



North Carolina Board of Pharmacy

P.O. Box H, 602H Jones Ferry Road, Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

Item 507—Board Member Election

Two Board of Pharmacy positions are up for election this spring. Pursuant to regulations, President Day appointed two committees to nominate at least two candidates for each position. Committees appointed and nominated are: South Central — Ed Fuller, Salisbury; Jesse Pike, Concord; Scott Dinkins, Monroe; Debra Smith, Charlotte. They nominated William Whitaker Moose of Mt. Pleasant and Ron Small of Winston-Salem. The Committee to select candidates from the northeastern part of the state included Rex Paramore, Nashville; Bill Mast, Henderson; Barry Mangum, Raleigh; Ronald Winstead, Durham. They nominated Bill Adams from Wilson and Bill Bradley from Raleigh. Other nominations may have been received after the printing deadline for this Newsletter, so please consult the enclosed material.

Each pharmacist licensed and residing in the state is eligible to vote in the annual election. Biographies along with ballots and an envelope for mailing to the Board office are provided with this Newsletter. Ballots must be received prior to counting in an open meeting in the Board office on Friday afternoon, May 30th at 5:00 p.m.

Item 508—Board Disciplinary Actions

November

Grady Shuford, Forest City. Dispensing Elixir of Terpin Hydrate with Codeine, a Schedule V controlled substance, in amounts so excessive that respondent knew, or should have known, that the purchases were for purposes other than legitimate medical needs. License suspended for a period of ten days; stayed for a period of three years with certain conditions — one being to submit a written policy for determining when legitimate medical needs exist for Schedule V controlled substances.

Joseph Finnan and Rutherford Rexall Drug Company, Inc., Rutherfordton. Failure to retain and preserve invoices of controlled substances purchases; failure to record refills of controlled substances and legend drug products; failure to properly record sales of Schedule V controlled substances in the Schedule V controlled substances record book; failure to record on prescriptions the dates of filling and refilling, patients' addresses, the letter "C" on controlled substances prescriptions filed with other prescriptions and failure to sign controlled substances prescriptions; failure to record the name of the manufacturer on prescriptions when

generic products were dispensed; substituting generic products for brand name products when the prescribing physician indicated to dispense the prescription as written; placing the brand name of a product on a prescription label containing generic products; filling prescription vials for legend drugs and controlled substances without authorization from the prescribing physician; refilling prescriptions without authorization from the prescribing physician; dispensing greater amounts of controlled substances than authorized by the prescribing physician; dispensing Schedule V controlled substances for reasons other than legitimate medical purposes; refilling legend drug products without proper authorization; filling call-in Schedule II prescriptions without verifying that an emergency existed; filling an obviously altered Schedule II prescription. License suspended 3 years; permit suspended 60 days; suspension of license and permit stayed for five years with an active suspension of 15 days against the pharmacist's license and an active 5 days against the pharmacy permit and other conditions.

January

James T. Moore, Spring Lake. Filling Schedule II prescriptions for Percocet in excessive amounts. License suspended 30 days; stayed 2 years.

Also at the January meeting, the Board suspended a pharmacist's license for 90 days; however, it is not included in this issue because the pharmacist intends to appeal.

February

Robert H. Reynolds, Robbins. Appropriating Schedules II, III and IV controlled substances for personal use without a valid prescription; indulging in the use of these substances to the extent that he was unable to perform properly his duties as pharmacist/manager. License suspended 5 years; stayed indefinitely with conditions.

William Memargut, Leland. Consuming Schedules II and III drugs for personal use without a valid prescription. Licenses suspended 5 years; stayed for an indefinite period of time with conditions.

Sanford Price, Salemburg. Appropriating Schedule IV controlled substances for personal use without a valid prescription. License suspended 90 days; stayed 3 years with conditions.

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National Pharmacy

(Applicability of the contents of articles in the National Pharmacy applies and can only be ascertained by examining the original article.)

