TALC FILE

RM

MEMORANDUM OF MEETING
March 11, 1976

BETWEEN: Heinz J. Eiermann, Director, HFF-440
John A. Wenninger, Deputy Director, HFF-441
Frances N. Marzulli, HFF-150
of the Food and Drug Administration

and

William C. Waggoner, Manager, Medical and Regulatory Affairs
DeWitt R. Petterson, Vice President, Research
Johnson & Johnson Baby Products Company

SUBJECT: Results of Studies Regarding the Presence of Nickel in Johnsons Baby Powder

Dr. Waggoner requested the meeting to discuss a report prepared by Johnson and Johnson (J & J) on Johnson's Baby Powder. The report included the following studies: (1) Study of the chemical and physical characteristics of nickel found in talc. (2) Study of the extraction characteristics of nickel found in talc. (3) Patch test results of talc in subjects sensitized to nickel. (4) Complete analytical characterization of Johnson's Baby Powder, lot 228p (the lot used in the Battelle Study). (5) Calculation of the safety factor of talc containing 0.2% nickel. A report of these findings dated March 10, 1976 and addressed to Mr. Eiermann was submitted to FDA at this meeting. A brief discussion of the contents of this report was also held at the meeting.

Also discussed were the recent findings reported to the press by Dr. Langer at Mt. Sinai that various commercial talc products were reportedly found to be contaminated with asbestiform minerals.

John A. Wenninger

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March 12, 1976

Dr. Norman Estrin
Cosmetic, Toiletry & Fragrance Association
1133 - 15th Street, N.W.
Washington, D.C. 20005

Dear Norman:

For some years, Chesebrough-Pond's Inc. has been concerned about reports that some talcs might contain asbestos as a naturally-occurring contaminant. As you know, we have cooperated with CTFA, and through CTFA with the FDA in developing suitable and practical methodology to resolve the very complex and difficult task of identifying asbestiform fibers in talc. We have also worked closely with responsible talc suppliers to identify high quality sources of talc.

By the beginning of 1973, we felt that practical methodology for the purpose was applicable. Since then, we have utilized the techniques described in the attachment to monitor incoming cosmetic talcs of three types that we have been using. These three are from three different geographical areas.

I have reviewed the results of these analyses on the incoming lots of these talcs used in recent production of cosmetic and toiletry products in the United States. The last 84 reports, covering a three-year period, are, without exception, negative for chrysotile and negative for fibrous amphiboles.

If it can be useful, we would be pleased to discuss these data with scientists at the Food and Drug Administration.

Sincerely,

Murray Berdick
Director of Regulatory Affairs

MB/bm
encl.

Chrysotile — An x-ray powder pattern showing both the 002 (7.3 ± 0.1A; I/I_o = 1.00) and 004 (3.65 ± 0.05A; I/I_o = 90 ± 20) reflections and showing no line in the 14.6A chlorite region is necessary and sufficient evidence for the presence of chrysotile. A line at 14.6A in addition to, and of the proper intensity relative to, the 7.3A and 3.65A lines identifies chlorite rather than chrysotile.

When the x-ray evidence is equivocal, optical crystallography may be used to confirm chrysotile. Positive identification will then be based on the known morphological and optical properties of chrysotile. The normal form of chrysotile is a parallel bundle of long fibers, each a hollow cylinder only about 220A in diameter. It is monoclinic with γ ranging from 1.545 — 1.566, β from 1.539 — 1.559 and α from 1.532 — 1.550. The sign of elongation is positive since γ lies nearly parallel to the length of the needles. The birefringence is about 0.015 hence a 5 μm thick bundle will show a retardation of 75 nm (gray). The birefringence of a 2 μm thick bundle of chrysotile fibers would be barely detectable even with a first order red plate.

Dispersion staining is a sensitive and specific method for long-fiber chrysotile. In the Cargille high dispersion liquid n_D^{25} = 1.550 most chrysotile fiber bundles show λ_o colors in the blue-magenta region with the central stop for the vibration direction parallel to the length and in the blue for vibration directions crosswise. Unfortunately, in a preparation of quartz particles about 10% will lie in a position showing the same two colors for vibration directions 90° apart. These can usually be identified as quartz by morphology or by the fact that the sample contains many other particles of similar morphology but showing blue central stop colors in all positions of stage rotation. All chrysotile fiber bundles are constrained by shape to lying flat, hence always showing both blue (crosswise) and blue-magenta (parallel to the length) for central stop colors.

Tremolite — Necessary and sufficient evidence for the presence of tremolite is an x-ray powder diffraction pattern with lines at 8.4 ± 0.1Å, 3.27 ± 0.05Å, 3.03 ± 0.05A and 2.92 ± 0.05Å. (Note: zinc and magnesium stearate may interfere at 8.4Å and calcite at 3.03Å.)

When the x-ray evidence is equivocal, optical crystallography may be used to verify the presence of tremolite. Positive evidence will then be based on accepted morphological and optical properties of tremolite. The common form is monoclinic rods elongated nearly parallel to γ (about 1.63) but with oblique extinction of 10-21° for crystals lying on the 010 face. The optic axial plane is 010, hence α (about 1.60) is also shown on the 010 view. The view showing β (about 1.615) and γ' (about 1.63⁻) shows parallel extinction. The optic axial angle is about 80° with a negative sign and weak dispersion, $v > r$. Polarization colors are moderate and approximately 100 nm (gray) for a 10 μm thick rod in all crosswise orientations, 200 nm (yellow) for a 30 μm thick crystal. Characteristic dispersion staining colors are observed in Cargille high dispersion liquid 1.605: about 430 nm is λ_o for γ, blue-violet with the annular stop and yellow with the central stop; about 490 nm for β, blue-green (annular stop) and golden magenta (central stop); and about 600 nm for α, yellow-orange (annular stop) and blue (central stop).