FILE NAME: Johnson & Johnson (JAJ)

DATE: 0000

DOC#: JAJ201

DOCUMENT DESCRIPTION: J&J Concentration Method - as prepared by JC Metcalf

- **1) CONCENTRATION METHOD J&J**
- **2) 730125 Shelly to Goodman others. Subject Talc/Asbestos JNJNL61_ 000035160**
  - 1) When we were at the height of the last FDA controversy Washington last fall Tom Shelley told Colorado to go ahead in looking into an idea they had to concentrate an asbestiform in talc
  - 2) The attached is the progress on the matter
  - 3) I see no advantage in going into it more deeply and see nothing over recent similar tests from Pooley.
- **3) 730226 CSMRI Project C10704 JNJNL61_000008084**
  - 1) Relative to possible asbestos type minerals the above table shows that Samples 30 -71-S and 30-B -71-S **contain slight traces of tremolite actinolite minerals**. Sample 32-71-S is suspected to contain a very minor amount of serpentine which may be chrysotile. In addition a slight trace of possible anthophyllite was observed in this sample. **Positive for Tremolite, actinolite, anthophyllite and chrysotile**
  - 2) Positive for Tremolite, actinolite, anthophyllite and chrysotile
  - 3) The purpose of these studies was to determine the mineralogy of these samples with an emphasis on the occurrence of any asbestos type minerals. X-ray Diffraction and microscopic studies were made on as received samples, heavy liquid separates,
- **4) 730516 Shelley to Rolle et al JNJAZ55_000001892**
  - 1) England is considering method of preconcentrating the asbestos so as to be able to analyze by X-ray. They find no "asbestos" by doing this with Italian talc. **They find (Pooley) 0. 05% of a tremolite-type in** Vermont
    - 1) The second technique developed also by Dr. Pooley involves preconcentration of tremolite in talc (different procedure) followed by X-ray diffraction analysis. This technique has not been written up yet, but evidently when applied to Vermont talc, 0.05% of tremolite-type is found. Positive. The limitation of this method is that it may be too sensitive. (May 22, 1973 report)
- **5) 730604 Shelley to Ashton et al JNJ 000231419**
  - 1) One important point which was covered was that the British Toilet Preparations Federation is drafting specifications for the analysis of "asbestos" in talc. Their methods, Involve concentration techniques and will therefore be much more sensitive than our proposed specifications.
- **6) 730604 Shelley to Rolle JNJNL61_000008090**
  - 1) The British Toilet Preparations Federation is in the process of drafting specifications on talc. These will involve density concentration techniques followed by x-ray analysis. Fred Pooley has developed the methods and checked the Italian talc for chrysotile and other asbestos contaminants. He found none; however, I am concerned that o**ur Vermont talc will from time to time show traces of tremolite.**
- **7) 730606 Petterson to Mortimer et al JNJNL61_000007246**
  - 1) Note the use of concentration techniques in the drafted specification for the analysis of asbestos. Also, I have discussed with Shelley that the samples to be sent by Dr. Rolle will be the 20 recent samples of powder in which we found no tremolite-actinolite, by the optical technique. Shelley reports that Pooley **has found actinolite in our Vermont talc by his concentrating technique**. Italian talc, by-the same technique, appears to be free of amphiboles. I have sent the report referred (of I. W. Sloan) on to Roger Miller for their study.
- **8) 730606 Rolle to Dean JNJAZ55_000005082 JNJNL61_000008092**

- 1) We are particularly interested in the British Toilet Preparations Federation specification on talc since it might be picked up and used in this country. Tom Shelley mentioned that they use a density concentration technique in their analysis for asbestos minerals and we are interested in applying this procedure to our Vermont Talc. Could you please send me, as soon as you get the first draft, a copy of the TPF specification on talc, including the procedure for the density concentration technique.

9) 730606 Rolle to Pooley JNJNL1_000022207, JNJAZ55_000005081

- 1) Following the request of Tom Shelley, I will be sending you shortly, 26 ten-gram split production samples of Vermont Talc to be put through the British Toilet Preparations Federation density concentration technique after I receive the proposed procedure for this density concentration technique from Bob Dean, I will have the same samples put through this procedure by us. Also, in the same shipment will be 3 three-hundred gram samples of production Vermont Talc for your study to remove tremolite in talc.

