The Cosmetic, Toiletry and Fragrance Association, Inc.

1625 EYE STREET, N.W., WASHINGTON, D.C. 20006 202/393-2070

James H. Merritt
President

Norman F. Estrin, Ph.D.
Vice President—Science

December 26, 1973

Hearing Clerk
Food & Drug Administration
Department of Health,
Education and Welfare
Room 6-86
5600 Fishers Lane
Rockville, MD 20852

Re: Proposed Order Method for Asbestos in Talc Published in the Federal Register (38 F.R., No. 188, pgs. 27076-27081) September 28, 1973

Dear Sir:

This letter and attachment is being submitted in response to the proposal published on September 28, 1973 (Federal Register, Vol. 38, No. 188, pages 27076-27081) in which a method is proposed for the determination of asbestos particles in food and drugs. The comments are being submitted on behalf of The Cosmetic, Toiletry and Fragrance Association, Inc., a national association representing manufacturers and packers of cosmetic products as well as the manufacturers and vendors of cosmetic product ingredients and supplies. Members of the Association manufacture approximately 85% of the cosmetic products distributed in the United States. While the Association is not directly affected by the Federal Register Proposal cited above, one of its scientific subcommittees, the CTFA Talc Subcommittee, has completed a critical review of the optical microscopic method published in this proposal. In the belief that this review is revelant for your consideration of this proposal, the report of the CTFA Talc Subcommittee, dated December 10, 1973. is attached as part of this submission.

As a result of round robin testing of five different types of talc, by members of the CTFA Talc Subcommittee, the subcommittee concluded that the proposed method does not provide a reliable means for the detection of asbestos in talc and that it results in both

75P-0261

C48

false-positive and false-negative findings. The procedure is also tedious and may consume as much time as one-half day per sample. The subcommittee has also reviewed several alternative methods to detect chrysotile and tremolite in talc including modifications of the optical microscopic method. As a result of its review the subcommittee feels confident that a feasible method can be developed, and recommends a collaborative effort between FDA and industry to develop such a method.

The questions concerning asbestos detection and the relationship of asbestos to human health are indeed complex ones. At a conference last month, sponsored by the National Institute of Environmental Health Sciences and the Environmental Protection Agency, three serious difficulties in determining the effects of asbestos on human health were presented:

1. "The term asbestos itself is misleading, for it encompasses a whole group of minerals that are distinct from each other in chemical composition, particle size, and probably biological effect.

2. Many of these particles are so small that detection is extremely difficult and time consuming, placing restraints on the scope of research that can be reasonably undertaken.

3. Perhaps the most serious difficulty in asbestos research, however, is the very long period between initial exposure and evidence of biological effects."(1)

Other points made at this Government sponsored meeting that merit consideration were:

1. Chrysotile fibers are too small to be detected by conventional optical microscopy.

2. Amphibole asbestos fibers are larger. But they also require sublight microscopes for careful examination and cannot be positively identified without additional microchemical or selective area diffraction analysis.

3. A question yet to be answered is the effect of low-level exposure to asbestos on the general population.

4. Dr. Ian Webster of the National Institute for Occupational Diseases in Johannesburg, Republic of South Africa, reported at the conference that very little ingested asbestos penetrates the walls of the stomach and colon and that almost all that does is of the smaller chrysotile type.

(1) Chemical & Engineering News, December 10, 1973, pages 18-19.

Similarly, studies with inhaled asbestos also show that the fiber is absorbed is predominately the chrysotile type.

5. Dr. William Eisenberg of the Food and Drug Administration was quoted as stating that "at present, analysis by polarized light microscopy is used to determine purity of food and drugs, even though this method probably misses many of the smaller and more easily absorbed asbestos fibers that may be present in these materials."

In light of the perplexing questions raised at this conference, the Association considers it premature for FDA to impose its proposed optical method and place a limit on asbestos in talc for food use.

The CTFA urges deferment of promulgation of the proposal until:

1. Determination of the standard deviation of the proposed compliance test method.

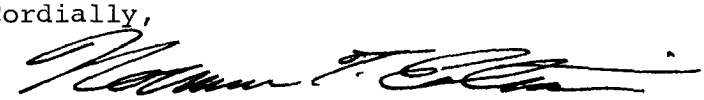
2. Evaluation of the validity of the assumption that a single milligram sample can be taken as statistically representative of any lot as well as the limit size of any lot so sampled.

3. A re-evaluation of the economic cost and practicality of the proposed Compliance Test Methods.

4. An intensive search is undertaken for an alternate procedure that is more reliable and more practical than the proposed test methods.

The Cosmetic, Toiletry and Fragrance Association, Inc., stands ready to assist the Food and Drug Administration in method development research as well as to provide assistance in other areas discussed above where as its scientific expertise may be of value.

Cordially,



Norman F. Estrin, Ph.D.
Vice President - Science

NFE:mp
Attachment

cc: CTFA Talc Subcommittee
CTFA Scientific Advisory Committee