

August 2004



Alabama State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Changes to Code of Alabama 1975, Title 34 Chapter 23, Practice of Pharmacy Act 205, Enacted by the Legislature of Alabama

§34-23-30. Every pharmacy, hospital pharmacy, drug-store, pharmacy department, prescription department, prescription laboratory, dispensary, apothecary or any other establishment with a title implying the sale, offering for sale, compounding, or dispensing of drugs in this state shall register biennially and receive a permit from the [Alabama State] Board of Pharmacy. Any person desiring to open, operate, maintain, or establish a pharmacy in this state shall apply to the [B]oard for a permit at least 30 days prior to the opening of the business. No pharmacy shall open for the transaction of business until it has been registered, inspected, and a permit issued by the [B]oard. The application for a permit shall be made on a form prescribed and furnished by the [B]oard which when properly executed shall indicate the ownership desiring such permit and the names and license numbers of all licensed pharmacists employed as well as the location of the pharmacy and other information as the [B]oard may require. If more than one pharmacy is operated by the same owner, a separate application for registration shall be made and a separate permit issued for each such establishment. All permits issued under this section shall become due on October 31 and shall become null and void on December 31 of even-numbered years. Every application for a permit for a new pharmacy shall be accompanied by a fee to be determined by the [B]oard, but said fee shall not be less than one hundred dollars (\$100) nor more than two hundred dollars (\$200). Every application for a renewal permit shall be accompanied by a fee to be determined by the [B]oard, but the fee shall not be less than fifty dollars (\$50) nor more than one

hundred fifty dollars (\$150). Every application for a permit due to transfer of ownership shall be accompanied by a fee to be determined by the [B]oard, but the fee shall not be less than fifty dollars (\$50) nor more than one hundred fifty dollars (\$150). Each application for the renewal of a permit shall be made on or before October 31 of each even-numbered year, at which time the previous permit shall become null and void on December 31 of even-numbered years. A penalty of twenty-five dollars (\$25) for each overdue month shall be assessed in addition to the permit fee for renewal of delinquent permits. The secretary of the [B]oard shall issue a permit for each pharmacy whose application is found to be satisfactory by the [B]oard. Permits issued under this section shall not be transferable. Any change in the control of ownership or licensed pharmacists shall be reported to the [B]oard in writing within 10 days of such occurrence. If the pharmacy is owned by a corporation, the permit shall be issued in the name of the corporation. It shall be the duty of the owners of pharmacies who are not licensed pharmacists to immediately notify the [B]oard upon the termination of employment of licensed pharmacists and to cause the surrender of permits as indicated. The further operation of the pharmacy in the absence of licensed pharmacists is forbidden; provided, that the nonregistered owner shall have a period of 30 days within which to comply with this provision. The next of kin of any deceased licensed pharmacist owner shall have a period of 30 days within which to comply with the provisions of this chapter, during which time no prescriptions shall be filled unless a licensed pharmacist is on duty. No mail order pharmacy shall transact business in this state without a permit from the [B]oard.

Any person who violates this section shall be guilty of a misdemeanor.

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FDA Issues Final Rule Prohibiting the Sale of Ephedra Supplements

On February 6, 2004, Food and Drug Administration (FDA) announced the issuance of a final rule prohibiting the sale of dietary supplements containing ephedrine alkaloids (ephedra).

At the end of last year, FDA issued letters to manufacturers who market ephedra-containing supplements, informing them of the upcoming rule. FDA also urged consumers to stop using ephedra-containing dietary supplements immediately. Studies show that ephedra-containing dietary supplement have adverse effects on the cardiovascular and central nervous systems including high blood pressure, heart palpitations, tachycardia, stroke, and seizures. FDA has linked at least 155 deaths with the use of dietary supplements containing ephedra.

For more information, including a Web link to the final rule, visit the following Web site: www.fda.gov/bbs/topics/NEWS/2004/NEW01021.html.

The final rule became enforceable on April 12, 2004. California, Illinois, and New York were the first states to ban the sale of ephedra.

