

# North Carolina Board of Pharmacy

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

Published to promote voluntary compliance of pharmacy and drug law.

## ITEM 307—NEW MAILING SCHEDULE

This issue of the North Carolina Board of Pharmacy News has been mailed with Pharmacists License Renewals to assure maximum coverage. Beginning with the prior issue, August of 1979, this will be published on a quarterly schedule for the foreseeable future. Mailings are made to the pharmacists preferred mailing address as indicated on the renewal form so you can expect the Newsletter at that location.

## ITEM 308—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. If you have any questions regarding the status of a particular physician's prescribing privileges you should contact: Mr. Bryant D. Paris, Jr., Director, North Carolina Board of Medical Examiners, Suite 214, 222 North Person St., Raleigh, North Carolina 27601.

**James Richard Hughes of Snow Hill** surrendered all DEA privileges on March 9, 1979; **Charles E. Wiley of Banner Elk** had Schedule II and 2N privileges reinstated on March 17, 1979; **Edward R.P. Spicer of Salisbury** surrendered his license to practice medicine on March 12, 1979; **Francis O. Miles of Old Fort** surrendered Schedule II and 2N privileges on March 26, 1979; **Lewis W. Hagna of Marion** surrendered all Schedule II and 2N privileges on March 26, 1979; **Wilson Lyday of Brevard** surrendered privileges in all schedules on March 27, 1979; **Richard Stuelke of Durham** temporary reinstatement of license to practice medicine, March 17, 1979 and reinstatement of Schedule IV and V privileges June 15, 1979; **Lewis W. Hagna of Marion** surrendered all Schedule III and 3N privileges, May 3, 1979; **William P. Jordan of Windsor** reinstatement of Schedule II and 2N June 15, 1979; and, **Moye Freymann of Chapel Hill** surrendered all DEA privileges June 15, 1979.

## ITEM 309—SUNSET COMMISSION

The Board, along with other licensing boards and some state

agencies, is currently submitting information to the Sunset Commission in response to their requests. The Commission will make a recommendation to the General Assembly regarding the continuance of the Board of Pharmacy and any suggested changes. As the situation now stands, the General Assembly must re-establish the Board of Pharmacy before the end of the 1981 session for the Board to continue in operation. There is a possibility that the Board could be considered during the short session in 1980 but at the time of this writing we have not been specifically notified. Ordinarily public hearings regarding the Board would be held around the state and we will attempt to keep pharmacists informed of significant developments.

## ITEM 310—DISCIPLINARY ACTIONS OF THE BOARD OF PHARMACY

A quorum of the Board met for a hearing in Yadkinville in August to consider charges against a pharmacist which involved the dispensing of legend drugs without a prescription and allowing unlicensed personnel to dispense legend drugs while not under the supervision of a pharmacist. After extensive testimony and evidence from five physicians the Board issued a five year suspension of the pharmacist's license to practice with a stay order on the suspension on the condition that he surrender his license for a 30 day period beginning before October 1, 1979. The pharmacist and his attorney presented numerous character references in person and by letter since he operates the only pharmacy in town.

## ITEM 311—PHARMACISTS CORRESPONDING RESPONSIBILITY

This is important. Some pharmacists may not be aware that federal regulations for the Controlled Substances Act specifically state that the pharmacist bears a corresponding responsibility with the prescribing practitioner for the completeness and validity of all prescriptions dispensed for controlled substances. The Code of Federal Regulations states:

"A prescription for a controlled substance to be effective

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# National Pharmacy

## FDA ESTABLISHES REGIONAL SERVICE DESKS

The Food and Drug Administration (FDA) has opened service desks in four regional offices to advise and assist small businesses in complying with FDA rules. The service desks are in East Orange, NJ; Chicago, IL; Atlanta, GA; and Santa Ana, CA. Sherwin Gardner, Acting FDA Commissioner, said the service desks are part of an FDA program that responds to President Carter's directive for regulatory agencies to give special assistance to small businesses.

FDA employees at the four service desks will help small businesses understand FDA rules, obtain information, fill out applications, and, on invitation, will visit a small company to discuss its concerns. The service desk personnel and phone numbers are:

**East Orange, NJ: George Walden, (201) 645-6365**

**Atlanta, GA: Bradley Eichorst, (404) 881-3576**

**Chicago, IL: Danny Horner, (312) 353-9406**

**Santa Ana, CA: J. Lawrence Stevens, (714) 836-2377**

The desks in New Jersey and California will deal only with medical devices while the Georgia and Illinois desks can also help businesses involved in drugs, foods, cosmetics, biologics and radiation-emitting products. Each desk will serve the regional area, not just a single city or state. After the service desks have been open for a year, the program will be evaluated by FDA to see if it should be expanded or changed.