10) 730919 Russell re Pooley visit JNJNL61_000035808

- 1) They (in UK) are proposing a method which concentrates the asbestiform fibers for easier detection.
- 2) A concentration technique will therefore become part of the method since the asbestiform must be present at 1% by weight or greater to be detected by the x-ray.
- 3) **Vermont talc contains 1% fibrous talc.** No asbestiform fibers so far.

11) 731023 Ashton to Petterson. JNJ 000233714

- 1) Johns Manville requests information and assistance in the concentrating of asbestos minerals from talc systems. This will cause our friends at Golden to look deeply into the use of heavy liquids, density gradient separation, and iodine staining techniques. Such a method could be expected to elicit subtrace quantities of associate minerals not presently known to exist in many talc systems.

12) 731220 Schelz to Reynolds JNJNL61_000008105

- 1) See cover letter 8104.
- 2) Enclosed please find four (4) samples of talc, labeled STD C, D, E, and F, which I am sending as a result of our discussion concerning a possible concentration technique for chrysotile in talc.

13) 731227 CSMRI Project C10704 JNJNL61_000021618

- 1) We are pleased to enclose three copies of our report entitled "A Procedure to Examine Talc for the Presence of Chrysotile and Tremolite-Actinolite Fibers."
- 2) Though cumbersome and difficult to use, the advantage of this apparatus is that it can perform separations on the basis of very small specific gravity differences and should have the capability of separating pure talc from talc containing inclusions of some other phase, e.g., chrysotile, chlorite, tremolite-actinolite, etc.

14) 731227 CSMRI project C10704 JNJNL61_000021543

- 1) Report on Procedure to Examine talc for the presence of Chrysotile and Tremolite-actinolite fibers.
- 2) The separation arid concentration technique involves heavy liquid separations and is therefore dependent upon specific gravity differences. Identification of the phases thus separated and concentrated is based upon their optical and morphological properties. It is estimated that the following procedure will allow the detection of chrysotile and/ or tremolite actinolite when each is present at a level of approximately 1 ppm or greater .

15) 740131 CSMRI Krause to Ashton JNJNL61_000021636

- 1) The objective of the program will be to evaluate the applicability of heavy liquid separation preconcentration followed by x-ray diffraction screening for the presence of possible asbestiform minerals.

- 2) The prepared standards will be subjected to heavy liquid separation and the fractions collected.
- 3) I am confident that the program proposed here will result in a screening method that will have a low detection level and be relatively easy to use. We look forward to providing this service for. you.

16) 740207 Dean to Meijer JNJNL61_000021277

- 1) Dean writing to Dutch Scientist about report of asbestos in J&J Talc
- 2) Dean (J&J UK) represents that numerous examinations of the talc, in every case the talc was proved to be completely free of the specific asbestos minerals.
- 3) Pooley's concentration methods shows "our talc" to be free from the asbestos minerals.
- 4) Says that Pooley has examined hundreds of the "fibers" found in our talc and in every case showed the particles to be talc.

17) 740300 Reynolds to Windsor Minerals JNJNL61_000029410

- 1) Analysis of Talc Products and Ores for Asbestiform Amphiboles
- 2) **Actinolite is the dominant fiberform amphibole in the ore and talc product provided by Windsor Minerals. Small amounts of anthophyllite may be present.**
- 3) For the reasons described above, a concentration technique is **mandatory** because it brings the amphiboles into a reasonable concentration range for optical or other methods of analysis. Such a method has been developed, and it is described in this report.

18) 740311 Carpe to Schelz and Rolle, JNJNL61_000062982

- 1) **I have tested** the heavy liquid flotation methods described by Dr. Reynolds.
- 2) Methods of concentration of Asbestos in Talc-Project #0503-00
- 3) The procedure for "heavy" fibers (actinolites and tremolite) permits the **detection of asbestos at original concentration as low as 0.02 percent by weight,** while the existing procedures (step-scanning x-ray diffraction) are effective to 0.2 percent.
- 4) There is another method, developed by Dr. F. Pooley, which is as effective for chrysotile as that of Dr. Reynolds and will simultaneously concentrate the heavier forms of asbestos. I plan to test the method as soon as I receive the apparatus which Dr. Pooley is submitting.

