



Consumer Healthcare Products Association
Attn: R. William Soller, Ph.D.
Senior Vice President and
Director of Science and Technology
1150 Connecticut Avenue, N.W.
Washington, DC 20036

September 21, 1999

Re: Docket No. 98N-0337

Dear Dr. Soller:

This letter is written to follow-up on procedural issues discussed in our OTC Labeling Final Rule working group meeting on September 17, 1999.

The next working group meeting to discuss issues related to the OTC Labeling Final Rule is scheduled for November 1, 1999. In the interest of a productive working session, we will discuss one or two issues that have been clearly identified and outlined prior to the meeting. We intend to identify these issues from proposed topics for discussion prior to developing the agenda several weeks in advance of the meeting.

In order to promote positive working conditions and to maximize our ability to come to closure on these identified issues as soon as possible, we suggest that you submit your proposals for the topic(s) of discussion for the November 1, 1999 meeting by September 30, 1999. Proposals should be specific so that the objectives of the meeting can be clearly outlined. After reviewing all proposals, the Division of Over-the-Counter Drug Products (DOTCDP) will outline the agenda for the working group discussion. Once the agenda is developed, presenters will be asked to provide any supporting material (e.g., handouts, slides, specific issue development) to identified meeting participants, including FDA representatives, at least two weeks in advance of the scheduled meeting. If the Division has not received the supporting documentation needed to conduct a productive meeting within this time frame, the meeting may have to be substituted, postponed, or cancelled by the Director, DOTCDP.

We look forward to future productive working group interactions on this important public health initiative.

Sincerely yours,

/S/

Charles J. Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research