July 18, 1975

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WHITTAKER, CLARK & DANIELS, INC.

SUBJ: F.D.C. Report - Talc

INTER - OFFICE CORRESPONDENCE

BULLETIN:

The attached copy of the July 14th issue of the F.D.C. Report clearly describes the safety of Talc for use in aerosols.

Please arrange for copies to be sent to all our Talc customers. It is one of the most important detailed reports on Talc safety from Washington.

Use it to good advantage and as soon as possible.

FRED RCESCH

FFR/dm

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WCD0300

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T&G *DRUG/COSMETIC* PRODUCTS' INTERMEDIATE COMPONENTS: Chemical industry witnesses were joined by HEW during Rep. Van Deerlin's (D-Calif.) Consumer Protection & Finance Subcmte. July 9-11 hearings on toxic substances legislation in urging further exemptions from Environmental Protection Agency (EPA) control of *intermediates* destined for inclusion in *drugs* and *cosmetics* (see preceding T&Gs). The Senate's Tunney-Hart Magnuson bill and three House bills already exempt drugs *per se* from EPA control of chemicals presenting "unreasonable risk to health or the environment" ("The Pink Sheet" June 9, T&G-2).

¶ Reps. Eckhardt (D-Tex.) and McCollister (R-Neb.) conducted a constant duel during Q-&-A with witnesses over their bills. The chemical industry leaned toward the less stringent controls of the McCollister bill (HR 7664), which includes exemption of research chemicals (also exempted by S 776), and objected to Eckhardt's (HR 7229) tougher provisions, such as "excessively broad premarket testing" and reporting health and safety studies for the *past 40 years* on all chemical substances.

Dow Chemical, General Counsel J.H. Hanes testified, was opposed to passage of "*any* toxic substances bill," which Dow termed the "Chemical Industry Control Act," giving "sweeping" and "near dictatorial powers" over the chemical industry to EPA. SOCMA VP Normand Phaneuf, who is president of Lakeway Chemicals, also complained of "near dictatorial powers" the bills would give EPA.

¶ Most negative bill of all, in the chemical industry's view, is Rep. Brodhead's (D-Mich.) HR 7548, which makes EPA premarket certification *mandatory* for most new chemicals substances and *new uses for established chemical substances* where: substantial amounts of a chemical are produced; the chemical will result in substantial consumer or worker exposure; the chemical is closely related to chemicals known to be hazardous; and other federal agencies have listed the chemical as causing cancer, birth defects or gene mutations.

¶ "The Senate," Eckhardt warned, "might not stand for a bill" without strict premarket screening of chemicals questionable as to unreasonable risk to health or environment. The Eckhardt and McCollister bills restrict premarket screening to selective chemicals on a list to be compiled by EPA. HEW's David Rall testified that the dept. is already deeply into toxicity controls with the HEW Cmte. to Coordinate Toxicology & Related Programs, created by former Asst. Secty. for Health Edwards. Joseph K. Wagoner added that Natl. Institute for Occupational Safety & Health (NIOSH), Center for Disease Control, puts out an annual list of 17,000 toxic substances.

Rall sided with industry not only on the *jurisdictional* question, but in opposing controls on research chemicals. He voiced a need "to clarify the delineation of authority" between EPA and HEW over "control of chemical substances which may be used in products regulated by the FD&C Act."

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T&G USE OF TALC "OKed" BY FDA's OTC ANTIPERSPIRANT ADVISORY PANEL at July 9-10 meeting, following industry presentation at open session organized by the Cosmetic, Toiletry & Fragrance Assn. (CTFA). Talc can be used in antiperspirants, OTC panel reportedly decided in closed session, if it meets the 0.5% limit for asbestos content, as determined by the CTFA analytical method. Panel expressed hope for further refinements in the method for detecting asbestos content, and indicated that the limit was established primarily on the basis of detectability, rather than on a determination of safety. Tentatively, panel has decided that no existing antiperspirant can be considered safe and effective, but there was no implication in this decision that aluminum chlorhydrate is in any danger. Basis of panel's decision, it is understood, is a desire to spur [illegible] containing ingredients regarded as safe. Mid-Aug.

WCD0301

meeting of panel is expected to tackle the problem of establishing testing criteria for determining effectiveness. Sept. meeting will get into the question of statistical evaluation of the effectiveness of antiperspirants, based on flora readings after application to axilla.

¶ "We strongly believe that the data presented and reviewed support the conclusion that cosmetic grade talc as used in cosmetic and toiletry products is not a hazard to health and should be categorized as generally recognized as safe," asserted Gavin Hildick-Smith, MD, J&J medical affairs director during open session presentation. He said: "No publication has been found which shows that any adverse effects arise from the normal use of cosmetic or toiletry products containing cosmetic grade talc." Furthermore, no data show cosmetic talc to be a carcinogen, nor have human skin tests demonstrated it to be a sensitizer, and thus an allergan, he noted. *In vitro* studies of cosmetic talc's biological activity, he said, indicate the substance is biologically inert when compared to free silica and asbestos dusts.

Cosmetic talc is much more refined and purer than industrial talc and should not be judged in the same way, F.R. Rolle, PhD, J&J asst. manager of analytical research explained, noting industrial talc is a very impure product, often containing less than 50% talc. He defined cosmetic talc as a "material used in cosmetic and pharmaceutical applications (containing) more than 90% talc."

¶ CTFA's task force on talc's asbestos content convinced him that "there is no detectable amount of chrysotile in cosmetic talc," its chairman Rolle said. He said a practical way for mfrs. to analyze the fiber content of their talc would be through use of X-ray diffraction equipment. Outside panel consultant Albert Miller of Mt. Sinai Hospital disagreed, stating X-ray diffraction was less sensitive than electron microscopy. He also maintained that any light microscopic method would miss the very small fibers which "might very well be the most pathogenic."

¶ Miller, in his closing remarks to the panel, said the most important issue was the asbestos content of cosmetic talc. He asserted that Arthur Langer, also of Mt. Sinai's Environmental Sciences Lab, had analyzed over 50 different cosmetic talc bath and baby powders and found many contained up to 30% finely ground quartz. Langer also discovered one widely-sold product contained 30% anthophyllite and tremolite, he said. Rolle said that Langer's study had been the subject of a *New York Times* article in the early 1970s, which was retracted the day following its publication after Langer informed the paper that the study was highly premature and the figures were wrong.

¶ Carter-Wallace Asst. Research Director R. Wulf, PhD, reported that his firm had conducted 90-day inhalation tests on monkeys and albino rats exposed to *Light Powder Arrid* and *Arrid XX*. "No adverse effects attributed to inhalation of the talc material were observed," he stated. The talc in these antiperspirants, he reminded the panel, was an inactive vehicle. "No claims of efficacy are made for the inactive talc ingredient," he said. A.P. Wehner, DMD, Batelle Pacific Northwest Labs, informed the panel of a completed study, about to be published, of inhalation of J&J Baby Powder by hamsters. The study, which involved 30-day and 300-day exposures, found no treatment effects in the test animals' larynx, trachea, heart, liver, kidney, stomach, or uterus, he said.

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RED NO. 2 "ROLLER COASTER": CHANCES NOT MUCH BETTER than 50/50 that FDA's carcinogenicity rat study can be salvaged. FDA Div. of Food & Color Additives Consumer Safety Officer Gerald McGowin explained that all the rats have been sacrificed – following the discovery that a still undetermined number of the total

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