19) 741126 Schelz to Rolle JNJNL61_000062964

- 1) Our preliminary investigation of experimental techniques for the concentration of asbestos minerals in talc has been in two areas;
- 2) The concentration of actinolite/tremolite and chrysotile from talc by individual heavy liquid separation techniques developed by Dr. Robert Reynolds, Dartmouth College. Dr. Reynolds, of the Department of Earth Sciences, had been requested by Mr. V. Zeitz of Windsor Minerals to work on an actinolite concentration technique. This method utilizes the difference in densities between actinolite {and other amphiboles) and talc to effect separation in a heavy liquid medium.
- 3) **Following Dr. Reynolds procedure, we have been able to detect tremolite by optical microscopy/ dispersion staining in the separated fraction frorn a sample containing initially as little as 0.01% by weight tremolite in Vermont talc.**
- 4) Each of these experimental techniques warrants additional work. We have not been able to pursue the concentration of asbestos minerals from talc because of a shortage of personnel and the low priority which had been set for the project.

20) 741217 Steinberg to Estrin CTFA JNJMX68_000009139

- 1) We believe it is critical for the C.T.F.A. to now recommend these methods (CTFA Methods) to the F.D.A. before the art advances to more sophisticated techniques with higher levels of sensitization.

21) 750211 "Concentration of Amphibole and Serpentine Asbestos From Talc by Froth Flotation." JNJAZ55_000007947

- 1) 750211 Pooley to Rolle (JNJAZ55_000007946) encloses report on Froth Flotation Concentration of Asbestos.
- 2) Froth flotation would appear to be a most efficient means of separating amphibole and serpentine asbestos from talc for both detection and quantification of the asbestos phase.
- 3) This concentration technique has been applied to the concentration of commercial and non commercial forms of asbestos minerals from talc. It has been shown to be very efficient in reducing the asbestos content of a powder and producing a residue (which is referred to in mineral separation terms as a 'tailings' in which the asbestos minerals can be easily detected and quantified.

22) 750218 Sloan to Rolle JNJNL61_000062953

- 1) We deliberately have not included a concentration technique as we felt it would not be in worldwide company interests to do this.

23) 750228 Rolle to Sloan JNJNL61_000028657 JNJ 000300438, JNJNL61_000028657.

- 1) Review of CTFA Methodology for the Detection of Asbestos in Talc, as well as, Comments on TPF Methodology
- 2) We really want to exclude concentration techniques in any proposed analytical procedure and are really looking at this method very quietly so that we will be informed and up-do-date with this area of technology. We want to avoid promotion of this approach.

24) 761006 CTFA Method J4-1 JNJNL61_000005062

- 1) CTFA published test method: Enrichment or concentration techniques using flotation cells have been tried as a means of improving the detection level; however, all efforts so far have been unsuccessful.

25) 761124 Ashton to Lee JNJNL61_000017453

- 1) Attached is a copy of a disturbing proposal request which the FDA has currently made available to qualified bidders. The scope of the work is the Separation of Asbestos in Foods, Drugs and Talc for Identification and Determination.
- 2) As I have pointed out many times, there are many talcs on all markets which will be hard pressed in supporting purity claims, when ultra sophisticated assay separation and isolation techniques are applied. Chances are that this FDA proposal will open up new problem areas with asbestos and talc minerals .
- 3) Up to now, our main problems have had to do with identification, whereas, now it looks like the FDA is getting into separation and isolation methodology which will mean concentration procedures.

26) 770225 Krause (CSMRI) to Ashton JNJNL61_000017288

- 1) The methods of examination and identification were x-ray diffraction (XRD) before and after concentration by heavy liquid separation, handpicking for x-ray diffraction, and electron microprobe analysis.
- 2) Several acicular grains were handpicked from the >2. 8 specific gravity fraction of the product, and x rayed in a Gandolfi camera in an attempt to confirm the presence of anthophyllite. The XRD pattern of these grains showed only talc. Photographs of the five grains x-rayed are attached, and it appears as though they are talc pseudomorphous after amphibole. Amphibole was not conclusively identified in the sample.
- 3) No TEM performed.

- **27) 910000 Blount JNJNL61_000014431**
- **28) 980423 Blount to J&J Lawyers JNJNL61_000052427**
  - 1) The separation and concentration technique involves heavy liquid separations and is therefore dependent upon specific gravity differences.