Johnson & Johnson
BABY PRODUCTS COMPANY

Safety

RARITAN, N.J. 08869

June 14, 1977

SUBJECT: Ciba-Geigy Purchase of Windsor Talc

To: Mr. D. D. Johnston

Ted undoubtedly filled you in on the situation. At our last contact point, he had left it that the development man at Geigy would call me to give me the details. I have attached some supporting documents, but here is the problem in a nut shell:

1. Ciba-Geigy apparently decided to use Windsor Talc Grade 100 as a pharmaceutical adjunct in the manufacture of Preludin (an anti-depressant normally prescribed only for adults with moderately continuous use). Approximately three years ago, they pleaded with us to supply them more material since they had not cleared another talc for this drug.

2. Roger Miller cannot retrieve a copy of the former Geigy purchase order. He does recall that he was directed by someone in our management to ship the order to Ciba, an action he was not in favor of.

3. In April the Geigy purchasing people got to Ted West in an effort to buy another 20,000 lbs. of talc. In the course of doing so, they sent two purchase orders, one to Windsor, one to New Brunswick. The purchase orders create two problems. First, they state that the talc is USP grade. Windsor talc will sometimes pass the USP test, but we never test product for it, nor is it part of our specification. The second portion of the requirement (present on the New Brunswick copy of the purchase order, but not on the Windsor) was a microbial requirement. While I feel that the Windsor talc would pass that requirement, I am not ready to certify that to Ciba-Geigy.

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Situation at Ciba-Geigy:

Dr. Shibica, who is Vice President of Development and Control, has indicated that the purchasing people had informed his laboratory people sometime ago that a new talc was going to be required for this product. Shibica, however, just found out about it last week. He indicates that he believes it could take between six and twelve months for them to clear a new talc. He was not sure that they had secured new talc samples for evaluation. It is obvious that there was a mix-up between their purchasing people and the laboratory about the necessity of clearing a new talc for this product. My guess is that they will not have ample supply of the Windsor material to carry them through and will therefore have to make a management decision about whether they wish to switch sources of supply.

The FDA Problem:

We investigated the implications of selling a pharmaceutical aid to a drug manufacturer on Windsor. If the talc is used as an aid and not as a drug, Windsor will not have to register as a manufacturer of raw materials for the drug industry. However, it is possible that we may be inspected in the future as a supplier, as a result of any implication of that drug product or an inspection of Ciba-Geigy.

On the other hand, Ciba may purchase a talc which is not certified as USP and then perform their own testing to demonstrate that it meets USP requirements for their use.

Recommendation:

Neither Roger Miller, George Lee, nor I are anxious to sell talc to Ciba-Geigy. I would recommend that we inform them that we do not plan to supply any further talc to the drug industry, regardless of the specification requirements.

If you feel that position is too extreme, I would suggest that we provide them quantities for twelve months of production and that the talc be shipped to them clearly identified not as USP and without a microbial specification. Geigy is perfectly capable of testing the talc to determine if it is USP and they also advised me they are capable of decontaminating the talc in the event that it does not pass their microbial standards.