Child Resistant Packaging For Lidocaine® and Lindane® Called For

As part of the Consumer Product Safety Commission's continuing work under the Poison Prevention Packaging Act, the Commission has directed staff to pursue voluntary packaging and labeling specifics of two topical preparations — Lidocaine and Lindane. Although the number of ingestions of Lidocaine has not been large, two accidental deaths in young children were reported in 1981 and 1984 due to the ingestion of 2 percent Viscous Lidocaine. Lindane preparations have been associated with a large number (438) of ingestions over the five year period from 1977 to 1981. Case histories of several hospitalizations after the ingestion of Lindane demonstrated that the drug has the potential to cause serious illness and injury.

While manufacturers of preparations containing Lidocaine or Lindane sometimes use child resistant packaging on prepackaged sizes of the drugs, these drugs are also commonly dispensed from bulk packaging by pharmacists. The Consumer Product Safety Commission is seeking the cooperation of pharmacists by asking that they dispense both Lidocaine and Lindane preparations in child resistant packaging. The cooperation of both pharmacists and manufacturers will greatly aid in the prevention of injury or death in small children from accidental ingestion of these topical preparations.

Clarification of DEA Order Form Issue

The following should clarify somewhat the information that was previously published on what pharmacists should do with the third copy of the DEA Order Form (DEA Form 222) when pharmacists supply Schedule II controlled substances to other DEA registrants.

First, DEA Form 222 must be executed by the purchaser of a Schedule II item regardless of the source supplying the item. A pharmacist, physician or dentist who is purchasing a Schedule II drug must prepare the triplicate order form whether he is purchasing the drug from a manufacturer, a distributor or a nearby pharmacy.

Secondly, the supplier of that Schedule II item, whether it be a practitioner (an unlikely occurrence), a retail pharmacy, a hospital pharmacy, a manufacturer or a distributor, must retain a copy for their records of drug disbursement. The DEA copy, or third copy, must be forwarded to the nearest DEA office which has jurisdiction.

Frequently, because of the volume involved, wholesalers/distributors and manufacturers send all such forms received to DEA on a monthly basis. However, for a retail or hospital pharmacy that might be supplying Schedule II drugs to another pharmacy or to a licensed practitioner, it is recommended that the DEA copy of the 222 form simply be mailed to DEA as soon as it is received from the purchaser since this type of business

is not all that common to a retail or hospital pharmacy.

Pharmacists who are regularly engaged in the distribution of drugs to other pharmacies or to licensed practitioners should also be sure to check with their local board of pharmacy for any additional licensing requirements or additional recordkeeping requirements.

Regulation of Veterinary Drugs Still a Concern to FDA

FDA still considers the illegal distribution of veterinary prescription drug products as one of the most pervasive and persistent problems faced by the Food and Drug Administration. Numerous factors reportedly contribute to the problem, not the least of which is a general lack of understanding by the professional and lay community alike of the agency's rationale for the veterinary prescription drug status. The following is a synopsis of information recently made available by FDA.

The Federal Food, Drug and Cosmetic Act governs the safety and effectiveness of new animal drugs just as it also governs the safety and effectiveness of human use drugs. A reading of the statute will show that the director of the Center for Veterinary Medicine may restrict approval of a new animal drug to the precise conditions for which it has been shown to be safe and effective, which may include appropriate restrictions on use.

The regulations implementing the Federal Food, Drug and Cosmetic Act set forth the requirements for evidence that must be submitted to demonstrate a drug is safe and effective for the proposed conditions of use. Accordingly, the case law and regulations demonstrate that FDA may restrict the use of an animal drug to the order of a licensed veterinarian. The parameters within which veterinary prescription drugs may be legally distributed are contained in Title 21 of the Code of Federal Regulations (CFR) Section 201.105. This regulation is sometimes referred to as an "exempting regulation" because it identifies conditions under which certain drugs may be exempted from Section 502(f)(1) of the Federal Food, Drug and Cosmetic Act. Section 502(f)(1) deems all drugs to be misbranded unless their labeling bears adequate directions for use. The regulations define "adequate" directions for use as meaning directions under which the layman can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). Obviously, there are many drugs which should only be used by or under the supervision of a veterinarian, since adequate directions for safe and effective use by laymen cannot be written. While the Act has no explicit prescription provision, a federal court has interpreted the law as providing implicit authority under Section 502(f)(1) for restricting some drug products to a prescription status. Those drugs for which adequate directions for use by laymen cannot be written could, therefore, not be legally marketed if they were not for the exemption provided by 21 CFR 201.105. Among