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## DESCRIPTION OF DISPENSING CONTAINER MANDATED FOR PRESCRIPTION DRUGS

A statement to the pharmacist describing the type of dispensing container necessary for maintenance of the identity, strength, quality and purity of each prescription drug product has been added to the labeling requirements for drug manufacturers. Products intended to be dispensed in the manufacturer's original container are exempt, however.

The rule was adopted by publication in the **Federal Register** on August 25, 1978, with an original effective date of August 27, 1979. The Food and Drug Administration (FDA) has postponed the effective date, however, until February 27, 1980. The new requirement will apply to all products introduced into interstate commerce on or after February 27, 1980, but voluntary compliance may begin immediately.

FDA advises, however, that the compendial standards for tightness of seal and light resistance are in effect and compliance with these requirements are necessary at this time in accordance with Section 5029(g) of the federal Food, Drug and Cosmetic Act. These standards apply to both the containers used by pharmacists for dispensing compendial drugs as well as the container used by manufacturers. The new regulation requires manufacturers to

include on their drug product labels an instruction to pharmacists about what type of container should be used in dispensing the product.

An excerpt of the amended section in the Code of Federal Regulations follows:

**21 CFR 201.100(7)** "A statement directed to the pharmacist specifying the type of container to be used in dispensing the drug product to maintain its identity, strength, quality and purity. Where there are standards and test procedures for determining that the container meets the requirements for specified types of containers as defined in an official compendium, such terms may be used. For example, 'Dispense in tight, light-resistant container as defined in the National Formulary.' Where standards and test procedures for determining the types of containers to be used in dispensing the drug product are not included in an official compendium, the specific container or types of containers known to be adequate to maintain the identity, strength, quality and purity of the drug products shall be described. For example, 'Dispense in containers which (statement of specifications which shall enable the dispensing pharmacist to select an adequate container)...'"

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## FDA INVITES PUBLIC COMMENT ON PROPOSED PPI REGULATIONS

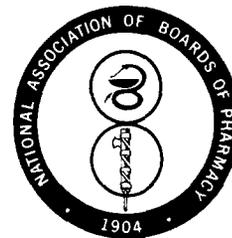
As the Food and Drug Administration (FDA) moves ever so slowly toward final promulgation of the controversial patient package insert (PPI's) regulations, regional hearings were conducted this fall in Washington, D.C.; Chicago, Illinois; and Los Angeles, California; to hear public comment on the issue.

While the public hearings are now completed, written comments are still invited and may be sent to: Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857.

While FDA now requires PPI's for a few drugs such as birth control pills, estrogen for menopausal women and progestins, the agency is considering regulations to require PPI's for an undetermined number of prescription drugs. Manufacturers would be responsible for printing the information, including drug uses, risks and side effects, but the dispenser—physician, pharmacist or nurse—would be responsible to provide the PPI to the patient.

The PPI proposal has been met with strong opposition by many national, state and local medical and pharmacy organizations. They contend that PPI's will add unnecessarily to the cost of medication and that less expensive and time-consuming alternatives to patient information dissemination should be developed by FDA in cooperation with medical and pharmacy organizations and manufacturers.

# Compliance News



## UPDATE ON SEDATIVE HYPNOTICS

A recently issued Institute of Medicine (IOM) study advised physicians to restrict use of hypnotic drugs for insomnia to short-term treatment. The committee concluded that there is little evidence that sedative hypnotics in general continue to be effective when used nightly over long periods. Sleep laboratory research on most hypnotics has found them to lose their sleep-promoting properties within three to fourteen days of continuous use.

The Food and Drug Administration (FDA) is in the process of instituting changes in package inserts for widely used sedative hypnotics to indicate the duration of the efficacy, as established through research. The table below summarizes this information with portions from newly approved labeling for four drugs. FDA is also processing similar changes in labels on five other drugs in this class.

Drug	New Approved Labeling
Ethinamate (Valmid)	"The prolonged administration of Valmid is not recommended, since it has not been shown to be effective for a period of more than 7 days."
Methaqualone (Sopor)	"The prolonged administration of Sopor is not recommended since it has not been shown to be effective for more than 14 days."
Sodium butabarbital (Butisol Sodium)	"The prolonged administration of Butisol Sodium as a hypnotic is not recommended since it has not been shown to be effective for a period of more than 14 days. Should insomnia persist, drug-free intervals of one or more weeks should elapse before retreatment is considered."
Triclofos sodium (Triclos)	"Triclos has not been shown effective for more than 14 days except in persons over age 65 where it was effective for up to 42 days in one inpatient study."