DEA Issues Clarification of the Exemption of Sales of Pseudoephedrine and Phenylpropanolamine

In attempts to clarify existing laws and regulations regarding the over-the-counter (OTC) sale of pseudoephedrine and phenylpropanolamine, Drug Enforcement Administration (DEA) issued an interpretive rule this past January. This interpretive rule does not change any of DEA's regulations, nor will it have an impact on individual retail customers of such products who have been purchasing them from retailers that have been properly following DEA's regulations.

Specifically, the interpretive rule emphasizes that sales transactions of ordinary OTC pseudoephedrine and phenylpropanolamine products ("safe harbor" products) are exempt from being regulated transactions as long as each transaction is below the 9-gram threshold to an individual for legitimate medical use. Apparently, some retail distributors have misinterpreted current DEA regulations and believe that they may sell as much "safe harbor" pseudoephedrine and phenylpropanolamine to any person for any purpose as often as that person wishes to make a purchase. The DEA interpretive rule clearly dispels that belief.

Currently, retail distributors of ordinary OTC pseudoephedrine and phenylpropanolamine products are exempt from registering with DEA as a distributor of List I chemicals and complying with the record keeping and other regulatory requirements as long as individual transactions for legitimate personal medical use remain below the 9-gram threshold (in packages of not more than 3 grams).

To obtain more information, please visit DEA's Diversion Control Program Web site, www.DEAdiversion.usdoj.gov.

Note: Although most products containing phenylpropanolamine were discontinued pursuant to the action of FDA in November 2000, there remains some legitimate veterinary uses for phenylpropanolamine that will ensure some level of its continued production and availability. Therefore, these products are subject to the existing DEA regulations and this interpretive rule.

DEA Introduces Pharmacy Theft Prevention Program

In response to increasing theft and armed robberies against pharmacies, DEA's Office of Diversion Control has introduced the Pharmacy Theft Prevention Program. The program is based on a previous initiative that was developed during the late 1970s and early 1980s when there was a similar unprecedented spike in the occurrence of thefts and robberies against pharmacies.

The intent of the program is to provide education and increased communication to pharmacists and pharmacy staff to prevent pharmacy theft. The program includes collaboration with and participation from law enforcement, regulators including state pharmacy boards, state and federal prosecutors, the media, and the public along with the pharmacy community. The Pharmacy Theft Prevention Program will also provide a means to maximize the use of limited resources available to law enforcement to address, minimize, and eliminate pharmacy thefts in areas that experience such problems.

Staff members of the DEA's Office of Diversion Control have begun a series of regional meetings to promote the program to DEA Diversion field elements, state pharmacy boards, and local pharmacy associations. To implement the program in your community, or to obtain more information regarding the program and its operation, call DEA Headquarters, Office of Diversion Control, Liaison and Policy Section, at 202/307-7297.

Concentrated Morphine Solutions and Serious Medication Errors

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. 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.



According to a recent newspaper report, a 91-year-old man being treated for a mild heart attack was mistakenly given a 100-mg dose of ROXANOL™ (concentrated morphine solution) instead of 5 mg as prescribed. The error may have contributed to the patient's death the following day. Last fall, Elan Pharmaceuticals (the manufacturer of Roxanol at the time; aaiPharma recently acquired the product from Elan) issued a safety alert warning about deaths from accidental overdoses (www.fda.gov/medwatch/SAFETY/2003/roxanol.htm). Most overdoses involved morphine solutions that were mistakenly ordered, dispensed, and labeled by volume (mL), not milligrams. For example, in some cases, patients received 5 mL of



Roxanol 20 mg/mL (100 mg) instead of the prescribed 5 mg. The newspaper report did not describe how this most recent error happened; however, it mentioned that Roxanol 100 mg had been given instead of 5 mg, pointing once again to the scenario described in the recent safety alert from Elan.

