

North Carolina Board of Pharmacy

P.O. Box 471, Chapel Hill, NC 27514

Published to promote voluntary compliance of pharmacy and drug law.

ITEM 300—NEW FORMAT

As you can see, this publication has changed its format in an effort to bring more complete information to North Carolina pharmacists. Both federal and state news is included and we would appreciate hearing your comments. **The Board expects the Pharmacist Manager of each pharmacy to keep this publication filed in the News Bulletin binder provided to each pharmacy for this purpose.**

ITEM 301—STATE IMPOSES SANCTIONS ON PHARMACISTS

The Fraud and Abuse section of the Division of Medical Assistance, not the Board of Pharmacy, has taken action against several pharmacy providers for Medicaid. A summary of these actions appears below so that pharmacists may be more conscious of their activities. Nine pharmacists and/or pharmacies received sanctions for misrepresentation, dispensing generic and billing for brand names or billing for drugs which were not received from September of 1978 through May of 1979. Each made restitution to the state and was placed on probation for 12 months. Six of these pharmacies were suspended from the program for 30 days, two for 60 days, and one for 90 days. In addition, two pharmacists were referred to the Attorney General for possible prosecution for fraud and another was forwarded to the Board of Pharmacy for possible violation of the state and federal Controlled Substances Act.

ITEM 302—BOARD EXAM DATES

The Board has established examination dates for candidates for licensure. They are **September 24, 25, and 26, of 1979**. These have changed slightly from an earlier announcement, so please notify candidates of the revised dates. Applications are available from the Board and must be filed 30 days before the exam.

ITEM 303—PRODUCT SELECTION (SUBSTITUTION) LAW ENACTED

At the last session of the General Assembly, the Anti-Substitution law, G.S. 90-76, was changed effective for the most part on January 1, 1980. The new law provides that equivalent generic drugs may be

dispensed on brand-name prescriptions if the following conditions are met: the manufacturer's and/or distributor's name is on the stock package label, the drug is manufactured according to G.M.P.'s the manufacturer has adequate recall and return policies and, effective January, 1982, tablets and capsules must bear a logo or other identifying mark.

The new statute also provides for a two-line prescription form on which a prescriber may indicate the use of brand-name or generic drugs in the following manner on two signature lines:

Product Selection Permitted	Dispense as Written
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If the prescription document format above is not available, prescribers can require brand-name drugs by writing: "Dispense as Written" or "DAW". The prescription on file must contain the established name and manufacturer when product selection is exercised. Violation of the law is a misdemeanor.

ITEM 304—AMENDMENT TO CONTROLLED SUBSTANCES ACT

The Controlled Substances Act was amended in 1979 to require pharmacists to label tranquilizer or sedative prescriptions with the warning, "The consumption of alcoholic beverages while on this medication can be harmful to your health," if so directed by the prescriber. The prescriber must specifically state this on the prescription. It will be interesting to note how many prescribers actually write these 15 words on prescription documents, thereby requiring pharmacists to repeat them on a label. If this becomes a problem, auxiliary labels appear to be the most practical means of compliance.

ITEM 305—DISCIPLINARY ACTIONS OF THE BOARD February 1979

A pharmacist who appeared at the January meeting for a hearing returned for a continuance of the process this month. The pharmacist entered a plea of guilty to the charge of obtaining Controlled

Contd. page 4



National Pharmacy

WELCOME TO YOUR STATE BOARD NEWSLETTER INAUGURAL EDITION!

In cooperation with the National Association of Boards of Pharmacy (NABP), your board of pharmacy is one of the first to join the NABP Bureau of Voluntary Compliance State Board Newsletter Project. This isn't just another pharmacy newsletter, however, as our goal will be to promote voluntary compliance of pharmacy and drug law through improved board-to-practitioner communications. Education and information will be the key areas of concern in this newsletter, and while the subject matter won't be "entertaining," we hope it *will* be enlightening!

Our project is unique in that we will merge information from your state board of pharmacy with national pharmacy compliance news. Material from such agencies as the Consumer Product Safety Commission (CPSC), the Drug Enforcement Administration (DEA), the Food and Drug Administration (FDA), and NABP, will be condensed into this "national" section. Our National News Editor will be Karl W. Marquardt of Madison, Wisconsin. Marquardt is a licensed pharmacist, an attorney, a former state board of pharmacy administrative officer, and a recognized authority on pharmacy law. On the state level, your board of pharmacy will serve as "co-editors" to inform you of important news developing within your state.

In praising the establishment of this newsletter project, DEA Administrator Peter B. Bensinger recently said, "The underlying premise of this program is that self-established constraints are generally more effective than never-ending federal bureaucracy." Through improved communications explaining federal and state laws, you will be able to comply with these laws on a voluntary basis, and thus prove that an informed and responsible professional is one of the most effective means of protecting the public health.

