DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Rockville MD 20857

SEP 15 2003

Dr. Douglas Borys, Pharm.D.
President
The American Association of Poison Control Centers
3201 New Mexico Avenue, Suite 330
Washington, DC 20016

Docket No. 81N-0050

Dear Dr. Borys:

This letter is in follow-up to FDA's June 12, 2003 Advisory Committee meeting concerning the over-the-counter (OTC) status of ipecac syrup. We are requesting your assistance in obtaining additional information.

The Non-Prescription Drugs Advisory Committee met on June 12, 2003 to consider the safety and efficacy of ipecac syrup and to advise the FDA whether to continue its OTC status under 21 CFR 201.308. Ipecac syrup has been available without a prescription as an OTC drug product for use in the emergency treatment of poisonings since 1965. At that time the commissioner of FDA determined that it was in the interest of the public health to make ipecac syrup available OTC based on the views of medical authorities and the recommendations 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. In 1985, FDA published a Tentative Final Monograph (TFM) entitled "Poison Treatment Drug Products for Over-the-Counter Human Use" (50 FR 2244) in which ipecac syrup was the only active emetic ingredient classified as Category I (safe and effective) as an OTC poison treatment drug ingredient. Over the years, consumers have used ipecac syrup for home treatment of accidental poisonings.

Currently the safety and efficacy of ipecac syrup has been called into question by some medical authorities and poison experts. For example, The American Academy of Clinical Toxicology (AACT) and the European Association of Poison Control Centers and Clinical Toxicologists issued a position statement in 1997 that stated that data are lacking to demonstrate that ipecac improves the outcome of poisoned patients. This position has been endorsed by the American Board of Applied Toxicology and the Canadian Association of Poison Control Centers.

FDA is in the process of completing the final monograph for poison treatment ingredients and asked the Non-Prescription Drugs Advisory Committee for a discussion of pertinent issues including whether ipecac syrup should retain OTC status for home use to treat accidental poisonings. The Advisory Committee voted 6 to 4 that ipecac syrup should not retain its OTC status. The Committee heard anecdotal evidence to suggest benefit from ipecac syrup but felt that data was lacking on its effectiveness and there was little solid evidence that it has a beneficial effect on outcome when used to treat accidental poisonings in the home. Their decision was also influenced by ipecac's potential to cause adverse events and by its use by those with eating disorders. However, some members of the committee felt that ipecac syrup must be of value in certain situations and may be of benefit to a subgroup of patients yet to be defined.

It was reported at the June 12th meeting that there were approximately 16,000 cases last year reported by poison control centers where ipecac syrup was recommended for home use and the Advisory Committee felt that the details of these cases, particularly the type of poisonings, the outcomes and adverse events, and follow-up of these patients that ingested ipecac, would be very useful to FDA in its deliberations regarding the OTC status of ipecac. Please consider analyzing your database and providing information that would respond to the following questions:

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1. In what types of poisonings was ipecac syrup used?

2. Who recommended the home use of ipecac syrup (i.e. poison control center, health care provider) and why?

3. What were the outcomes of these poisonings?

4. How did the outcomes of these poisonings compare to similar cases where ipecac syrup was not recommended?

5. Were there adverse events associated with the use of ipecac syrup?

6. Will these data be used by your society in the development of a future position statement?

7. Will you be publishing the results of this analysis so that other societies can use this information in formulating their position statements?

FDA is considering several options and these data could make a very important contribution toward our final decision. Also, we would like to know if there is consensus among the Association of Poison Control Centers on the use of ipecac syrup in the treatment of poisoning and if it should retain OTC status.

Please submit the analysis of the data and answers to our questions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD, 20852. Electronic comments may be submitted to http://www.fda.gov/dockets/ecomments. Any submissions should be identified with the docket number shown at the beginning of this letter. You can contact Arlene Solbeck, Interdisciplinary Scientist, at 301-827-2297 if you have any questions or comments.

Thank you for your assistance.

Sincerely yours,

Curtis Rosebraugh, M.D., M.P.H.
Division of OTC Drug Products
Deputy Director
Office of Drug Evaluation V
Center for Drug Evaluation and Research

cc: Consumer Healthcare Products Association (CHPA)

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: SEP 24 2003

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 81N-0050

TO: Dockets Management Branch, HFA-305

☒ The attached material should be placed on public display under the above referenced Docket No.

☐ This material should be cross-referenced to Comment No. _____

Charles J. Ganley, M.D.

Attachment