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COMMISSIONER

FOOD AND DRUG ADMINISTRATION

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JOHNS-MANVILLE APPRECIATES YOUR PROMPT RESPONSE TO MR. PERRY MARTINSON'S TELEGRAM OF 8-24-73. MAY I REITERATE THAT IF FINAL FDA REGULATIONS ARE ADOPTED PROHIBITING THE USE OF TALC CONTAINING ASBESTOS IN FOOD AND FOOD PACKAGING MATERIALS UNLESS THE TALC IS 99.9% FREE OF AMPHIBOLE ASBESTOS FIBERS AND 99.99% FREE OF CHRYSOTILE ASBESTOS FIBERS, THE MERE PUBLICATION OF SUCH REGULATIONS IN THE FEDERAL REGISTER WILL CAUSE IRREPARABLE AND IRREVERSIBLE HARM TO JOHNS-MANVILLE AND OTHER COMPANIES IN THE TALC INDUSTRY.

WE UNDERSTAND THAT FDA IS PROPOSING TO USE A TEST METHOD ENTITLED "MICROSCOPIC DETECTION OF ASBESTOS IN TALC" FORMULATED BY ARNOLD E. SCHULZE AND WILLIAM V. EISENBERG TO DETECT THE PRESENCE OF ASBESTOS IN TALC PURSUANT TO THE CONTEMPLATED REGULATIONS AND THAT FDA IS OF THE OPINION THAT ALL "FOOD GRADE" TALC WILL PASS THIS TEST USING THE DESCRIBED METHOD. JOHNS-MANVILLE'S RESEARCH CENTER HAS ANALYZED OUR TALC USING THIS TEST METHOD AND OUR TALC DOES NOT PASS THIS TEST NOR WILL THE TALC PRODUCED BY MANY OTHER COMPANIES PASS THIS TEST.

WE HAVE OBSERVED MARKED AND SERIOUS INCONSISTENCIES BETWEEN THE PROPOSED SPECIFICATION AND THE PROPOSED TEST PROCEDURE. IN THE INTEREST OF FDA AND THE INDUSTRIES INVOLVED, THESE INCONSISTENCIES SHOULD BE ANALYZED AND RESOLVED PRIOR TO PUBLICATION OF ANY REGULATIONS. THE PROPOSED TEST WOULD REQUIRE A DEGREE OF PURITY WHICH EVEN THE FINEST GRADE OF ANALYTICAL REAGENTS CANNOT BE ASSURED OF MEETING. OBVIOUSLY WE ARE NOT COMMUNICATING EFFECTIVELY ON TECHNICAL AND SCIENTIFIC PROCEDURES. SUCH COMMUNICATIONS ARE ABSOLUTELY ESSENTIAL IF WE ARE TO AVOID INADVERTANTLY CAUSING IRREPARABLE HARM DUE TO A LACK OF UNDERSTANDING.

WE RESPECTFULLY SUGGEST THAT THE MEDICAL AND SCIENTIFIC LITERATURE IS DEVOID OF ANY EVIDENCE WHATSOEVER OF A CAUSAL RELATIONSHIP BETWEEN THE INGESTION OF TREMOLITE (THE MOST COMMON ASBESTOS CONSTITUENT OF COMMERCIAL TALC) AND ANY INCREASED INCIDENCE OF GASTROINTESTINAL CANCER AMONG INDIVIDUALS EXPOSED FOR PERIODS IN EXCESS OF 25 YEARS TO TALC CONTAINING UP TO 70% TREMOLITE.

WE SPECIFICALLY INVITE YOUR CAREFUL ATTENTION TO THE EPIDEMIOLOGICAL STUDIES CONDUCTED BY DR. MORRIS KLEINFELD ET AL (1967) "MORTALITY AMONG TALC MINERS AND MILLERS IN NEW YORK STATE." ARCHIVES OF ENVIRONMENTAL HEALTH 14: 663-667 AND TO DR. KLEINFELD'S LETTER TO JOHNS-MANVILLE DATED JANUARY 24, 1973, A COPY OF WHICH WAS ATTACHED TO JOHNS-MANVILLE'S COMMENTS TO FDA DATED APRIL 20, 1973, AS EXHIBIT G.

