

# 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 603 — Ballots Due By May 15th For Board Member Election**

Each Spring there is an election for at least one position on the board of pharmacy. This year the northeast and south central regions of the state are due for an election. Pharmacists residing in either of these regions can have their name placed on the ballot by committee selection by a committee or through a petition from ten pharmacists in the region.

President Lloyd appointed the following committees to nominate at least two pharmacists from their region: northeast-Bill Adams, Jimmy Jackson, Pam Joyner and Don Peterson; southcentral-Jesse Pike, Gary Judd, Debbie Edwards and Tom Dagenhart.

The committee for the northeast region met in Southern Pines on February 10th and nominated two candidates. Petitions were received from five additional candidates as of the copy deadline for this Newsletter. The south central region met in Charlotte on February 27th and nominated six individuals for the ballot. As of the copy deadline for this Newsletter, the candidates had not yet consented to have their names placed on the ballot as required by Board regulation.

A ballot and return envelope is enclosed. Please return the marked ballot to the Board office prior to May 15th. Ballots will be tallied immediately following the regular reciprocity session in the Carolina Inn Chapel Hill at approximately 5 p.m. Interested pharmacists are welcome to attend.

## **Item 604 — Disciplinary Actions Of The Board**

September: Pre-Hearing Conferences Held. Accepted by the Board. *Jeffrey Pribyl*, Hendersonville. Violations of state statute involving insurance fraud. Probation of license for two years with conditions. *James P. Rice*, Conover. Misbranding. Official Board Reprimand. *Hugh Kenneth Idol*, Raleigh. Suspected use of controlled substances. Forego a hearing providing agreement to unannounced urine screens on four occasions per year for the next two years.

November: *Francis E. Raper & Raper Drugs*, Goldsboro. Ten counts of unlawful refillings of a controlled substance. License suspended for 14 days, stayed for three years with conditions. No action taken on pharmacy permit.

January: *Thomas H. Lever, III*, Matthews. Pled guilty to three felonies in connection with the practice of pharmacy or the distribution of drugs; appropriating and dispensing prescription drugs without valid prescriptions; failing to keep and maintain adequate records of the dispensation of prescription drugs; failure to carry out adequately his duties as pharmacist-manager. License revoked. *Helen Copening*, Lenoir. Appropriating Schedule IV controlled substances for her own use without obtaining authorization from a physician. License suspended six months, stayed five years with specific conditions pertaining to a prescribed program of treatment. *David A. Perdue*, Charlotte. Failing to carry out adequately his duties as pharmacist-manager of a pharmacy. No action taken.

## **Item 605 — Quarterly Query**

Child-resistant containers are to be used:

- I. For all oral legend drugs for human use except Nitroglycerin and Isordil products.
- II. Unless a non-child-resistant container is requested by the patient.
- III. Unless a non-child-resistant container is requested by the pharmacist.

Answers: 1. I only. 2. II only. 3. III only. 4. I and II only. 5. I, II and III.

## **Item 606 — Don't Forget The Trade**

The Prescription Drug Marketing Act of 1987 provides stiff penalties for violations. It is a violation to buy, sell, or trade prescription drug samples. Pharmacists may not recognize some formerly common business practices as "trading".

The practice of giving credit on a bill for a box of samples is clearly "trading" samples. Replacing outdated merchandise with samples is also clearly within the meaning of "trading" samples. A violation of the Act can result in a fine of \$250,000 and/or ten years in prison.

## **Item 607 — August Board Meeting**

The Board will hold its regular monthly meeting August 22, 1989

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## **CONDITIONS UNDER WHICH HOMEOPATHIC DRUGS MAY BE MARKETED**

*The following is the second half of a two-part article on the Food and Drug Administration's compliance policy regarding Homeopathic Drugs. This information was provided to NABP by the FDA in response to a number of requests regarding FDA's policy on this subject. The first half of the article appeared in last quarter's newsletter. We hope that this information will minimize the confusion and misconceptions regarding homeopathic products.*

### **PRESCRIPTION DRUGS**

The products must comply with the General Labeling Provisions listed in last quarter's newsletter, as well as the provisions for prescription drugs below.

**Prescription Drug Legend** — All prescription homeopathic drug products must bear the prescription legend, "Caution: Federal law prohibits dispensing without prescription," in conformance with Section 503(b)(1) of the Act.

**Statement of Identity** — The label shall bear a statement of identity as provided for under 21 CFR 201.50.

**Declaration of Net Quantity of Contents and Statement of Dosage** — The label shall bear a declaration of net quantity of contents as provided in 21 CFR 201.51 and a statement of the recommended or usual dosage as described under 21 CFR 201.55.

**General Labeling Requirements** — The labeling shall contain the information described under 21 CFR 201.56 and 21 CFR 201.57. A package insert bearing complete labeling information for the homeopathic practitioner must accompany all homeopathic products.