Compliance News



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: law of such state or jurisdiction.)

other labeling requirements, 21 CFR 201.105 requires that veterinary prescription drugs be labeled with the veterinary prescription legend "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." The Center for Veterinary Medicine makes the determinations as to which veterinary drugs require the veterinary prescription drug legend. Note that some drug product labels reflect the manufacturer's sales policy with statements that the drug is sold to licensed veterinarians only. However, only the statement quoted above legally designates a veterinary prescription drug.

The primary basis then for distinguishing prescription (Rx) and over-the-counter (OTC) animal drug products under the Federal Food, Drug and Cosmetic Act and its implementing regulations is the ability (or lack of ability in the case of Rx products) to prepare "adequate directions for lay use" which would allow persons other than licensed veterinarians to use the product safely and effectively. In effect, the system establishes, when appropriate, a method of control intended to ensure that Rx products reach only the hands of persons trained to use the products. Products for which adequate directions for lay use can be written must be labeled for over-the-counter use. In determining whether directions for use are adequate, an important point for consideration is whether it is reasonably certain the conditions for use prescribed, recommended, or suggested in the proposed labeling will, in fact, be followed in practice.

Evaluating toxicity and potentiality for harmful effect includes an evaluation of safety to treated animals, safety of food products derived from the animals, safety to persons associated with the treated animals, and safety in terms of the drug's impact on the environment.

Effective use of the drug product assumes that an accurate diagnosis can be made with a reasonable degree of certainty, that the drug can be properly administered, and that the course of the disease can be followed so that an assessment can be made of the success or lack of success of the drug product in terms of its intended use. This assumption also implies that a timely adjustment can be made in the event that an expected effect is not seen.

In the past, the same drug products used in varying species of animals may have been labeled "prescription" in one instance and "non-prescription" for other uses. The primary question is whether adequate directions for lay use can be written to assure safe and effective use. If an average food animal producer can safely and effectively administer a product, but a companion animal owner, regardless of label directions, cannot administer it safely and effectively, then the status of the product must be different relative to its intended uses. If directions can be written for use for a particular route of administration (I.V., I.M., etc.) for one animal species but not for another, it is not inconsistent with the regulations to grant OTC status for the one use and require the prescrip-

tion legend for the other.

Each drug must be considered in light of the labeled use and characteristics of the drug, whether adequate directions can be written for the safe and effective use of the product, and whether it is reasonably certain the directions will be followed in actual practice.

Prior to being sold or dispensed, prescription veterinary drugs must remain either in the possession of persons regularly and lawfully engaged in the manufacture, transportation, storage, or retail or wholesale distribution of veterinary drugs and be sold only to or on the prescription or order of a licensed veterinarian for use in the course of his/her professional practice or must remain in the possession of a licensed veterinarian for use in the course of his/her professional practice. If at any point in the distribution of the drug there is a failure, either on the part of the veterinarians or non-veterinarians to meet these requirements, the drug becomes misbranded within the meaning of section 502 (f) (1) of the Act. The drug and the individuals responsible for the misbranding may then be subject to regulatory action by FDA. Actions available to FDA include seizure of the drugs and an injunction or criminal prosecution levied against the individuals.

In making determinations as to whether veterinary prescription drugs have been illegally distributed under FDA's laws, much depends on the requirements of various state laws. FDA does not regulate the practice of medicine nor of veterinary medicine. This is done by the individual states under their own laws. The requirements for distribution of veterinary drugs have been met for FDA's purposes if they have been met under the respective state laws.

If prescription drugs are not prescribed or dispensed by the licensed veterinarian within the course of professional practice, the fact that the individual is a veterinarian does not provide any exemption which is not also available to non-veterinarians. Veterinarians who are in the employment of drug manufacturers or distributors and veterinarians who operate their own drug distributorships cannot legally sell prescription drugs or issue prescriptions for them outside the scope of a professional practice. Likewise, practicing veterinarians and their employees cannot legally sell prescription drugs to walk-in customers unless a valid veterinarian/client/patient relationship exists.