THE SOLE EPIDEMIOLOGICAL STUDY OF WORKERS OCCUPATIONALLY EXPOSED TO TREMOLITE WAS CONDUCTED BY DR. KLEINFELD. HE CONCLUDED AS FOLLOWS:

> "WITH REGARD TO CANCER OF THE GASTROINTESTINAL TRACT AND PERITONEUM AMONG THE TALC WORKERS, WE DID NOT FIND ANY SIGNIFICANT DIFFERENCES BETWEEN THE OBSERVED AND EXPECTED VALUES IN THE OVERALL AND SPECIFIC AGE GROUPS STUDIED. THESE FINDINGS DIFFER FROM THOSE OBSERVED IN ASBESTOS INSULATORS WHERE A SIGNIFICANT INCREASE IN THE OBSERVED INCIDENCE OF GASTROINTESTINAL MALIGNANCY WAS FOUND IN THE OVERALL AND SPECIFIC AGE GROUP STUDIED BY US PREVIOUSLY. THE ASBESTOS DUST EXPOSURE AMONG INSULATORS IS CHIEFLY CHRYSOTILE. OUR FINDINGS AMONG ASBESTOS INSULATORS WAS SIMILAR TO THOSE REPORTED BY SELIKOFF, HAMMOND, AND CHURG."

STUDIES CONDUCTED BY SELIKOFF AND OTHERS AS TO BIOLOGICAL EFFECT OF CROCIDOLITE, AMOSITE AND CHRYSOTILE CANNOT BE VALIDLY RELATED TO TREMOLITE WHICH IS PHYSICALLY AND CHEMICALLY DIVERGENT FROM THOSE MINERALS. IT WOULD BE SCIENTIFICALLY IRRESPONSIBLE TO INCRIMINATE TREMOLITE AS A HEALTH HAZARD TO THE GENERAL PUBLIC ON THE BASIS OF THE SELIKOFF STUDIES AND IN THE FACE OF THE FINDINGS OF THE SOLE SCIENTIFIC STUDY ON THE QUESTION WHICH CONCLUDED NO EXCESS OF GASTROINTESTINAL CANCER AMONG WORKERS OCCUPATIONALLY EXPOSED TO TREMOLITE TALC. IT MUST BE NOTED

THAT ALL THE STUDIES INDICATING ANY SORT OF EXCESS GASTROINTES-
TINAL CANCER RELATED TO CROCIDOLITE, AMOSITE AND CHRYSOTILE AND
NOT TO TREMOLITE. AS DR. GEORGE WRIGHT CONCLUDED IN HIS PAPER
ATTACHED AS EXHIBIT E TO OUR COMMENTS, IT WOULD BE MOST UNSCI-
ENTIFIC AND, IN FACT, NOT AT ALL CORRECT TO ASSUME THAT TREMOLITE
HAS THE SAME PROPERTIES IN THIS REGARD AS DO CHRYSOTILE, CRO-
CIDOLITE, AND AMOSITE.

AS DR. WRIGHT STATES IN HIS PAPER, "THE EVIDENCE AVAILABLE AT
THIS TIME CLEARLY INDICATES THAT THE ROLE OF ASBESTOS IN
CARCINOGENESIS VARIES FROM IMPORTANT TO NON-EXISTENT DEPENDENT
UPON THE VARIETY OF FIBER AND ESPECIALLY UPON THE CIRCUMSTANCES
OF OCCUPATIONAL EXPOSURE. THE ASSUMPTION THAT ASBESTOS IN ALL
OF ITS VARIED FORMS AND USES IS UNIFORMLY CARCINOGENIC IS NOT
VALID.....BOTH TREMOLITE AND ANTHOPHYLITE HAVE BEEN SHOWN TO
BE FREE OF ASSOCIATION WITH AN EXCESS OF EITHER MESOTHELIOMA
OR GASTROINTESTINAL CANCER."

