

To: Rick Zagorabek**Center for Regulatory Effectiveness**

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Dr. Kenneth Olden
Director, National Toxicology Program and
National Institute of Environmental Health Sciences
U.S. Department of Health and Human Services
P.O. Box 12233
Research Triangle Park, NC 27709

Dear Dr. Olden:

We have received a copy of the letter recently sent to you from CTFA. The letter contained further analysis of the scientific evidence for consideration in connection with possible further NTP deliberations on whether to again nominate cosmetic talc for listing in the Report on Carcinogens. The additional information and analysis submitted by CTFA appear to address important gaps in the Draft Background Document, which set out the evidence and analysis which NTP believed to support the initial listing nomination for talc not containing asbestiform fibers.

We believe your decision to defer any listing action pending further consideration of the evidence, and your invitation for continuing scientific collaboration during reconsideration, reflect well on the RoC program and its review process. We think that the decision was particularly important in view of the new data quality legislation and rules, which require that Federal agencies seek to maximize the quality and utility of information disseminated to the public.

The new OMB rules also require that "influential" scientific information must meet higher standards of quality and utility than other information. We believe the Report on Carcinogens would surely be considered "influential" scientific information, and that the information originally proposed to support a listing would not have met basic data quality standards due to lack of accuracy and completeness on a number of key points highlighted by CTFA which relate to the new data quality standards:

1. It appears that the basic premise that cosmetic talc is similar to asbestos in its biochemical effects was unwarranted. The failure of the DBD to focus sufficiently on the large body of evidence indicating that pure talc has not evidenced carcinogenic activity was a substantial omission and rendered the DBD "incomplete" and "inaccurate" under the OMB guidelines.

Center for Regulatory Effectiveness

2. Similarly, the failure to give adequate attention to the issue of potential bias in the case-control studies, as indicated by the extremely wide disparities in subjects' recall of use, appears to have been a substantial omission.
3. Inconsistencies in the case-control study findings were not given sufficient attention.
4. It appears there was not sufficient discussion of the conflicting evidence, and scientific views on that evidence, concerning potential translocation of cosmetic talc to the ovaries.
5. The position taken in the DBD that it should be "assumed" as a matter of policy that current-day cosmetic talc still contains asbestos represented an impermissible "bias" in what should be an "objective" scientific appraisal. On the other hand, the distinct possibility that some brands of cosmetic talc contained significant asbestos contamination prior to 1976 seems to present an insurmountable obstacle to further use of the case-control studies as evidence that pure cosmetic talc can be reasonably anticipated to cause cancer in humans.

As far as we are aware, there has been no NTP announcement of the talc deferral and the intention to engage in further review. As a temporary matter, we do not believe this was inappropriate; however, we believe that, given the evidence and analysis now at hand, it appears necessary to notify the public that the proposal to list cosmetic talc was deferred due to lack of sufficient evidence for listing, and that further review of the evidence has indicated that listing is not warranted and there are no imminent plans to re-propose it for listing. We are aware that some groups seized on the original listing proposal and informed consumers that this was a signal that they should avoid use of cosmetic talc. When something like this happens, particularly on a significant consumer issue, we believe that government agencies have a responsibility to set the record straight reasonably soon.

We would appreciate it if you would advise us, along with other stakeholders, of any new developments on this matter, particularly if NTP believes there is new evidence or analysis that should be considered, if it intends to engage in further consultation, and if it will notify the public as set forth in the above paragraph.

Sincerely,



Jim J. Tozzi
Member, CRE Advisory Board