

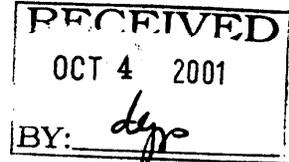


Producers of Quality
Nonprescription Medicines and
Dietary Supplements for Self-Care

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

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October 4, 2001



Charles J. Ganley, M.D.
Director, Division of OTC Drug Products
Food and Drug Administration
9201 Corporate Boulevard, S205 (HFD-560)
Rockville, MD 20850

VIA FAX

RE: Request for Meeting

Dear. Dr. Ganley:

Based on our task group's review of information pertaining to potential AERs related to OTC drug product use, we request a meeting with FDA to address approaches to cross-dosing and use as recommended on the label.

Among the areas for dialogue are:

- Methodological issues related to retrospective research to determine why consumers may undertake cross-dosing or use a product inconsistent with product labeling.
- Potential research options for labeling and public education solutions to issues related to cross-dosing and use according to label directions.

Our group is prepared to meet with your team in the very near future, and we suggest the following dates, but are open to your suggestions: the morning of October 10, the afternoon of October 12 or October 15. We anticipate that our meeting should last about two hours.

We would like to suggest that the individuals who attended the last Scientific Dialogue on September 19th might be a good starting point for deciding on the attendance list. From our end, certain members from our Task Group will attend to help facilitate in the discussion.

I look forward to your response.

Sincerely yours,

R. William Soller, Ph.D.
Senior Vice President
and Director of Science & Technology

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