### **OTC DRUGS**

Product labeling must comply with the General Labeling Provisions and the provisions for OTC drugs listed below, as current labeling stocks are depleted, or by June 11, 1990, whichever occurs first.

**Principal Display Panel** — The labeling must comply with the principal display panel provision under 21 CFR 201.62.

**Statement of Identity** — The label shall contain a statement of identity as described in 21 CFR 201.61.

**Declaration of Net Quantity of Contents** — The label shall conform to the provisions for declaring net quantity of contents under 21 CFR 201.62.

**Indications for Use** — The labeling for extemporaneously compounded OTC products and those products offered for OTC retail sale must bear at least one major OTC indication for use, and must be stated in terms likely to be understood by lay persons. For combination products, the labeling must bear appropriate indication(s) common to the respective ingredients. Industry must

comply with the provisions concerning indications for use as current labeling stocks are depleted, or by June 11, 1990, whichever occurs first.

**Directions for Use** — See the General Labeling Provisions.

**Warnings** — OTC homeopathic drugs intended for systemic absorption, unless specifically exempted, must bear a warning statement in conformance with 21 CFR 201.63(a). Other warnings, such as those for indications conforming to those in OTC drug final regulations, are required as appropriate.

### **PRESCRIPTION/OTC STATUS**

The criteria specified in Section 503(b) of the Act apply to the determination of prescription status for all drug products, including homeopathic drug products. If the HPUS specifies a distinction between nonprescription (over-the-counter (OTC)) and prescription status of products which is based on strength (e.g., 30x) - and which is more restrictive than Section 503(b) of the Act - the more stringent criteria will apply. Homeopathic products intended solely for self-limiting disease conditions amenable to self-diagnosis (of symptoms) and treatment may be marketed OTC. Homeopathic products offered for conditions not amenable to OTC use must be marketed as prescription products.

### **HOME REMEDY KITS**

Homeopathic home remedy kits may contain several products used for a wide range of conditions amenable to OTC use. When limited space does not allow for a list of those conditions on the labels of the products, the required labeling must appear in a pamphlet or similar informational piece enclosed in the kits. However, as a minimum, each product must also bear a label containing a statement of identity and potency.

### **OTHER REQUIREMENTS**

All firms which manufacture, prepare, propagate, compound, or otherwise process homeopathic drugs must register as drug establishments in conformance with Section 510 of the Act and 21 CFR 207. Further, homeopathic drug products must be listed in conformance with the sections above. (*Note:* For a given product, variations in package size and potency are not required to be listed on separate forms 2657 but instead, may be listed on the same form). Homeopathic drug products must be packaged in accordance with Section 502(g) of the Act and manufactured in conformance with current good manufacturing practice (Section 501(a)(2)(B) of the Act and 21 CFR 211). However, due to the unique nature of these drug products, some requirements of 21 CFR are not applicable, as follows:

1. Section 211.137 (expiration dating) specifically exempts homeopathic drug products from expiration dating requirements.

# Compliance News

Compliance News to a particular state or jurisdiction should not be assumed (regarding the law of such state or jurisdiction.)



2. Section 211.165 (testing and release for distribution): In the *Federal Register* of April 1, 1983 (48 FR 14003), the Agency proposed to amend 21 CFR 211.165 to exempt homeopathic drug products from the requirement for laboratory determination of identity and strength of each active ingredient prior to release for distribution.

Pending a final rule on this examination, this testing requirement will not be enforced for homeopathic drug products.

## REGULATORY ACTION GUIDANCE

Those firms marketing homeopathic drugs which are not in compliance with the conditions described above will be considered for regulatory follow-up. In general, minor misbranding violations should be considered as a basis for issuance of a Notice of Adverse Findings Letter (NAF Letter) or, if imports, Release with Comment. The Office of Compliance, HFD-304, Center for Drug Evaluation and Research, should be consulted before such letters are issued.

Those homeopathic drug products which are not in compliance and do not meet the criteria for issuance of an NAF Letter are candidates for the issuance of Regulatory Letters, and should be referred to the Office of Compliance, HFD-304, for review.

Recommendations for the issuance of regulatory letters or other regulatory sanctions must be submitted in accordance with the *Regulatory Procedures Manual* and other Agency guidelines concerning the review of regulatory actions.

## PICTOGRAMS ASSIST IN PATIENT COMPLIANCE

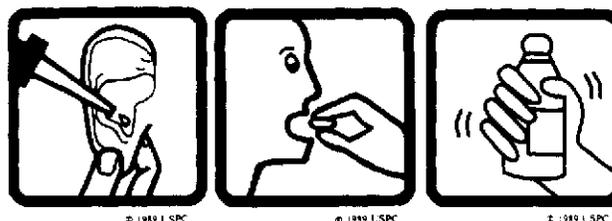
The problem of illiteracy extends far beyond the classroom. Its prevalence in our society is high, and the consequences unfortunate. Illiteracy is not always readily apparent. Its manifestations may be as subtle as a patient asking you to complete his check because he left his glasses at home.