Several manufacturers distribute morphine solution in different formulations, primarily labeled (and listed in drug references) in mg/mL (eg, 20 mg/mL) or mg/5 mL (eg, 100 mg/5 mL, 20 mg/5 mL). When concentrated morphine is stored in pharmacies or in patient care areas in hospitals or long-term care facilities, it is often kept next to conventional concentrations. Thus, it is easy to confuse these products and dosage strengths. Also, some physicians have prescribed the medication in terms of mL instead of mg, which has led to errors because multiple concentrations exist. Because we continue to hear about these tragic overdoses, we make these recommendations to reduce the risk of errors with concentrated morphine products:

- ◆ If you consult with nursing homes or hospitals, avoid stocking concentrated morphine solutions in patient units when possible, including the emergency department. Keep in mind that the drug is used primarily to treat chronic pain.
- ◆ Dispense concentrated solutions only when ordered for specific patients who require higher-than-usual doses due to severe chronic pain.
- ◆ Affix an auxiliary label to the morphine concentrate bottle to warn about its high concentration and segregate the solution from the other concentrations.
- ◆ Working with local physicians, purchase and dispense concentrated solutions in dropper bottles (available from at least two manufacturers) to help prevent dose measurement errors and differentiate the concentrated product from the conventional products. For patients in hospitals or long-term care, dispense concentrated solutions in unit doses whenever possible.
- ◆ Educate others to never prescribe or dispense liquid medications without the dose specified in milligrams.
- ◆ Educate staff about the risk of morphine errors and develop guidelines to promote its safe use.
- ◆ Manufacturers should standardize the way strength is expressed on labels, preferably in terms of mg/mL for all forms. This would improve clarity when comparing product labels (eg, it is easier to differentiate 4 mg/mL and 20 mg/mL; harder to differentiate 20 mg/mL and 20 mg/5 mL).

Finally, we disagree with Elan's suggestion in its recent safety alert for prescribers to include the desired concentration of morphine along with the patient's dose in milligrams and the corresponding volume (eg, Roxanol 10 mg/5 mL, give 10 mg [5 mL] prn pain). Listing the desired concentration could actually lead to confusion and errors. If the prescribed concentration is not available and a different concentration is substituted, the prescriber's directions regarding the volume to administer would no longer apply. Yet, if these directions remain on a medication administration record, or a prescription bottle, the wrong dose could be administered.

NABP Releases Updated Model Rules for the Licensure of Wholesale Distributors

On February 20, 2004, the National Association of Boards of Pharmacy® (NABP®) released the updated Model Rules for the Licensure of Wholesale Distributors. The updated Model Rules, part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, were provided to assist state boards of pharmacy in maintaining the integrity of the US medication distribution system through the regulation of wholesale distributors. The updated Model Rules are the result of a concerted effort between NABP and other representatives from pharmacy, government, and the wholesale distributor industry to protect the public from the ill effects of counterfeit drugs and devices.

In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific drug pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products." Also, the updated Model Rules introduce the position of "Designated Representative." The "Designated Representative" of a wholesale distributor is the person who is actively involved in and aware of the actual daily operation of the Wholesale Distributor.

The Model Rules for the Licensure of Wholesale Distributors along with the National Specified List of Susceptible Products can be downloaded from NABP's Web site, www.nabp.net.

New Bar Code Requirements Aim to Reduce Risk of Medication Errors

In late February, FDA issued the final rule Bar Code Label Requirements for Human Drug Products and Biological Products. This final rule requires the inclusion of linear bar codes on most prescription drugs and certain OTC drugs. Each bar code must, at minimum, contain the drug's National Drug Code number, but companies are encouraged to include additional information such as the product's lot number and expiration date. For blood and blood products used in a transfusion, the final rule also requires the use of machine-readable information in a format approved for use by FDA. The machine-readable information must include, at a minimum, the facility identifier, the lot number relating to the donor, the product code, and information on the donor blood type.

FDA is hoping that the bar code rule will encourage the widespread adoption of advanced information systems that, in some institutions, have reduced medication errors by 85%.

