SYNTEX [redacted]TORIES INC.
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PALO ALTO, [redacted]IF. 94304

December 19, 1973

Hearing Clerk
Food and Drug Administration
Room 6-86
5600 Fishers Lane
Rockville, Maryland 20852

Re: Federal Registered Document 73-20711
Filed 9/27/73
Asbestos Particles in Food and Drugs

Gentlemen:

Submitted herewith in quintuplicate are comments regarding the analytical procedures described in the above referenced petition. We would appreciate it if you would take these comments into consideration in drafting the final regulation.

Sincerely,

SYNTEX LABORATORIES, INC.

James D. Mutch

James D. Mutch
Associate Director
Regulatory Affairs
(415) 855-5436

JDM:mam

Enclosures

CERTIFIED MAIL
Return Receipt Requested

75P-0261

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We believe that the degree of polarization in the microscope should be defined. In our studies we employed a Leitz Ortho-Lux microscope which permits a continuous range of polarizations to be used in conjunction with the two refractive index fluids specified in the regulation. We found that the count of asbestos particles changed when the degree of polarization was changed in the microscope.

When the microscope is set at 400X with either refractive fluid, one experiences serious depth of field problems which make it difficult to determine axial ratios for a number of sizes of particles. It is particularly difficult to focus on large particles as when one portion of the particle is in focus the other part is out of focus and disappears. This in turn makes it difficult to determine the exact size of the particle since the whole particle is not in focus at any one time. A magnification of 100X would give a better depth of field yet this choice of magnification would also make the particle size selection process somewhat more difficult.

One of the significant problems that we encountered was the large number of counts obtained and the time employed making these counts using either refractive index fluid. Possibly a way to more easily perform counts and be able to determine sizes more accurately would be to use a device such as a hemacytometer, a microscope slide with a grid which is presently used to permit counting of blood cells in a specified volume and area.

In some of the talc we have been examining, we have found quite high levels of the chrysotile asbestos fibers and question the limit of not more than 100 fibers per milligram slide. Perhaps the data on which these limits have been set could be published in the Federal Register.

In summary, we found the analytical method as written to be ambiguous, time consuming and the apparently arbitrarily set limits to be somewhat tight. We feel the procedure could be run more easily at 100X magnification on a set amount of a dispersion at a set concentration delivered from a micropipette with the count being made in a given area, for example, on a hemacytometer.