Illiteracy affects pharmacists because illiterate patients cannot read the prescription labels on their medication containers. Without proper counseling, such patients are not likely to be able to comply with the therapy prescribed for them.

*USP DI* is addressing this problem with pictograms. The 1989 edition of *USP DI* includes simple line drawings that represent common directions about using drugs appropriately. Pictograms draw on the international geometric shapes for communicating. A circle with a diagonal line through it means "do not." Precautions are represented within triangles. Pictograms within rectangles show basic information about medication use.

While pictograms can be important parts of communicating with illiterate patients, they can be misinterpreted. Verbal counseling is therefore even more important when a pharmacist dispenses a prescription accompanied by pictogram instructions.

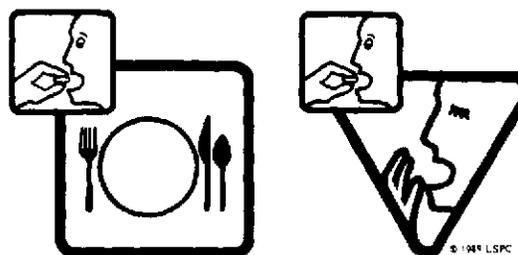
Some examples of pictograms follow. More can be found beginning on page 1345, Appendix III of the 1989 *USP DI*. These pictograms are being presented to the public for the first time, and are considered draft versions. USP welcomes your comments, reactions, and ideas.



Place drops in ear

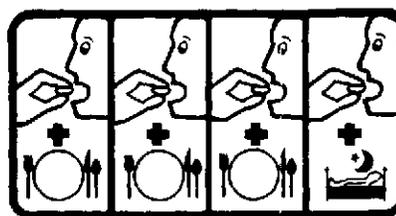
Take by mouth

Shake well

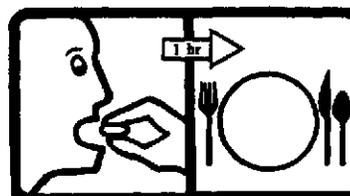


Take with meals

This medicine may make you drowsy



Take 4 times a day, with meals and at bedtime



Take 1 hour before meals

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### **Item 608 — Prescription Drugs And Physical Therapists**

On several occasions, the Board of Pharmacy has discussed at length, the provision of prescription drugs to physical therapists. Physical therapists are now beginning to use prescription drugs in their practice, and the Board was queried by a pharmacist on the legality of providing prescription drugs to these individuals. After considering and reconsidering the matter, the board has adopted the position that pharmacists can provide prescription drug products to a physical therapist for use by that therapist in the treatment of a patient, provided that a physician has ordered the drug.

### **Item 609 — FDA Begins Drug Quality Reporting System**

In November 1988, the Food and Drug Administration announced their initiative to obtain information about problems experienced with drug products. Any problems with drug products discovered by a pharmacist can be reported directly to the FDA at 800-FDA-1088. A peel-off label with this information is enclosed with this Newsletter. Place it in location in your pharmacy.

### **Item 610 — Prescription Transfer Regulations**

Several years ago, the Board adopted regulations on the transfer of prescriptions for refill purposes (see 21 NCAC 46.1806). Inspectors report that pharmacists need to be reminded that when a prescription is transferred it must be cancelled at the original location (see section 1806(a)(1)).

The regulation is permissive in nature and does not require a pharmacist to transfer the prescription. If the request for transfer is refused, the requesting pharmacist can always contact the prescriber and obtain a new prescription. This can result in the patient having two, or perhaps more, active prescriptions if the physician is not alert to the situation.

The regulations provide that transfer must be from pharmacist to pharmacist and cannot be accomplished by accessing a common data base. It clearly prohibits prescription transfer by technicians or unlicensed clerks. The Board staff has no objection to interns participating in the prescription transfer process as part of their experience requirement.

The answer to the Quarterly Query, Item 605 is 4, I and II only.

### **Item 611 — Legislature In Session**

Although material must be submitted for this Newsletter one month prior to publication, it's a safe prediction that the North Carolina General Assembly is usually considering some newsworthy topic in April. As a citizen you may have an interest in a specific issue and want to contact your representative in Raleigh. If you don't know who to contact or how to reach your representative, contact Mr. Al Mebane at the North Carolina Pharmaceutical Association at 800-852-7343.

State law prohibits the North Carolina Board of Pharmacy from supporting or opposing legislation.

### **Item 612 — Inventory Of Controlled Substances Due On May 1st**

Federal regulations provide for a biennial inventory of controlled substances, and many pharmacies have adopted the standard May 1 date for this activity. The inventory record for each controlled substance in finished form must contain the name of the controlled substance, the dosage form and unit strength, the number of units of volume and the number of commercial containers. The Board of Pharmacy has a form for this purpose, which is available at a charge of \$3. Any form can be used, there should be an indication when the inventory is taken, (at the opening or closing of business) on the inventory day.

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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