FDA expects that, with full implementation, the linear bar codes will result in more than 500,000 fewer adverse events over the next 20 years and a 50% reduction in medication errors that would otherwise have occurred upon dispensing or administration. New medications covered by the rule must comply within 60 days of their approval and previously approved medications and blood/blood products must comply within two years.

More information including a link to the final rule is available on FDA's Web site at www.fda.gov/oc/initiatives/barcode-sadr.

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§34-23-32. (a) Every manufacturer, bottler, packer, repackager, or wholesale drug distributor, of drugs, medicines, chemicals, or poisons for medicinal purposes shall register biennially with the [B]oard by application for a permit on a form furnished by the [B]oard and accompanied by a fee to be determined by the [B]oard as follows:

- (1) The fee shall not be less than five hundred dollars (\$500) nor more than two thousand dollars (\$2,000) for a new establishment.
 - (2) The fee shall not be less than two hundred fifty dollars (\$250) nor more than one thousand dollars (\$1,000) for a renewal permit.
 - (3) The fee shall not be less than two hundred fifty dollars (\$250) nor more than one thousand dollars (\$1,000) for a permit due to transfer of ownership.
- (b) A holder of a permit shall employ a full-time licensed pharmacist whose principal duty shall be confined to on-premise pharmaceutical operations. Wholesale drug distributors, who strictly limit their operation to distribution of drugs, medicines, chemicals, or poisons for medicinal purposes are exempt from the requirement to employ a full-time licensed pharmacist.
- (c) The professional practice of any physician licensed to practice medicine is exempt from the requirements of this section.
- (d) All permits issued under this section shall become due on October 31 and shall become null and void on December 31 of even-numbered years. Each application for the renewal of the permit shall be made on or before December 31 of even-numbered years. A penalty of twenty-five dollars (\$25) for each overdue month shall be assessed in addition to the permit fee for renewal of delinquent permits. For each application for a permit made and found to be satisfactory by the [B]oard, the secretary of the [B]oard shall issue to the applicant a permit for such manufacturing or wholesale establishment, which permit shall be displayed in a conspicuous place.
- (e) All holders of a permit shall, before shipping any drug bearing the legend, "caution, federal law prohibits dispensing without prescription" or similar wording causing these drugs to be known as legend drugs to new customers, assure themselves that the recipient is either a duly licensed doctor of

medicine, dentistry, or veterinary medicine or holds a registered pharmacy permit from the [B]oard by contacting the office of the [B]oard. No holder of a permit shall ship any legend drug to any person or firm after receiving written notice from the [B]oard that the person or firm no longer holds a registered pharmacy permit. Any person violating this section shall be guilty of a misdemeanor.

§34-23-52. (a) All certificates of licensure shall expire on December 31 of even-numbered years. Every licensed pharmacist in order to continue to be licensed shall pay a biennial renewal fee to be determined by the [B]oard, but the fee shall not be less than twenty-five dollars (\$25) nor more than one hundred fifty dollars (\$150) to the secretary of the [B]oard, the fee being due on October 31 and delinquent after December 31 of even-numbered years except, that holders of life certificate to practice pharmacy previously issued shall not be required to pay a renewal fee. The payment of the renewal fee shall entitle the registrants to renewal of their certificates at the discretion of the [B]oard. If any pharmacist shall fail to pay a renewal fee on or before the due date, the holder of the certificate may be reinstated as a licensed pharmacist only upon payment of a penalty of ten dollars (\$10) for each lapsed month and all lapsed fees, provided the lapsed time of registration shall not exceed five years, in which case reinstatement may be had only upon satisfactory examination by the [B]oard.

- (b) In addition to any fee requirements, each pharmacist is required to complete 15 hours of continuing education per calendar year, of which three hours shall be live presentation.

§34-23-131. (a) A pharmacy technician shall not perform pharmacy functions or be present in the prescription department of a pharmacy unless he or she is under the direct supervision of a licensed pharmacist. A pharmacy technician shall not perform pharmacy functions or be present in the prescription department of a pharmacy unless he or she is registered by the [B]oard.

