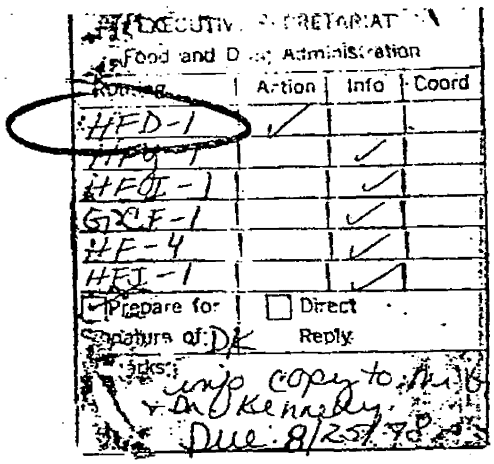
Public Citizen



August 4, 1978

Dr. Donald Kennedy
Commissioner
Food and Drug Administration
200 C Street, S.W.
Room 6815
Washington, DC 20204

Dear Dr. Kennedy:

The strong likelihood that talc is carcinogenic was the subject of a letter from Dr. Marshall E. Deutsch to the New England Journal of Medicine on February 16, 1978 (page 405).

A more recent letter to the same journal by Drs. W.R. Moorehead and T.O. Oei (June 15, 1978, pp. 1365-66) states that:

(a) talc is still used by U.S. drug companies both in the manufacturing process and as a filler in certain tablets;

(b) a major drug firm "has not used talc in any of the new drugs that it has developed in the last five years because it recognizes the possible danger of talc;"

(c) FDA regulations discourage its replacement in older drugs because the new formulation without talc would have to be resubmitted and approved by the FDA--and this procedure would take a long time.

If there is good reason to believe--even if the evidence is not conclusive--that talc is carcinogenic, prudence would dictate that its use be eliminated promptly in FDA-regulated products such as drugs and cosmetics.

It would be greatly appreciated if you would let us know what steps FDA is taking to achieve this objective.

Sincerely,

Sidney M. Wolfe, M.D.

Benjamin Gordon

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SMW & BG:pm

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