Johnson & Johnson
BABY PRODUCTS COMPANY

RARITAN, N.J. 08869
June 15, 1977

SUBJECT: Talc Advisory Review Meeting

TO: Distribution

The Talc Advisory Group met on June 8th in the J & J East Research Conference Room with the following in attendance:

Mr. W. H. Ashton
Mr. G. Heinze
Dr. G. Hildick-Smith
Mr. A. J. Huetteman
Dr. L. L. Kaplan
Mr. G. Lee
Dr. G. H. Lord
Dr. J. R. Marshall
Dr. W. Nashed
Dr. F. R. Rolle
Dr. J. P. Schelz
Dr. B. Semple
Dr. W. C. Waggoner

1. Lovelace Study Update

Dr. Waggoner reported that Dr. G. Thompson of the FDA agreed to exchange copies of all the Lovelace Progress Reports for a copy of our Battelle Deposition Study final report. These reports have since been furnished to Dr. Waggoner by June 14th. Bill Waggoner summarized the status of this study as coinciding with the Mokler summary to G. Lee.

Dr. Rolle expressed doubts as to the accuracy of the talc quantitation methodology which relies on magnesium determination.

2. Battelle Macrophage Study

Dr. Semple informed the group that the budget of this project has been increased by a few thousand dollars. A full review report is expected shortly.

3. OTC Misc. External Panel
-Talc

Dr. Semple had no further developments to report concerning the Panel's preparation of its formal submission to FDA.

729-10

4. NIOSH Morbidity Study

No further information has been received from NIOSH concerning the final report of the Mortality Study. Dr. Hildick-Smith has not learned any new information from Drs. Peter or Weigman on the Morbidity study and will check with Dr. Kleinfeld whether there have been any further developments. G. Lee will follow up on Vernon Zeitz and his analysis of the Windsor pulmonary data.

5. OSHA/NBS Asbestos-in-Talc Status

Mr. Ashton brought the group up to date on the NBS testing which concluded that the OSHA/NIOSH procedure for examination is useful only for determining "fiber" content and not "asbestos" content. No J & J affiliated consumer products were included in the sampling.

NBS is organizing a Workshop in Washington July 18-20/77 on "Asbestos: Definitions and Measurement Methods". The program will include a session on "Relationship between Chemical & Physical Properties and Health Effects" with Selikoff-Langer and Stanton as speakers. Krause and Ashton will deliver a paper on "Misidentification of Asbestos in Talc".

G. Lee will convene a task group consisting of Hildick-Smith, Rolle, Ashton and Lee to plan and organize coverage, fact presentation during discussions, etc. MRC tremolite data needs to be surfaced.

G. Lee will contact Dr. N. Estrin and coordinate representation under the banner of the CTFA. J & J will maintain low visibility on asbestos discussions.

6. CTFA Talcum Product Round Robin

Dr. Schelz outlined the status wherein Mt. Sinai has refused to use the CTFA methods. Their written report using Sinai methods has not been received. A retest has been agreed to amongst the company participants and samples will be mailed on or around June 10th. Elaborations of the step II procedure have been prepared for this retest.

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7. JBP Communication Literature

Dr. Waggoner reported on:

a) a 1½ page Talc White Paper has been prepared for the CTFA at their request.

b) the draft of the professional brochure has been restylized and is being held in readiness for publication after the FDA OTC talc monograph has been issued. Photographs are in the process of preparation.

c) the desirability of providing FDA with a package of safety data for JOHNSON'S Baby Powder was unanimously supported. Dr. Waggoner will talk to FDA on the concept of providing a data package which they can furnish to inquirers on request. This packet will consist of published papers and articles.

d) Dr. Waggoner will be sending to the FDA, copy of the Langer "Consumer Talcum Products" paper with the two rebuttals from Dr. Hildick-Smith and Dr. Krause

8. JBP Baby & Adult Exposure Study

The Advisory group agreed that this study should be published, but needs to appear as an adjunct study to the Battelle Inhalation Study for the purpose of establishing multiples of safety.

G. Lee will coordinate preparation of this paper.

9. Francis Roe Editorial

Dr. Hildick-Smith discussed Dr. Francis Roe's proposed talc editorial for the Lancet. Suggestions for amendments were to be presented through Dr. Hildick-Smith.

George Lee

/by

D I S T R I B U T I O N

Dr. J. B. Appino - McNeil

Mr. W. H. Ashton

Dr. G. A. Braun - Ortho

Mr. W. R. Dean - J&J England

Mr. S. P. Falk

Mr. G. Heinze

Dr. G. Hildick-Smith

Mr. A. J. Huetteman - Personal Products

Mr. D. D. Johnston

Mr. W. R. Jones - McNeil

Dr. L. L. Kaplan

Mr. C. E. La Rosa

Dr. G. H. Lord

Dr. J. R. Marshall

Mr. R. N. Miller - Windsor Minerals

Mr. J. Murray

Dr. W. Nashed

Dr. D. R. Petterson

Dr. F. R. Rolle

Mr. A. P. Ruffo - J&J Canada

Mr. R. F. Schwenker
to
Dr. G. K. Morbey - Personal Products

Dr. B. Semple

Dr. T. H. Shelley

Mr. R. L. Steelman - McNeil

Mr. R. C. Stites

Dr. W. C. Waggoner