



MINERALS & CHEMICALS DIVISION
ENGELHARD MINERALS & CHEMICALS CORPORATION
MENLO PARK • EDISON NEW JERSEY 08817 • PHONE (201) 548-2200
CABLE ADDRESS MICOR

November 19, 1973

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

Dear Sir:

The following comments regarding the Proposed Rule published in the Federal Register, Vol. 38, No. 188, 9/28/73, pp 2706 ff, titled F.D.A.(21 CFR Parts 121, 128, 133), "Asbestos Particles in Food and Drugs" are submitted to the attention of and for consideration by the Commissioner in accordance with the invitation for filing relevant comments by interested persons.

The Minerals & Chemicals Division of Engelhard Minerals and Chemicals Corporation mines, processes, and markets an industrial or commercial platey talc product through a wholly owned subsidiary, the Eastern Magnesia Talc Company, and is therefore sensitive to any possible impact of the proposed Rule and especially to the proposed Analytical Method by which the Rule would be enforced and test specification limits be established. Our comments are directed especially to five major areas as follows:

(1). Paragraph 133 --- Talc containing asbestos. "Talc is a naturally occurring hydrous magnesium silicate which may reasonably be expected to be contaminated with asbestos particles . . .".

We strongly object to the phrase "may reasonably be expected";

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while it is indeed true that many industrial talc minerals consist of a mixture of mineral (crystallographic) talc together with a variety of commonly associated minerals some of which may be either chrysotile or one or more of the fibrous amphiboles, it is also true that a very substantial annual tonnage of talc mineral is mined and marketed that is not so contaminated. We deplore the continued reinforcement of the myth that all talcs are necessarily fibrous or contaminated with fibri-form minerals, and the burden of proof should be that industrial talcs are indeed so contaminated rather than that they are not.

(2) The toxicological documentation reviewed by the Commissioner does seem to be most relevant, but it is also quite incomplete (see especially our remarks in section (5) to follow). We have no reservations concerning the harmful biological activity of either respirable or interparentally or subcutaneously injected asbestos mineral particles. But every reference cited regarding the possible hazard from ingestion of asbestos particles is either inconclusive or directly contrary. The studies of Swinburn (Ref 40) and of Smith et al (Ref. 41) clearly demonstrate zero response to ingested asbestos while the reports by Westlake et al (Ref. 42) and by Cunningham et al (Ref. 43 and 44) deal with massive dosages of the fibrous mineral material far in excess of any possible cumulative dosages that appear to be normally ambient in both common water sources and in the atmosphere. We do indeed agree with the conclusions of the Food and Drug Administration Review of Ref. 52, namely, that much further objective research is necessary as listed in Paragraph (1), a, b, c and in (2), pg 27078 of the proposed Rule.

MINERALS & CHEMICALS DIVISION
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(3) Our concern, however, is aroused especially with respect to the proposed promulgation of a final regulation for Talc under Section 121.2006 which, as properly noted, cannot be promulgated until a reproducible and accurate analytical method can be specified for compliance purposes. The proposed specification limits for fibers in talc as determined by the proposed fiber counting method (i.e., not more than 1000 amphibole fibers and not more than 100 chrysotile fibers --- which somehow becomes equated to a weight estimation to insure that the talc contains no more than 0.1% by weight of amphibole fibers and not more than 0.01% by weight of chrysotile fibers - - -) would seem to be totally unrealistic, and, in fact, not subject to either reproducible nor accurate determination by the proposed method for determination of compliance, especially by para-professional Field Inspectors. Our objections are more specifically based on several grounds summarized as follows:

(a). First, it must be conceded that the basic principle of the proposed method (Section 121.2006, (2)) is indeed a technically sound and a fundamentally applicable method for the optical identification of and discrimination between the listed amphibole minerals, chrysotile, and talc. Our objection is based on the length of time required for the test procedure and the consequent cost, the high level of professional or technical competence and skill required for proper application of the test method, and the fact that there is no accompanying statement setting out the limits of precision and reproducibility.

We estimate that a highly skilled mineralogical microscopist could complete no more than 2 to 3 complete sample evalu-

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ations per working day. This estimate has been confirmed by conversation with McCrone Research Associates of Chicago to whom we have submitted some production samples of talc mineral to determine present degree of compliance with the suggested specification limits at an estimated cost (not yet firmly established) of between \$100 to \$180 per sample. This is a cost which no talc producer could absorb if a compliance certificate were required for every shipment which might range from a lot of a few hundred pounds to a 40 ton carload.

(b). There is neither enough time nor a sufficient number of trained and skilled microscopists available to meet such a demand which is far beyond the technical capacity of the ordinary paraprofessional Field Compliance Inspector. Even though the technical personnel finally became available, the length of time required for compliance testing before shipment would require talc producers to hold in inventory an amount of talc far in excess of any present storage capacity.

(c). But even more critical to the validity of the proposed test method is the bland assumption that a single randomly selected 1 milligram sample taken for the test can be considered to be representative of the lot --- an assumption contrary to all sampling theory and practical experience. The proposed test procedure can only be found acceptable after completion of a properly designed Round Robin Test Comparison between a sufficient number of laboratories, microscopists, and samples to determine the standard deviation of the test procedure (± 20 at 95% confidence limits) and the analysis of variance due to differences between

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laboratories, microscopists, and the probable sampling error inherent in taking only 1 mg samples. Only then can it be determined how large a difference between test results is a significant difference and if the proposed count specifications have any relevance to reality at all.