Pharmacists can play an important role in controlling the distribution of veterinary drugs. Pharmacists should bring to the attention of their local Board of Pharmacy any unusual activities involving veterinary drug products that come to their attention.

Item 509—Professional Responsibility Can Yield C.E. Credit

Pharmacists have an unwritten professional responsibility to convey their wisdom, expertise and experience to younger generations by being a preceptor. A preceptor can also obtain up to 5 hours of contact continuing education credit for supervising at least 400 hours of internship. Contact Dr. Jack Wier at the UNC School of Pharmacy, Beard Hall 200H, Chapel Hill, NC 27514, 919/962-0097 or Dr. Daniel Teat at Campbell University School of Pharmacy, Buies Creek, NC 27506, 919/893-4111 for prospective summer interns.

Credit will be assigned by the Board office on a copy of the internship form filed at the end of the experience period. One copy indicating the number of hours of experience obtained will be sent to the student, and one copy of the form indicating the number of hours of continuing education obtained by the preceptor will be mailed to the pharmacist. This underscores the necessity of filing forms in a timely manner both at the beginning and ending of the experience period.

Item 510—Quarterly Query

A pharmacist may supply a generic equivalent drug on a properly written prescription provided: (I) The patient requests it; (II) The physician signs his name on the "substitution permitted" line; (III) The physician does not write "Dispense As Written" or "D.A.W." on the face of a one-line prescription.

1. I Only. 2. II Only. 3. I and II Only. 4. II and III Only. 5. I, II and III.

Item 511—Drugs Sent to Summer Camp

The Board's Inspector for the western part of the state discovered that some pharmacies are providing prescription drugs to summer camps for use by campers. These items included controlled substances in some cases, and the drugs were to be administered, or perhaps dispensed, by camp employees who are college students without training in a health profession.

Pharmacists who receive requests to send drugs to a summer camp for their use are advised to observe the following procedure. Obtain an order for the pharmaceuticals and supplies from a physician licensed in this state and deliver it to the doctor's office or to his custody at the camp. Care needs to be taken in this matter since there have been reports that out-of-state physicians "cover" a camp for a week or two in exchange for a free stay for their child. The physician may or may not be at the camp or even in

the state during the "cover" period. To confirm a physician's licensure, contact the North Carolina Board of Medical Examiners, Suite 214, 222 N. Person St., Raleigh, NC 27601, 919/833-5321.

The key to Quarterly Query is — 4. II and III Only.

Item 512—Messages from Inspectors

Board Inspectors, during regular inspection visits, will be asking for evidence of continuing education obtained by pharmacists during the last year. Regulations provide that certificates must be kept at the pharmacist's place of practice.

Questions continue to arise regarding the transfer of prescriptions for controlled substances. The January issue of the Newsletter contained regulations for prescription transfer with a note at the end that controlled substance prescriptions cannot be transferred. Confusion continues, however, partially because Sec. 1306.26 of the Code of Federal Regulations allowing controlled substance prescription transfers is printed at the back of the green pharmacy law book. Please note that Sec. 1306.26(d) provides that this is effective only if allowable under state statute and regulations. A regulation of the Commission on Mental Health, Mental Retardation and Substance Abuse prohibits the transfer of controlled substances prescriptions in North Carolina.

What do you do if, in an emergency oral (telephone) prescription for a Schedule II drug, the prescriber does not provide a signed document within 72 hours? Federal regulations instruct the pharmacist to notify the nearest DEA office which is 75 Spring St., Ste. 734, Atlanta, GA 30303, 404/331-7328. Failure to do so exposes the pharmacist to charges of violating Federal regulations.

Please note that prescription refills must be indicated on the prescription by the prescriber, see G.S. 106-134.1. Refills dispensed must also be recorded on the document or data system as noted in Section .2301 published in the January Newsletter and in the Pharmacy Law Book Supplement.

The North Carolina Board of Pharmacy News is published by the North Carolina 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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