

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Heinz J. Eiermann, Director
Division of Cosmetics Technology (HFF-440)

DATE: May 16, 1975

FROM : F. N. Marzulli

SUBJECT: Critique of J & J Report Submitted with Letter of April 3, 1975
to R. M. Schaffner, Ph.D.

I have read the report submitted by Johnson & Johnson Co. and am prepared to discuss this with their representatives in detail, at their convenience.

The J & J people do not appear to be using the modified Draize technique as described in Illustrated Guide of 1965 (see attached photocopy). At that time, the grading method was changed so that each portion of the eye is considered independently without reference to a total score and four parameters are measured, i.e., a-conjunctival redness, b-conjunctival chemosis, c-corneal injury and d-iritis. Furthermore, area of involvement is not taken into consideration.

In the J & J paper, only one parameter for conjunctival effects is reported and it is not clear which this is. In addition, area of involvement is used in arriving at the score and this is no longer recommended.

In their (J & J) evaluation of the method we propose, the main point of difference appears to be with regard to the fluorescein technique. We are prepared to discuss this in detail with them. I bring the following points to their attention at this time.

1. Ophthalmologists generally recognize the usefulness of the fluorescein technique for disclosing of the corneal epithelium and corneal erosion. They use it in particular in evaluating the fit of contact lenses as well as disclosing various forms of corneal injury.
2. J & J recommends using fluorescein solutions in place of steri-strip paper. We should point out that ophthalmologists have discarded the use of fluorescein solutions in favor of steri-strip paper because the former provides a growth medium for *P. aeruginosa*.

Mr. Heinz Eismann, HF7-440

March 31, 1975

Raf

Epidemiology Unit, HF7-108

Asbestos Minerals in Cosmetic Talc

I had the opportunity to visit with Professor Salikoff, in New York on Friday, March 21st, 1975. During this time, part of the discussion dealt with the identification of asbestos minerals in talc. The minerals of concern were: chrysotile, tremolite and anthophyllite. It was my understanding that by talc was meant cosmetic talc only, the samples being obtained over the counter at the retail level. It also was my understanding that while most of the samples were from the United States, there were several from Great Britain.

Their laboratory is using step-scanning electron microscopy for quantification. They are now, with this technique, well below 1% sensitivity for chrysotile and tremolite, and at about 1% for anthophyllite.

Several British samples showed asbestos, more than reported by Fred Pooley at his seminar here. It should be noted that Pooley's samples were taken at the import source, not at the retail level. In addition, the sensitivity of method in Professor Salikoff's survey was greater than in the study done by Dr. Pooley a few years ago. The two data bases, therefore, are not incompatible.

According to Professor Salikoff, some of the American samples also contained asbestos. We did not go into details as this is an ongoing survey.

Professor Salikoff did note that chrysotile, with their analytical techniques, has been found in some cosmetic talcs. He stated that they are there because the chrysotile was in the rock beds from which the talc was obtained.

Raymond E. Shapiro, Ph.D.

4-3-75