- (b) When supervision is required, a licensed pharmacist shall be jointly responsible and liable for the actions of a pharmacy technician.
- (c) A pharmacy technician shall register and pay a fee as determined by the [B]oard before performing any pharmacy functions. The [B]oard shall develop rules and regulations relating to the registration of all pharmacy technicians. The registration of a pharmacy technician shall be renewable biennially in odd-numbered years upon payment of the required fee.

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- (d) In addition to any other registration requirements, a pharmacy technician shall complete three hours of continuing education annually, of which one hour shall be live presentation.

Change to Code of Alabama, Title 20 Chapter 2, Alabama Uniform Controlled Substances Act, §20-2-190

Please visit the Board Web site at www.albop.com to view the entire law.

Board Hires Director of Education/ Compliance

The Alabama State Board of Pharmacy recently hired Joyce C. Altzman as director of Education/Compliance.

Joyce was most recently the director of pharmacy and Clinical Services at Baptist Princeton Hospital in Birmingham, AL. She has been associated with the Baptist Health Systems' pharmacies in various capacities since 1979, even as a pharmacy student.

Joyce received her bachelor of science degree in pharmacy, a certificate in Clinical Pharmacy Practice, and has completed course work towards her master of business administration degree from Samford University.

She is a member of the Alabama Society of Health-System Pharmacists, the American Society of Health-System Pharmacists®, and the Southeastern Society of Hospital Pharmacists. She is the adjunct professor of Pharmacy Practice at Harrison School of Pharmacy and McWhorter School of Pharmacy, and served as the president of the Alabama Society of Health-System Pharmacists in 2000-2001.

Joyce has been married to her husband James for twenty-five (25) years and they have two (2) children, Jimmy (22) and Elizabeth (11).

Administrative Hearings – April 2004 Through June 2004

Technicians' names: **Shauna R. Jenkins** #T05172; **Marsha Cole Champion** #T13813; **Kimberly Freeman Goodwin** #T14968; **Christina Marie Cuesta** #T06443. Dispensing controlled substances, Schedule III, without a prescription. Action – Revoked.

Manufacturer/wholesaler/distributor's name: **Net Wholesale** #700056. Distributing List I Chemicals without a valid permit. Action – Probation three (3) years/\$1,000 monetary fine.

Technician's name: **Jennifer R. McDuffie** #T05678. Dispensing controlled substances, Schedules II, III, and IV, without a prescription. Action – Revoked.

Technician's name: **Tracey LaQuene Gamble** #T15457. Obtaining pharmacy technician registration by fraudulent

means. Action – Application for registration granted and placed on probation for one (1) year.

Technician's name: **Tanja Davis Dudley**, applicant for technician. Attempting to obtain technician registration by fraudulent means. Action – Application denied.

Pharmacist's name: **Brett S. Enabrit** #13745. Failing to inform Board that a licensed pharmacist was terminated based upon conduct which violated the provisions of the Alabama Pharmacy Practice Act. Action – Suspended one (1) year/immediately reverted to probation; \$2,000 monetary fine.

Pharmacist's name: **Suellen Dempsey** #14554. Failing to inform Board that a licensed pharmacist was terminated based upon conduct which violated the provisions of the Alabama Pharmacy Practice Act. Action – Suspended six (6) months/immediately reverted to probation; \$2,000 monetary fine.

Technician's name: **Gerald Muhoro Chege** #T13432. Stealing merchandise from pharmacy where employed. Action – Suspended for indefinite period, may apply for hearing to determine if registration may be reinstated after six (6) months; \$100 monetary fine.

Technician's name: **Ronda Lynn Bean** #T05469. Dispensing prescription legend drugs for self without a prescription. Action – Revoked.

Technician's name: **Candace D. Roberson**. Dispensing controlled substances, Schedules III and IV, without a prescription. Action – Revoked.

Technician's name: **William D. Tyree** #T05641. Taking drugs without paying for them. Action – Probation two (2) years; \$100 monetary fine.

