

BABY PRODUCTS COMPANY

NEW BRUNSWICK, N. J.

September 5, 1975

SUBJECT: Talc Advisory Group Review Meeting
September 3, 1975

The Talc Advisory Group meeting was held in the East Research Conference Room on September 3rd with the following in attendance:

Dr. G. Hildick-Smith	Dr. F.R. Rolle
Dr. L.L. Kaplan	Dr. W.C. Waggoner
Mr. G. Lee	

The meeting was also attended in part by:

Mr. G. Heinze	Dr. J.A. Rafter
Dr. G.H. Lord	Dr. B. Semple
Dr. D.R. Petterson	

1. Battelle Chronic Inhalation Study

Dr. Lord has received 30 copies of the final report and after review has recommended an addition to the conclusions section which would emphasize the multiples of exposure to median use.

Dr. Hildick-Smith requested an appropriate change in the Report Title which would identify the test material more definitely as being talc. The present title reads "Investigation of Effects of Inhaled Baby Powder In Hamsters".

It was agreed that a copy of the final report should be given to Dr. Wagner of the MRC during the Brighton discussions. Dr. Rubino should also receive a copy.

ACTION:

Dr. Lord will discuss feasibility of these report changes with Battelle.

We will also update Dr. Schaffner of the FDA on this study.

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2. Battelle Deposition/Clearance Study

Dr. Lord reported that the Lot 228/P powder for the deposition study will be activated in the Hanford Reactor on September 22nd.

Dr. Waggoner reviewed the status of our response to the Sedatives Panel and the issue of ingestion hazard which has been raised by Selikoff's statement to this Panel. With this question presently being addressed to the Sedatives Panel and possibly in the near future, to the Miscellaneous External Panel, there is a strong probability of talc being placed in Category III. There is an immediate need for us to anticipate this situation by gathering GAVAGE DATA. Dr. Hildick-Smith concurred with this situation analysis and the meeting unanimously recommended launching the gavage study simultaneously with the deposition/clearance study.

ACTION:

Dr. Semple will convene a meeting of interested J&J personnel to derive meaningful doses for the GAVAGE study. This must be carried out before our Brighton discussions with MRC.

3. Rubino Talc Workers Mortality Study

Dr. Rafter presented corrected calculations based on Rubino's raw data.

ACTION:

Dr. Hildick-Smith will discuss the newly interpreted tables with Dr. Rubino at Brighton and a new set of slides will be supplied to him in the event that he should wish to present them at the conference. Dr. Rafter will arrange for slide production through Ken Young.

4. Italian Millers Pulmonary Study

The Rubino proposed study will be put into abeyance and we shall review the need for this type of data after monitoring the tone of the Brighton and Edinburgh meetings.

5. OTC Sedatives Panel

Dr. Waggoner reported that the J&J reply was sent to the Sedatives Panel on July 25th. Our letter has been tabled and will be considered before preparation of the Panel's monograph.

ACTION:

Dr. Semple will send a copy of our response to Dr. Kanig, the Industry Liason member, so that through the Panel, Selikoff would be challenged to offer data substantiating his accusation of ingestion hazard.

6. OTC Contraceptives, Vaginal Product Panel

Dr. Hildick-Smith suggested that we might consider sending the BIBRA animal vaginal implantation report to the panel. We will consult with Mr. W.R. Dean on this proposal.

ACTION:

Dr. Hildick-Smith will discuss this with Mr. Dean at Brighton.

7. USP XIX Talc Dispensing Advice Statement

It is apparent that galley proofs of the XIX Edition Talc advice statement were overlooked during J&J's review. Mr. Heinze recommended writing to the USP Monograph Committee.

ACTION:

Mr. Heinze will write to the USP Director of Revision requesting a modification of the "Do Not Inhale" statement.

8. OTC Antiperspirant Panel

Dr. Hildick-Smith has arranged for manuscripts of the J&J presentations to be transmitted to Dr. Waggoner for suitable distribution.

It was decided that a "package" of talc presentations and study reports will be prepared through Dr. Waggoner's office and held in readiness for distribution to OTC Panels and J&J affiliates on a "as requested" basis. Material will only be sent to OTC Panels during the time of review.

ACTION:

Dr. Waggoner and G. Lee will be responsible for putting the package together.

9. Other OTC Panel Reviews

We anticipate that Talc will be reviewed by the Miscellaneous External Panel and possibly by the Anti-Microbial II Panel (Dr. Semple and Dr. Hildick-Smith, respectively sit on these panels). In order to be posted on other panel deliberations concerning talc, we will request Ms. Claudia Wolbach to alert us to agenda notices.

10. Great Britain Asbestosis Research Council

Mr. Ian Sloan was commended for his most effective and successful handling of the proposed paper "Airborne Fiber Concentrations Generated During the Use of Cosmetic Talcum Powder" by Dr. S. Holmes of the Asbestosis Research Council. Mr. Sloan has persuaded Dr. Holmes that the draft paper should not be published and has arranged for Drs. Hildick-Smith and Rolle to meet with Dr. Holmes in Brighton.

11. NIOSH - Windsor Study

The first medical and environmental examinations have been completed at Windsor. Dr. G. Green has consented to act as our medical consultant.

Dr. Hildick-Smith reported that Dr. Sylwester, statistician on Dr. Green's staff, has criticized Dr. Fine's Regression Analysis treatment in the Rubber Workers Study. Dr. Sylwester agreed to furnish his written critique.

12. Brighton Conference

Dr. Hildick-Smith will chair the evening dinner meeting which will be attended by the MRC personnel, Pooley, Wehner, Rubino, Stefano and J&J staff. We will use this meeting to receive MRC's critique of the various J&J talc data and to draw out MRC's views and thoughts on talc. Possibly, we can get a preview of the MRC Edinburgh presentation. We will avoid discussions of the proposed Rubino prospective study.

ACTION:

Dr. Hildick-Smith will draw up an agenda for prior discussion with Mr. Dean to seek his agreement.

Dr. Hildick-Smith will pre-advise Rubino of our decision to hold his proposal for further consideration.

13. Starch and Other Body Powder

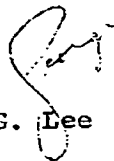
Dr. Petterson stated the need for J&J to establish internal guidelines for safety evaluation of inhalable body dusting powders. This should cover starch, as well as Shower-to-Shower* deodorant powder.

ACTION:

Health Care and Baby Products personnel will meet to prepare general guidelines for safety and toxicity tests.

14. Talc Respirable Particles Removal

The increasing attention to inhalation hazard was seen by the Advisory Group as a requirement for J&J to expedite the development of a talc which would be free or have a minimum of respirable particles. This could provide J&J with a unique safety position which is marketable. P&G is following this approach with regards to the "Zirconium" in antiperspirants toxicity controversy.


G. Lee

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cc: Distribution