



MAR 28 2007

Joshua M. Sharfstein, M.D.
Commissioner of Health
Baltimore City Health Department
210 Guilford Avenue, 3rd Floor
Baltimore, Maryland 21202

RE: Docket No. 2007P-0074
Comment No. CP1

Dear Dr. Sharfstein and other Petitioners,

This letter pertains to your citizen petition, submitted to FDA on March 1, 2007, filed under Docket No. 2007P-0074 in the Division of Dockets Management. The petition requests FDA to take several actions related to over-the-counter (OTC) cough and cold drug products for children under 6 years of age. In order to consider and address the issues raised in your petition, we would like clarification and additional information on the following matters:

1. The safety discussion in the petition focuses on cases of misuse, unintentional overdose, and excessive dosing of OTC cough and cold drug products. Your petition does not address the safety of OTC cough and cold drug products for children under the age of 6 when used in accordance with the labeled instructions. Please provide any data or information of which you are aware concerning the safety of these ingredients if these ingredients are used as directed on the label.
2. The petition cites several references that describe clinical efficacy studies in children. The petition concludes that these studies demonstrate that the drug products are not effective for the treatment of cough or cold symptoms. As noted in some of the Federal Register notices cited in your petition, conducting successful clinical efficacy studies in children with symptoms of cold or allergic rhinitis has always been difficult because of the limited ability of children to subjectively quantify the severity of their symptoms. Because of this, FDA has extrapolated efficacy data from adults to children, not only in the OTC monograph for cold and cough drug products, but also for the approval of pediatric indications for NDA products when the studies conducted in children failed to establish a significant effect of active therapy over placebo. Do you have comments on the use of extrapolation of efficacy data from adults to children?

The petition emphasizes the lack of efficacy of cold and cough products in children under the age of 6. Given that the extrapolation of efficacy from adults to children has been used to determine efficacy for all children ages 2 through 12, please clarify

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why you have limited your comments to children less than 6 years.

3. The petition proposes that the labeling of cough and cold products include the following statement: "These products have not been found to be safe or effective in children under 6 years of age for treatment of cough and cold. These products should not be used for treatment of cough and cold in children under 6 years of age."

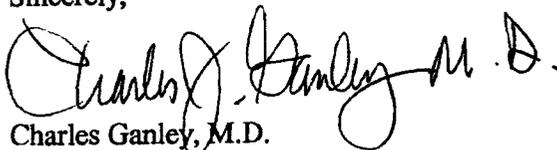
Please clarify what impact you expect such labeling to have on physicians' ability or decision to prescribe cough and cold medications for children under 6 years of age.

4. The petition lists reference 23, cited to support the statement that "[i]n 2004, approximately 900 children under the age of 5 overdosed on OTC cough and cold medications in Maryland[,] as a correspondence from the Maryland Poison Control Center. Please submit a copy of the correspondence, and provide more details on the content of this correspondence, specifically:
 - a. Did the cases include cases of accidental overdose?
 - b. Was there any analysis conducted that identified the root cause of these cases?
 - c. Was there any data provided that describes the outcome of these cases?
 - d. Did any of these cases occur with therapeutic doses?
5. The petition lists reference 24, cited to support the statement that "...over the last five years in Baltimore City, the medical examiner has linked at least four deaths of children under 4 years old to unintentional overdoses of OTC cough and cold combination drug products[,] as a correspondence from the Maryland Office of the Chief Medical Examiner. Please provide a copy of this correspondence, and provide a description of the history of the four cases of death in children less than 4 years of age related to unintentional overdose, including any information that assisted in the determination that the deaths were linked to the use of the cough and cold products.

Please submit your response to this letter to the FDA Division of Dockets Management directed to Docket No. 2007P-0074. If you have any questions concerning this letter, you may contact Walt Ellenberg, Ph.D., at 301-796-2060.

The issues raised in this petition may be the subject of a future public discussion. If FDA proceeds with a public discussion, appropriate public notice and opportunity to participate will be provided.

Sincerely,



Charles Ganley, M.D.

Director

Office of Nonprescription Products

Center for Drug Evaluation and Research