Pharmacist's name: **Marion T. Forrester** #9875. Failing to complete required continuing education as a nuclear pharmacist. Action – \$100 administration fine; complete four (4) additional hours of continuing education relating to nuclear pharmacy in 2004 in addition to yearly requirements.

Pharmacist's name: **Roland J. Naseman** #12149. Allowing a person not registered as pharmacy technician to be present in prescription department and/or to perform technician functions. Action – Probation two (2) years; send letter of apology to Board; \$3,250 monetary fine.

Technicians' names: **Deanna Lee Lucky** #T02927; **Ammy Sherie Chappell** #T10789; **Anne Brooks Cleveland** #T11887; **Justin Taylor Orick** #T05931. Performing pharmacy functions and working without current registration. Action – \$125 monetary fine.

Pharmacists' names: **Charles Ray Wall** #11981; **Joy Hall Williams** #10567; **Kay Elizabeth Long** #9393. Allowing technicians to perform pharmacy functions and work without current registration. Action – \$250 monetary fine.

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Pharmacists' names: **Michael Marion Hutcheson** #10472; **Jocelyn Vicki Stephens Phillips** #10533. Practicing pharmacy and working without renewing certificate of license. Action – \$500 monetary fine.

Pharmacists' names: **Henry Marion Hutcheson** #4902; **Jenella Wickersham Burton** #7420. Allowing pharmacist to practice pharmacy and work without renewing certificate of license. Action – \$500 monetary fine.

Pharmacies' names: **Super Bee Pharmacy** #109340; **Son's Discount Pharmacy, Inc** #108992; **Keller Community Pharmacy** #110459. Allowing pharmacist to practice pharmacy and work without renewing certificate of license. Action – \$500 monetary fine.

Retail Medical Oxygen Suppliers' names: **Beacon Respiratory Services of Alabama, Inc** #900393; **Danny Newman Home Healthcare** #900214; **Advantage Care Home Health Care Equipment, Inc** #900418; **Alacare Home Medical Equipment and Supply** #900440; **FMC Capital City** #900328; **Georgiana Medical Supply, Inc** #900384. Engaging in activities as a manufacturer/wholesaler/distributor without first renewing permit. Action – \$500 monetary fine.

Pharmacies' names: **Advanced Cardiac Solutions, PC** #111278; **CVS/pharmacy #4881**, #110868. Allowing a technician to perform pharmacy functions and work as a technician without first renewing certificate of license. Action – \$500 monetary fine.

Distributors of List I Chemicals' names: **Associated Grocers of the South, Inc** #700065; **American First Aid, Inc dba Xpect First Aid** #700085. Engaging in activities as a distributor of List I Chemicals without renewing permit. Action – \$500 monetary fine.

Nonresident Pharmacy's name: **Hollywood Healthcare Corporation** #112227/201080. Engaging in the selling, offering

for sale, compounding or dispensing of drugs without first renewing permit. Action – \$500 monetary fine.

Manufacturer/wholesaler/distributors' names: **Nealco Products, Inc** #500163; **Dey, LP** #192322; **Dey, LP** #192903. Engaging in activities as a manufacturer/wholesaler/distributor without first renewing permit. Action – \$500 monetary fine.

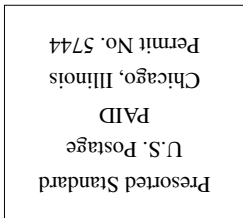
Pharmacist's name: **Valerie Bush Pickett** #13102. Failure to keep and maintain required records and/or to complete an inventory; allowing pharmacy to be open without a pharmacist being present; allowing unlicensed individuals to perform functions requiring a license to practice pharmacy, in convection with allowing individual other than a licensed pharmacist to have possession of key to pharmacy. Action – Probation one (1) year; \$3,000 monetary fine.

Manufacturer/wholesaler/distributor: **Bayer Corporation a/k/a Bayer Pharmaceuticals Corporation** #19177. Plea of guilt to violating 21 U. S. C §§331(p), 33(a)(2) and 360(j). Action - \$1,000 monetary fine.

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