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July 10, 2008

Dr. Janet Woodcock
Director, Center for Drug Evaluation and Research (HF-2)
Food and Drug Administration
10901 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Woodcock:

Thank you for the opportunity to discuss with you our current plans to address labeling issues regarding OTC oral pediatric cough and cold medicines. CHPA and its member companies who make oral pediatric cough and cold medicines strongly believe that the current data support the safety and efficacy of these medicines when used as directed; however, we are committed to working with FDA to better enhance consumer use of these products. Understanding the agency's ability to exercise enforcement discretion on labeling that goes beyond that currently required under the relevant monographs, our members plan to proceed with the following label changes:

Changes Within the "Drug Facts" Label

1. and 2. Label directions for children under age four. Companies would change "children under 2 years of age: ask a doctor" to "children under 4 years of age: do not use" in the directions section of all OTC oral pediatric cough and cold medicines under the relevant monographs. Secondly, for cough and cold products with a monograph antihistamine where current label directions read "ask a doctor" for children under 6 years of age, companies would add "do not use" for children under 4 years of age.

3. Cold products containing monograph antihistamines with labeling for children. Companies would add an additional statement to the directions section of the label of OTC oral cough and cold products containing a monographed antihistamine to read: "do not use unless directed by a doctor" in place of the existing direction to "ask a doctor" in children under 6 years of age.

4. Products containing monograph antihistamines with labeling for children. Companies would add a warning to the warnings section of the label for all OTC oral medicines containing a monographed antihistamine (whether for coughs and colds, or allergies) to read: "Do not use to sedate children" or, alternatively, "Do not use to make a child sleepy".

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Since these changes go *beyond* the label language required under the relevant cough and cold monographs or other label regulations, as opposed to departing from them, we would appreciate an indication from you on the agency's willingness to exercise enforcement discretion and not act against products labeled with these changes.

Illustrations of labels with these changes are attached (not all elements are to scale, and one of the labels does not include inactive ingredients): one with a monographed antihistamine and a cold indication, and a second with a cough suppressant and nasal decongestant.

Additional Labeling Change

1. **Principal display panel.** Companies plan to add the name of active ingredients in pediatric oral cough cold combination products to the principal display panel of packages, adjacent to the purposes.

These label changes will have a positive impact on the safe and responsible use of oral cough and cold medicines. With FDA's discretion, we look forward to moving ahead.

Sincerely,


Linda A. Suydam, D.P.A.
President

Attachments: 2 label illustrations