

October 3, 1997

Michael A. Friedman, MD
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Over-The-Counter Human Drugs: Proposed Labeling Requirements [Docket Nos. 96N-0420, 92N-454A, 90P-0201, and 95N-0259]

Dear Doctor Friedman:

Each of the undersigned physician organizations is in the process of reviewing the Food and Drug Administration's (FDA) Proposed rule, "Over-The-Counter Human Drugs: Proposed Labeling Requirements" (*Federal Register* 62: 9024-9062, [February 27] 1997). However, our organizations are deeply concerned by the FDA's suggestion that the phrase "Ask your doctor" be changed to "Ask your doctor or pharmacist" on over-the-counter (OTC) drug product labeling for certain products, as discussed on page 9039 of the Proposed rule. Therefore, we wish to express our collective and emphatic opposition to this specific proposal at this time.

Our organizations believe that pharmacists can be very helpful to consumers in selecting OTC drug products. For example, a knowledgeable pharmacist can help consumers understand the differences between the analgesics aspirin, acetaminophen, and ibuprofen. Furthermore, consumers and pharmacists should be free to dialogue about OTC drug products. For example, a consumer may wish to share personal health information with a pharmacist in order to make a more informed decision about the purchase of an OTC drug product. However, only the physician has the full medical history that may significantly affect any medical decision the physician makes regarding the individual patient.

We are especially concerned about problems that may emerge while the consumer is taking the OTC drug product that will require a medical evaluation and decision by a physician. Therefore, our organizations vigorously oppose any regulatory change in FDA-approved OTC drug product labeling that would revise the phrase "Ask your doctor" to "Ask your doctor or pharmacist." Such a change in OTC drug product labeling would inappropriately elevate the pharmacist to the same level as the physician regarding both the evaluation of patient-specific conditions, symptoms, side effects, concomitant therapies, and "off-label" dosages associated with the use of OTC drug products and the provision of diagnostic and treatment recommendations to individual patients.

The following three examples from current OTC product labels illustrate why consumers should be referred only to their physicians:

- Under the **Dosage and Administration** section of the OTC labeling for **ADVIL^R Tablets and Caplets**, there is the following statement: *"If pain or fever does not respond to one tablet or caplet, two tablets or caplets may be used but do not exceed six tablets or caplets in 24 hours unless directed by a doctor."* Failure to respond to the maximum recommended OTC dosage may signal a more serious condition (e.g., rheumatoid arthritis; pneumonia or other infection) for which a physician, but not a pharmacist, is adequately trained to evaluate and diagnose. Furthermore, exceeding the maximum recommended OTC dosage constitutes a prescribing decision that should only be made by a

physician who is licensed to prescribe medications. That ibuprofen tablets of strengths greater than 200 mg are prescription only products reinforces this point.

- Under the **Warning** section of the OTC labeling for **BENADRYL^R Allergy Decongestant Tablets**, there is the following statement: "*If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor.*" Any of the listed symptoms may signal a more serious condition or be side effects of the OTC drug product. Only a physician is qualified to evaluate and diagnose the patient who presents with such symptoms, since only the physician has the full medical history regarding the individual patient.
- Under the **Warning** section of the OTC labeling for **TAGAMET HB^R 200 Acid Reducer/Cimetidine Tablets 200 mg**, there is the following statement: "*If you have trouble swallowing, or persistent abdominal pain, see your doctor promptly. You may have a serious condition that may need a different treatment.*" Any of the above symptoms may signal a more serious condition (e.g., reflux esophagitis; peptic ulcer disease). Only a physician is qualified to evaluate and diagnose the patient who presents with such symptoms.

Many additional examples can be found in current labels for OTC drug products where a statement to ask or consult the physician, but not the pharmacist, is appropriate. In fact, we could not identify any examples where the addition of the pharmacist would provide greater benefit to the consumer.

Of the two health professionals, only a physician is adequately trained in areas such as medical history-taking, physical examination, clinical diagnosis, and medication prescribing to make the kinds of decisions required when OTC drug product labeling instructs the patient to "Ask your doctor" or "Consult a doctor." To expand this phrase to include the pharmacist will inappropriately place the pharmacist in a position for which he/she is not qualified, confuse patients, undermine the patient/physician relationship, and potentially jeopardize the health of some patients by delaying needed diagnosis and treatment.

In conclusion, our organizations strongly urge that the FDA not move forward with any regulatory change in FDA-approved OTC drug product labeling that would change the phrase "Ask your doctor" to "Ask your doctor or pharmacist." Thank you for the opportunity to comment on this vitally important issue.

Sincerely,

American Academy of Child & Adolescent Psychiatry
 American Academy of Dermatology
 American Academy of Facial Plastic & Reconstructive Surgery
 American Academy of Family Physicians
 American Academy of Neurology
 American Academy of Otolaryngology - Head & Neck Surgery
 American Academy of Physical Medicine & Rehabilitation
 American Association of Clinical Endocrinologists
 American Association of Neurological Surgeons
 American College of Cardiology
 American College of Chest Physicians
 American College of Emergency Physicians
 American College of Nuclear Medicine
 American College of Occupational & Environmental Medicine
 American College of Rheumatology
 American Medical Association
 American Osteopathic Association
 American Psychiatric Association
 American Society for Dermatologic Surgery
 American Society for Gastrointestinal Endoscopy