Comments of any nature, be they commendations or criticisms, are invited and should be directed to your state board of pharmacy office. (Their address is printed on the front page masthead.) Please keep your board informed of how we can improve this publication, or, bring to your board's attention some problem areas that need additional focus beyond the limits of this newsletter. We hope you'll find this a worthwhile and educational venture!

WARNING TO PHARMACISTS ON SUBSTITUTION OF PATENTS

Situations are developing in many states that have enacted drug product selection/formulary laws which confront pharmacists with the alternative possibilities of patent infringement or a violation of

state law. This occurs when state law mandates substitution of a less expensive drug product listed in the formulary and the formulary includes patented drugs where no substitutes have been authorized by the licensing of the patents.

The problem stems from the misunderstanding created when the Food and Drug Administration (FDA) approves a generic version of a patented drug. FDA does not consider whether a drug is patented in its NDA and ANDA evaluations or antibiotic batch-certification procedures. Accordingly, a formulary based on FDA approved drugs does not mean that those drugs which are patented can be marketed free of liability for patent infringement.

The approval for sale of a generic product by the FDA, or the sale of a generic product in a substitution state, in no way affects the application of the U.S. patent laws to products for which patent protection has been granted. The unauthorized sale of such a generic product by a pharmacist is an act of patent infringement for which the pharmacist can be sued and be held liable by a court.

METHOD OF NARCOTIC MEASUREMENT PROPOSED BY DRUG ENFORCEMENT AGENCY

The method used to calculate the quantity of a narcotic drug in a Schedule III, IV, or V controlled substance would be specifically based on the amount of free anhydrous base or alkaloid present in the preparation, according to a recent Drug Enforcement Administration (DEA) proposal. Although the narcotic substance in a preparation may be in the form of a free anhydrous base or alkaloid or combined in the form of anhydrous or hydrated salts, the proposal would not permit calculations of the narcotic quantity to be based on the amount expressed as the salt form. The proposal is intended to eliminate confusion among manufacturers wishing to place a narcotic preparation in less restricted schedules.

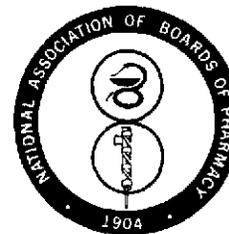
Excerpts of the narcotic drug calculation method proposal reads as follows:

Controlled Substances Proposal Drug Calculation Method

Summary: This is a notice of proposed rulemaking to specify the method to be used in calculating the amount of a narcotic drug present in a Schedule III, IV, or V preparation.

Supplementary Information: The Controlled Substances Act (Public Law 91-513) allows preparations containing certain Schedule I or II narcotic drugs to be placed in lower schedules if requirements specified in the Act are met. These requirements include a maximum permitted quantity of narcotic drug. Recent occurrences involving the scheduling of these types of preparations have demonstrated to DEA that confusion exists as to the correct method of calculating the quantity of narcotic drug present. The narcotic substances in a

Compliance News



preparation may be in the form of the free anhydrous base or alkaloid or combined in the form of various salts, both anhydrous and hydrated. All calculations of the quantity of a narcotic substance contained in a preparation are to be made based on the amount of free anhydrous base or alkaloid present and not on the amount expressed as the salt form. It is proposed to specify this procedure by modifying 21 CFR as follows:

Section 1308.13—Schedule III

(e) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or salts thereof (the quantity of narcotic drug shall be calculated as the free anhydrous base of alkaloid):

Section 1308.14—Schedule IV

(b) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof (the quantity of narcotic drug shall be calculated as the free anhydrous base of alkaloid):

Section 1308.15—Schedule V

(b) Narcotic drugs containing non-narcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs or any salts thereof, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone (the quantity of narcotic drug shall be calculated as the free anhydrous base or alkaloid):

ESTROGEN PATIENT PACKAGE INSERTS: NOT NEEDED FOR MALE PATIENTS

Estrogen drug products dispensed or administered to male patients would be exempted from patient-directed labeling requirements under a recent Food and Drug Administration (FDA) proposal. The proposed amendment would also permit distribution of a patient package insert (PPI) after administration of a drug when the patient was unable to read and understand the labeling at the time of administration. The FDA's proposal responds to concerns expressed by practitioners on the scope of the patient-directed drug labeling regulation for estrogenic drug products promulgated July, 1977.

Several comments pointed out that the emphasis of the substantive content for estrogen patient package inserts is on cautions regarding endometrial cancer and is solely to female patients. It was also noted that when estrogen is administered to hospitalized patients, they are occasionally sedated at the time of administration,

i.e. during surgery or shortly thereafter. In such situations, the PPI is not useful at the time of administration but should be provided at a later time for the patient's benefit.

