



CANCER PREVENTION COALITION

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November 17, 1994

Dockets Management Branch
Food and Drug Administration, Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Dear Commissioner Kessler,

Enclosed is a citizen petition submitted by the Cancer Prevention Coalition on behalf of Dr. Samuel S. Epstein, Chair and National Advisor of the Ovarian Cancer Early Detection and Prevention Foundation (OCEDPF), Nancy Nehls Nelson, member of OCEDPF, Dr. Peter Orris, and Dr. Quentin Young. This citizen petition is based on scientific papers dating back to the 1960s which warn of increased cancer rates resulting from frequent exposure to cosmetic grade talc.

We request the Commissioner of Food and Drugs to require that all cosmetic talc products bear labels with a warning such as "Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer."

Please send correspondence regarding the status of this petition to the Cancer Prevention Coalition.

Thank you.

Jill Cashen
Research Associate

94P-0420

CP 1

**Citizen Petition Seeking Carcinogenic Labeling on all
Cosmetic Talc Products.**

17 November 1994

David A. Kessler, M.D.
Commissioner
Food and Drug Administration, Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

The undersigned submits on behalf of the Cancer Prevention Coalition, Inc. (CPC), Samuel S. Epstein, M.D., Chair and National Advisor of the Ovarian Cancer Early Detection and Prevention Foundation (OCEDPF), Nancy Nehls Nelson, member of the Ovarian Cancer Early Detection and Prevention Foundation, Peter Orris, M.D. and Quentin Young, M.D. This citizen petition is based on scientific papers dating back to the 1960s which warn of increased cancer rates resulting from frequent exposure to cosmetic grade talc.

The undersigned submits this petition under 21 U.S.C. 321 (n), 361, 362, and 371 (a); and 21 CFR 740.1, 740.2 of 21 CFR 10.30 of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to require that all cosmetic talc products bear labels with a warning such as "Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer."

A. AGENCY ACTION REQUESTED

This petition requests that FDA take the following action:

- (1) Immediately require cosmetic talcum powder products to bear labels with a warning such as "Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer."
- (2) Pursuant to 21 CFR 10.30 (h) (2), a hearing at which time we can present our scientific evidence.

B. Statement of Grounds

Ovarian cancer is the fourth deadliest women's cancer in the U.S., striking approximately 23,000 and killing approximately 14,000 women this year. Ovarian cancer is very difficult to detect at the early stages of the disease, making the survival rate very low. Only three percent of ovarian cancer cases can be attributed to family history.¹ One of the avoidable risk factors for ovarian cancer is the daily use of talcum powder in the genital area.²

Research done as early as 1961 has shown that particles, similar to talc and asbestos particles, can translocate from the exterior genital area to the ovaries in women.^{3,4,5} These findings provide support to the unexpected high rate of mortality from ovarian cancer in female asbestos workers.^{6,7,8} Minute particles such as talc are able to translocate through the female reproductive tract and cause foreign body reactions in the ovary.

There is a large body of scientific evidence, dating back thirty years, on the toxicity and mineralogy of cosmetic talc products. As early as 1968, Cralley et al. concluded:

All of the 22 talcum products analyzed have a...fiber content...averaging 19%. The fibrous material was predominantly talc but probably contained minor amounts of tremolite, anthophyllite, and chrysotile [asbestos-like fibers] as these are often present in fibrous talc mineral deposits...Unknown significant amounts of such materials in products that may be used without precautions may create an

¹SEER Cancer Statistics, 1973-1990.

²Harlow BL, Cramer DW, Bell DA, Welch WR. "Perineal exposure to talc and ovarian cancer risk." Obstet Gynecol, 80: 19-26, 1992.

³Egli GE, Newton M.. "The transport of carbon particles in the human female reproductive tract." Fertility Sterility, 12: 151-155, 1961.

⁴Venter PF, Iturralde M. "Migration of particulate radioactive tracer from the vagina to the peritoneal cavity and ovaries." S African Med J, 55: 917-919, 1979.

⁵Henderson WJ, Hamilton TC, Baylis MS, Pierzepoint CG, Griffiths K. "The demonstration of migration of talc from the vagina and posterior uterus to the ovary in the rat." Environ Research, 40: 247-250, 1986.

⁶Newhouse ML, Berry G, Wagner JC, Turok ME. "A study of the mortality of female asbestos workers." Brit J Indust Med, 29: 134-141, 1972.

⁷Wignall BK, Fox AJ. "Mortality of female gas mask assemblers." Brit J Industrial Med, 39: 34-38, 1982.

⁸Acheson ED, Gardner MJ, Pippard E, Grime LP. "Mortality of two groups of women who manufactured gas masks from chrysotile and crocidolite asbestos: a 40-year follow-up." Brit J Ind Med, 39: 344-348, 1982.

unsuspected problem.⁹

As a follow-up to previous findings, Rohl, et al., examined 21 samples of consumer talcums and powders, including baby powders, body powders, facial powders and pharmaceutical powders between 1971-1975. (See Appendix I) The study concluded:

"...cosmetic grade talc was not used exclusively. The presence in these products of asbestiform anthophyllite and tremolite, chrysotile, and quartz indicates the need for a regulatory standard for cosmetic talc...We also recommend that evaluation be made to determine the possible health hazards associated with the use of these products."¹⁰

Talc is a carcinogen, with or without the presence of asbestos-like fibers. In 1993, the National Toxicology Program published a study on the toxicity of non-asbestiform talc and found clear evidence of carcinogenic activity.¹¹

Recent cancer research in the United States has found conclusively that frequent talcum powder application in the genital area increases a woman's risk of developing ovarian cancer.^{12,13,14,15} Cramer, et al., suggested that talc application directly to the genital area around the time of ovulation might lead to talc particles becoming deeply imbedded in the substance of the ovary and perhaps causing foreign body reaction (granulomas) capable of causing growth of epithelial ovarian tissue.^{16,17}

Harlow, et al., found that frequent talc use directly on the

⁹Cralley LJ, Key MM, Groth DH, Lainhart WS, Ligo RM. "Fibrous and mineral content of cosmetic talcum products." Am Industrial Hygiene Assoc J, 29: 350-354, 1968.

