

Minutes of Telephone Conversation

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Participants:

Charles Ganley, MD
Director
Division of OTC Drug Products
Food and Drug Administration
5600 Fishers lane
Rockville, MD 20857

To

Richard K. Bourne, Ph.D.
Vice-President – Regulatory Affairs
Block Drug Company
257 Cornelison Ave.
Jersey City, NJ
(201) 434-3000

Date: January 17, 2001

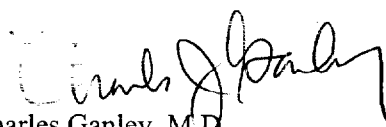
RE: Docket 77N-0094 (Salicylamide)

On January 17, 2001, a call was placed to Richard K. Bourne, Ph.D. (Block Drug Company) from Charles Ganley, M.D. (FDA). Dr. Ganley was returning a call from Dr. Bourne regarding their meeting request of November 7, 2000.

Block submitted protocols in 1989 and 1992 to study aspirin and salicylamide. They appear to have submitted a single study report that apparently contains data from both protocols. Each protocol had separate objectives and separate statistical analytical plans. Block needs to review their submissions to the Agency and clarify what they did in the analysis of these studies compared to what they originally proposed.

Block was given the option of withdrawing their request for the meeting and requesting a teleconference to discuss the issues just outlined or their meeting request would be denied with explanation. They were also told that the outline of a proposed study would not be sufficient to justify a meeting.

Block Drug Company needs to clarify the aforementioned issues before a meeting with the Agency could be considered.


Charles Ganley, M.D.
Director
Division of OTC Drug Products
Food and Drug Administration

77N-0094

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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: 1-19-2001

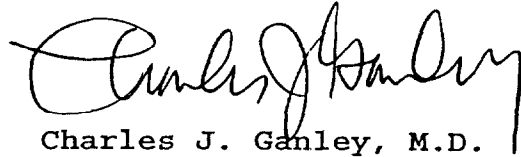
FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 77N-0094

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. _____


Charles J. Ganley, M.D.

Attachment