabilitating Impaired Pharmacists help line at the voice mail of Steve Moore at 205/975-8548. All calls are confidential.

The *Alabama State Board of Pharmacy News* is published by the Alabama 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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