## YELLOW NO. 5 (TARTRAZINE) LABELING TO BE REQUIRED

The Food and Drug Administration (FDA) will require the listing of Yellow No. 5 (Tartrazine) color additive as an ingredient present in food and drugs for oral, nasal, vaginal and rectal administration. The label declaration on drugs will assist physicians in choosing products free of Yellow No. 5 when they are prescribing for patients sensitive to the additive.

The information will also be useful to pharmacists and other

health professionals in dispensing drugs and in counseling Yellow No. 5-allergic patients on the use of OTC products. There are an estimated 47,000 to 94,000 persons in the United States allergic to Yellow No. 5, and an increasing number of medical reports indicate that susceptible individuals are primarily patients who also experience aspirin intolerance. Reactions to both aspirin and Yellow No. 5 include asthmatic symptoms, urticaria, angioedema, or nasal symptoms.

It is important that those affected be able to identify drugs containing Yellow No. 5. For example, some drugs used to treat allergy problems contain the dye. Patients who are allergic to Yellow No. 5 could, in the absence of the labeling requirement, continue to take drugs containing the color additive to treat conditions or symptoms that may be a result of previous ingestion of the dye. Information which FDA received in considering the new requirement indicates that there are wide selections of drugs not containing Yellow No. 5 in all therapeutic categories.

For all drugs with Yellow No. 5 as an ingredient, the labeling will include wording such as "Contains FD&C Yellow No. 5 (Tartrazine) as a color additive" or "Contains color additives including Yellow No. 5 (Tartrazine)." In addition, prescription drugs requiring package inserts will include in the "Precautions" section the following wording:

**"This product contains FD&C Yellow No. 5 (Tartrazine) which may cause allergic type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of FD&C Yellow No. 5 sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity."**

The new label requirement for drugs will go into effect at the next printing of the labeling, or June 26, 1980, whichever occurs first. The regulation does not apply to externally applied drugs containing Yellow No. 5, because FDA is not aware of any such products causing allergic responses in persons sensitive to the color additive. Any health professionals who become aware of allergic reactions to externally applied drugs or cosmetics containing Yellow No. 5 should submit the information to FDA.

## 16 STATES NOW PUBLISHING . . . .

The NABP-State Board Newsletter Project is now in its second quarterly publication cycle with sixteen states participating and five more states expected to join soon.

A national subscription service for all state newsletters has been established through NABP. If you are interested in receiving all state issues as published, contact the NABP Publications Desk, One East Wacker Drive, Suite 2210, Chicago, IL 60601, for more information.

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must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.”

Those who dispense controlled substances under obviously suspicious circumstances or pursuant to incomplete prescriptions or invalid prescriptions can face substantial problems. At least one pharmacist and one former pharmacist in the state, both of whom are appealing three year federal prison sentences, can verify this fact.

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#### **ITEM 312—SAFETY CLOSURES ON PRESCRIPTION CONTAINERS**

Pharmacists should be aware that safety closures on prescriptions are the rule rather than the exception. Recently, a pharmacist commented that prescriptions are packaged in non-safety closure containers unless safety closures were requested. This is the converse of what is specified in federal regulations and expected by authorities. Unless non-safety containers are requested by the patron, safety closure packaging must be used for controlled substances and for prescription legend drugs intended for oral administration with the exception of sublingual nitroglycerin, isosorbide dinitrate, certain sodium fluoride solutions and Betamethasone specified in the August issue. (16 CFR 1700.14 (a),(4),(10). Other products

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require safety closure containers, but most are provided by the manufacturer in commercial packages.

Obtaining the signature of patrons on a form requesting non-safety containers is not required by law but is a protection for pharmacist.

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#### **ITEM 313—PRODUCT SELECTION LAW EFFECTIVE JANUARY 1, 1980**

In the prior issue pharmacists were informed of a new law effective the first of the year allowing product selection by pharmacists in some cases. The law requires a two line form for prescriptions and permits product selection unless dispense as written or DAW is specified on the prescription.

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**FOR YOUR INFORMATION:** Our newsletter masthead, designed by NABP, is composed of three symbols, each representing a facet of this publication's purpose. The bowl of hygieia, representing the profession of pharmacy, is combined with the Roman fasces, symbol of authority, and the state seal. Together, these three emblems characterize the legal and professional duties which are entrusted by the citizens of this state in the board of pharmacy.

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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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