(d). In the course of making the total count of amphibole fibers according to the proposed method, it will be necessary to identify and count each of the proscribed amphibole types separately, since each is distinguished by its characteristic index of refraction; never-the-less, the total amphibole count is specified for compliance even though it has been well established that certain of the fibrous amphiboles, especially those high in iron content, are manifoldly more biologically active than those essentially free of iron. If the amphiboles are to be (and have to be) individually identified and counted, why should not the count limits be set inversely to their relative hazardness? Also, on what basis has it been established that chrysotile fibers are 10 times more hazardous than amphibole fibers?

(4). The so-called "fibrous" talcs which may indeed contain 20 to 40% or more of tremolite (amphibole) find important industrial applications because of the unique properties imparted by the fibrous mineral content. Such materials come under the asbestos regulation and would never be subjected to the proposed particle counting test in any case. Only the substantially asbestos-free talcs would be realistically subject to test for compliance to the proposed regulation. These are the type of talcs ordinarily used for cosmetic, pigment, and for paper filling and coating applications. The thrust of the proposed Rule is toward control of asbestos particles as they may be introduced into the digestive system by ingestion of either

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food or drugs. We have been informed that the Johnson and Johnson Co. have made exhaustive experimental investigations which clearly demonstrate essentially zero transfer of talc mineral (to say nothing of the fractional amount of asbestos mineral possibly present in the talc) from food board packaging into frozen food packed therein, and that this evidence has been submitted to the Regulatory Agencies which so far seem to have totally ignored this information.

The documentation further notes (pg 27077) that "asbestos fibers are ubiquitous in air, water, and a large percentage of the earth's crust". We suggest that the largest contribution to the "ubiquitous" presence of fibrous mineral material (as defined in OSHA-NIOSH terms) is not derived from commercial or industrial asbestos materials at all - - although it still remains appropriate to make every practical attempt to minimize entry of asbestiform material into the biosphere from this source. The fact is that the amphibole rocks make up a substantial percentage of the exposed earth's crust. The natural fracture or cleavage of the amphiboles imposed by the structural double silica chain crystallographic control is indeed surely the strongest influence towards degradation into relatively short but elongate assymetrical "fibrous" particulates that, arising from natural rock weathering processes, wind and water erosion and/or other abrasive action on amphibole rocks will introduce into the biosphere number-quantities of particulates identifiable as asbestos fibers under the NIOSH definitions and test methods far in excess of any fugitive sources of industrial asbestos contamination even where locally comparatively high, in comparison to the still much smaller possible fugitive contributions

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from relatively pure platey talcs containing up to and even much more than 0.1% "asbestos" the background fiber count in the biosphere remains enormous. This all seems to provide one more clear instance of a bureaucratic tendency to "swallow a camel but strain at a gnat".

(5) Finally, in spite of the technical disclaimers made by the Commissioner, his intention to include talc as defined and tested under Section 121.2006 rests most transparently, for the main part, on opinions prominently voiced and promoted by the Selikoff Group of the Mt. Sinai Hospital in New York. We think it most relevant that the Commissioner refer to and study the Transcript of the Testimony of Witness Irving J. Selikoff given in the case United States of America, Plaintiffs, vs. Reserve Mining Co. et al, Defendants, in the U.S. District Court, District of Minnesota, Fifth Division, Sept 21, 1973, the transcript of which can be obtained from O.C. Brevin and Richard K. Augustine, Court Reporters, 542 U.S. Court House, Minneapolis, MN 55401. The substance of this testimony should also be given due consideration and referenced in the Commissioner's preamble to the proposed Rule regarding Talc. When the additional technical information and evidence developed in the course of the Selikoff testimony is fully evaluated, there should be sufficient grounds to completely discredit the presently advanced opinion regarding the potential hazard to health arising particularly from the oral ingestion of talc mineral containing fibrous mineral particulates ranging from negligible amounts (less than 0.1%) up to reasonable substantial amounts not yet established but, say, as much as 5%.

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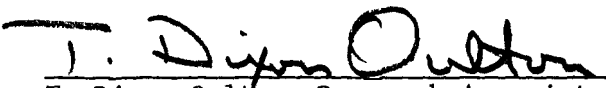
Based on the comments made and the questions raised in the preceding five sections, we therefore, request the Commissioner to defer promulgation of the proposed Rule, especially Section 121.2006, Talc, until such time as three vital conditions have been met. These are:

1. An objective determination of the standard deviation of the proposed Compliance Test Method and statement of the specification particulate number-count limits as a range of values covering $\pm 2\sigma$ (95% confidence limits) from the estimated mean; included in this investigation must be an evaluation of the validity of the assumption that a single 1 mg. sample can be taken as statistically representative of any lot as well as the limit size of any lot so sampled.
2. A reevaluation of the economic cost and practicality of the proposed Compliance Test Method in terms of availability of qualified personnel as well as time and cost requirements together with an intensive search for an alternate procedure more adaptable to practical industrial quality control capabilities.
3. An objective clinical demonstration subject to experimental verification of the minimum limits at which oral ingestion of talc particulates and/or asbestiform particulate material present in talc into the digestive system are actually hazardous to health and adjustment of the particulate number-count specification limits to be conservatively consistent with such a demonstration.

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We thank the Commissioner for the opportunity to submit these comments relative to the petition from the Center for Science in the Public Interest and the Environmental Defense Fund and to the Commissioner's proposed amendment to the Rule, Subpart F of part 121 and in particular Section 133which the Commissioner has published in response to the referenced petitions.

For the Minerals & Chemicals
Division of Engelhard Minerals
& Chemicals Corporation


T. Dixon Oulton, Research Associate

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