The proposed amendment to the FDA regulation 21 CFR 310.55 reads as follows:

Section 310.515 – Estrogens; Labeling Directed to the Patient

(d)(1) Except as provided in this paragraph, patient labeling for each estrogen drug product shall be provided in or with each package of the drug product intended to be dispensed or administered to the patient.

(i) Patient labeling for drug products dispensed in acute care hospitals or long-term-care facilities will be considered to have been provided in accordance with this section if provided to the patient before the first dose of estrogen is administered and every 30 days thereafter, as long as the therapy continues.

(ii) Patient labeling for estrogen drug products administered to a patient who, at the time of administration, is unable to read and understand the labeling (e.g., because the patient is unconscious, sedated, or under the effects of an anesthetic) will be considered to have been provided in accordance with this section if provided to the patient after administration of the drug.

(e) This action does not apply to the following:

(1) Estrogen-progestagen oral contraceptives and oral diethylstilbestrol (DES) products intended for postcoital contraception, which shall be labeled according to the requirements of Section 310.501, and intrauterine contraceptive devices which shall be labeled according to the requirements of Section 301.502.

(2) Estrogen drug products whose labeling limits the drug to treatment of male patients.

(3) Any other prescription estrogen drug product when prescribed for or administered to a male patient.

BETAMETHASONE TABLETS EXEMPTED FROM CHILD-PROOF PACKAGING RULES

Manufacturers' dispenser packages containing no more than 12.6 mg. of betamethasone have been exempted from special child-resistant container packaging requirements of the Poison Prevention Packaging Act by the Consumer Product Safety Commission (CPSC). The CPSC's decision to grant the exemption, requested by a manufacturer of the drug product, was based on the lack of reports of significant adverse human effects involving the drug. Although the petition for exemption referred specifically to Celestone Six-Day Tablet-Pack, the only betamethasone tablet product on the market, the CPSC granted the exemption for the generic product.

Substances through fraud or forgery. In lengthy testimony, the pharmacist explained that she obtained the prescription drug (on a telephone order from a physician who now resides in Baltimore) for a friend who lived in a city over 300 miles away. The Board suspended the pharmacist's license with a stay order effective coinciding with the suspended sentence from the guilty plea.

April 1979

A hospital pharmacist appeared before the Board to respond to allegations of unauthorized removal of cocaine from the hospital pharmacy. The pharmacist confessed the removal and personal use of 68 cocaine solvets, to his supervisor before the loss was discovered. The Board noted this was a first offense, that none had been diverted to other individuals, that he had volunteered a confession and placed him on probation for one year.

May 1979

A non-pharmacist owner and a pharmacist appeared to respond to charges of an unlicensed individual (the owner) dispensing prescription drugs including Controlled Substances while not under supervision of a pharmacist. Both individuals testified and near the conclusion of the hearing the non-pharmacist said "I'm guilty" and the Board, in effect, closed the pharmacy for 30 days and placed the pharmacist on 2 years probation.

June 1979

Two pharmacists appeared in two separate hearings evolving from evidence collected which was partially used in a criminal trial in which both were convicted for violations of the Federal Controlled Substances Act. Both pharmacists have appealed these convictions. One hearing lasted nearly one day and the other began at 9:30 a.m. and ended at 9:10 p.m. with a noon recess. Both pharmacists were represented by attorneys who requested a delay until the results of the appeal and on the basis that both had claimed their fifth amendment right not to testify in the criminal trial and were thereby precluded from testifying at these hearings. It was the decision of the Board to proceed with the hearings in each case.

Testimony in both hearings tended to establish that arrange-

ments had been made for controlled substances to be obtained through a physician's office by the "authorization" of a receptionist for the issuance of "prescriptions." The practice was frequent with many controlled substances. The testimony in the second hearing indicated much more activity including the dispensing of Dilaudid to the receptionist without a prescription when certain numbers of prescriptions per day were received by the pharmacy. It also indicated that over 60% of the Schedule II substances shipped by a major wholesaler over a 13-month period were to this store.

In one case the Board delayed a decision until the results of the appeal or until cited again by the Secretary. In the other case the pharmacist's license was revoked, the permit to operate the pharmacy was suspended for 30 days and the license of the pharmacist manager was suspended for 30 days.

ITEM 306—DISCIPLINARY ACTIONS OF THE BOARD OF MEDICAL EXAMINERS

This compilation is intended as an aid to pharmacists to their professional practice since these matters frequently are not covered by the News Media and may be subject to speculation. It is not intended as undue publicity for individuals.

The North Carolina Board of Pharmacy News is published by the North Carolina Board of Pharmacy and the National Association of Boards of Pharmacy (NABP) 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 NABP unless expressly so stated.

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