WE ARE SENDING TO YOU BY MAIL COPIES OF DR. WRIGHT'S PAPER AND
DR. KLEINFELD'S PAPER AND LETTER TO JOHNS-MANVILLE.

WE FIRMLY BELIEVE THAT A THOROUGH ANALYSIS OF THE MEDICAL AND
SCIENTIFIC LITERATURE ON ASBESTOS AND HEALTH WILL LEAD FDA TO
THE CONCLUSION THAT NO FURTHER REGULATIONS OF THE USE OF TALC
CONTAINING TREMOLITE IN FOOD AND FOOD PACKAGING MATERIAL IS
WARRANTED.

YOU ARE NO DOUBT AWARE OF THE IMPORTANT JOINT SYMPOSIUM OF THE EPA AND NEIHS CALLED BY DR. SELIKOFF FOR NOVEMBER 19 AND 20 ON THE EFFECTS OF INGESTION OF INORGANIC PARTICALS AT WHICH ALL LEADING SCIENTISTS IN THIS FIELD WILL BE EXPECTED TO ATTEND.

JOHNS-MANVILLE RESPECTFULLY REQUESTS THE FOLLOWING ACTION BY THE FDA.

FIRST, THE FDA IS REQUESTED TO INVITE QUALIFIED SCIENTIFIC PERSONNEL OF JOHNS-MANVILLE AND OTHER INDUSTRY LEADERS TO MEET WITH SCIENTISTS IN THE FDA TO ESTABLISH REASONABLE LIMITATIONS ON TREMOLITIC TALC AS AN INCIDENTAL FOOD ADDATIVE AND TO FORMULATE RESPONSIBLE TEST METHODS IN THAT REGARD.

SECOND, THE FDA PARTICIPATE IN THE JOINT SYMPOSIUM OF THE NEIHS AND EPA.

THIRD, NO FINAL OR PROPOSED REGULATIONS ON THE USE OF TALC IN FOOD PROCESSING OR PACKING BE DISSEMINATED UNTIL THE RESULTS OF THOSE SYMPOSIUM DELIBERATIONS ARE KNOWN.

FOURTH, IN THE EVENT ACTION DETRIMENTAL TO JOHNS-MANVILLE OR THE TALC INDUSTRY IS PROPOSED, OPPORTUNITY TO DISCUSS SUCH ACTION WITH THE FDA BE AFFORDED JOHNS-MANVILLE PRIOR TO PUBLICATION.

I WOULD GREATLY APPRECIATE YOUR SYMPATHETIC CONSIDERATION OF THESE REQUESTS AND YOUR RECOGNITION OF THE GENUINE CONCERN JOHNS-MANVILLE HAS THAT RUMORED ACTIONS BY THE FDA, IF TRUE, WOULD, ON THE BASIS OF HIGHLY SUSPECT DATA, UNNECESSARILY DESTROY AN INDUSTRY WITH A LONG HISTORY OF OPERATIONS FREE OF HEALTH HAZARDS.

WE AGAIN PLEDGE FULL COOPERATION WITH THE FDA IN CONDUCTING WHATEVER STUDIES MAY BE REASONABLY REQUESTED TO ESTABLISH THE BIOLOGICAL EFFECTS OF TREMOLITE ON HUMANS WHEN INGESTED.

I WOULD APPRECIATE HAVING A RESPONSE FROM YOU TO THIS TELEGRAM AND AM AT YOUR DISPOSAL IN THE EVENT FURTHER DISCUSSIONS WOULD BE HELPFUL IN REACHING A RESPONSIBLE CONCLUSION TO THIS MATTER.

SINCERELY YOURS,

FREDRICK L. PUNDSACK, PH.D.
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