

## **Nonprescription Drugs Advisory Committee Meeting**

June 12, 2003

Ipecac syrup has been available as an over-the-counter drug product under the Code of Federal Regulation 201.308 since Oct 27, 1965. Prior to this regulation, controversy existed regarding OTC status for ipecac syrup because it was felt that it should only be used under medical supervision, but it was also recognized that the immediate availability of ipecac syrup for use in poisoning emergencies necessitated easy and quick availability for consumers. Therefore, in its deliberations prior to codifying 201.308, the Food and Drug Administration obtained the views of medical authorities. It was the unanimous recommendation of the American Academy of Pediatrics, the American Association of Poison Control Centers, the American Medical Association, and the Medical Advisory Board of the Food and Drug Administration that ipecac syrup should be permitted to be sold without prescription so that it would be readily available in the household for emergency treatment of poisonings. The Commissioner of Food and Drugs determined that it was in the interest of public health for ipecac syrup to be available for sale without prescription with labeling that stated, "Before using, call physician, the Poison Control Center, or hospital emergency room..."

The use of gastric emptying in the management of poisoned patients has declined in recent years. Some societies and published literature reports are now questioning whether there is sufficient evidence of benefits of ipecac syrup in treatment of poison that outweighs the potential for misuse, abuse and adverse effects associated with its availability as an over-the-counter drug. These opponents suggest that since there is limited potential for use of ipecac syrup in the management of poisoned patients, the possibility of morbidity/mortality and abuse merit a re-evaluation of the current non-prescription status of ipecac syrup.

This package contains: 1) The regulatory background of ipecac syrup, 2) A brief clinical summary with selected references, and 3) A summary of MedWatch reports from The Office of Drug Safety. Four content experts will present their analysis of the clinical literature at the meeting. As NDAC committee members consider the information provided in this briefing document and in the meeting presentations they should prepare to address the Discussion Points listed below.

### **Draft Discussion Points**

1. Discuss the role of Gastrointestinal Decontamination (GID) in poison management.
2. Is the evidence available in the literature of adequate quality and quantity to establish the risk:benefit ratio of ipecac syrup?
3. Is the availability of emergency medical treatment (rural vs. urban setting) clinically relevant to whether Ipecac syrup is used for GID in poison management?
4. Should Ipecac syrup retain OTC status for use by consumers to treat accidental poisoning?