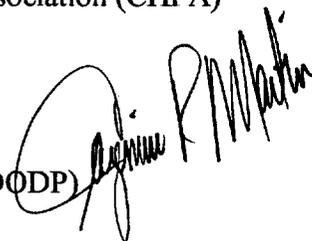


**MINUTES OF
TELEPHONE CONVERSATION**

DATE: May 13, 1999

BETWEEN: R. William Soller, Ph.D. 3 6 5 2 '99 MAY 27 P 1 :03
Consumer Healthcare Products Association (CHPA)
Telephone: 202-429-9260

AND: Cazemiro R. Martin, HFD-560
Food and Drug Administration
Division of OTC Drug Products (DODP)



SUBJECT: May 6, 1999 CHPA letter to the Division of OTC Drug Products requesting the use of column formatting as an alternative to the formats described in the new OTC labeling final rule (64 FR 13254).

Discussion points:

- Agency is continuing to review CHPA's request concerning the use of column formatting.
- CHPA clarified that the purpose of the column format would be to enable manufacturers to provide labeling in the standard format or modified format when labeling just exceeds either of these format designs. For example, if a manufacturer's labeling exceeds the modified format, a column format may avoid the need to submit a "Request for Exception."
- CHPA expressed their intention to provide examples to demonstrate the applicability of column formatting, particularly for those OTC products with labels too small to accommodate the standard and modified format requirements.
- FDA informed CHPA of concerns regarding the column formatting and examples (A, B, C, and D) attached to the May 13, 1999 CHPA letter. These were:
 - All examples submitted by CHPA used the modified format, even though many of these examples appeared to be able to fit the standard labeling format as described in section 201.66.
 - Example C had been previously reformatted in the standard labeling format and included as one of 31 labels filed in the public administrative record for this new labeling regulation.

Action Items:

- Based on CHPA's response and telecon clarifications, FDA requested that CHPA provide the Division with one or more examples of actual small package labeling formatted in the column format and to also include an example of a small package label that cannot fit either the standard or modified format included in section 201.66.
- FDA agreed to expeditiously review this issue upon receipt of these examples.

The conversation concluded amicably.

98N-0337

MMI

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:

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

SUBJECT: Material for Docket No. 98N-0337

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. _____.

Debra L. Bowen
Debra L. Bowen, M.D.

Attachment

3651 99 MAY 27 P1:03