¹⁰Rohl AN, Langer AM, Selifoff IJ, Tordini A, Klimentidis R, Bowes DR, Skinner DL. "Consumer talcums and powders: mineral and chemical characterization." J Toxicol Environ Health, 2: 255-284, 1976.

¹¹National Toxicology Program. "Toxicology and carcinogenesis studies of talc (CAS # 14807-96-6) in F344/N rats and B6C3F₁ mice (Inhalation studies)." Technical Report Series # 421, September 1993.

¹²Hartge P, Hoover R, Leshner LP, McGowan L. "Talc and ovarian cancer." letter, JAMA, 250: 1844, 1983.

¹³Rosenblatt KA, Szklo M, Rosenshein NB. "Mineral fiber exposure and the development of ovarian cancer." Gynecol Oncol, 45: 20-25, 1992.

¹⁴Whittemore AS, Wu ML, Paffenbarger RS, Sarles DL, Kampert JB, Grosser S, Jung DL, Ballon S, Hendrickson M. "Personal and environmental characteristics related to epithelial ovarian cancer. II. Exposures to talcum powder, tobacco, alcohol, and coffee." Am J Epidemiol, 1128: 1228-1240, 1988.

¹⁵Harlow, 1992.

¹⁶ibid.

¹⁷Cramer DW, Welch WR, Scully RE, Wojciechowski CA. "Ovarian cancer and talc: a case control study." Cancer, 50: 372-376, 1982.

genital area during ovulation increased a woman's risk **threefold**. That study also found:

"The most frequent method of talc exposure was use as a dusting powder directly to the perineum [genitals]...Brand or generic "baby powder" was used most frequently and was the category associated with a statistically significant risk for ovarian cancer."

In Harlow's report, arguably the most comprehensive study of talc use and ovarian cancer to date, 235 ovarian cancer cases were identified and compared to 239 controls, women with no sign of ovarian cancer or related health problems. Through personal interviews, Harlow, et al., found that 16.7% of the control group reported frequent talc application to the perineum.¹⁸ This percentage is useful in estimating the number of women in the general population exposed to cosmetic talc in the genital area on a regular basis. Harlow, et al., concludes:

"...given the poor prognosis for ovarian cancer, any potentially harmful exposures should be avoided, particularly those with limited benefits. For this reason, we discourage the use of talc in genital hygiene, particularly as a daily habit."

Clearly, large numbers of women - an estimated 17% - are using cosmetic talc in the genital area and may not be adequately warned of the risk of ovarian cancer from daily use.

C. Claim for Categorical Exclusion

A claim for categorical exclusion is asserted pursuant to 21 CFR 25.24 (a) (11).

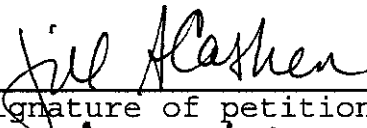
D. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition

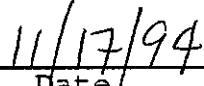
¹⁸Harlow, 1992.

This petition is submitted by:

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Cancer Prevention Coalition
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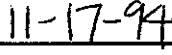
Signature of petitioner



Date



Signature of petitioner



Date

Council to the Cancer Prevention Coalition:
Center for Constitutional Rights
Michael E. Deutsch, Legal Director
666 Broadway
New York, NY 10012
212-614-6427

APPENDIX I:

Results from an informal survey of talc products in Chicago drug stores.

Baby Powders:

Johnson & Johnson Baby Powder (Johnson & Johnson, Skillman, NJ)
Contains: TALC, fragrance

Oscos Brand Baby Powder (Oscos Drug, Oak Brook, IL)
Contains: TALC, fragrance

Body Powders:

Jean Nate Perfumed Talc (Revlon, New York, NY)
Contains: TALC, kaolin, magnesium carbonate, fragrance.

Shower to Shower (Johnson & Johnson, Skillman, NJ)
Contains: TALC, cornstarch, sodium bicarbonate, fragrance, polysaccharides.

Oscos Brand Body Powder (Oscos Drug, Oak Brook, IL)
Contains: TALC, cornstarch, sodium bicarbonate, fragrance, polysaccharides.

Ammens Medicated Powder (Bristol-Myers Squibb, New York, NY)
Contains: Zinc oxide, cornstarch, fragrance, isostearic acid, PPG-20, methyl glucose ether, TALC.

Cashmere Bouquet Perfumed Powder (Colgate, New York, NY)
Contains: TALC, magnesium carbonate, zinc stearate, fragrance.

Gold Bond Medicated Powder (Martin Himmel, Hypoluxo, FL)
Contains: Menthol, Zinc oxide, boric acid, eucalyptol, methyl salicylate, salicylic acid, TALC, thymol, zinc stearate.

Feminine products:

Vagisil Feminine Powder (COMBE, Inc., White Plains, NY)
Contains: Cornstarch, aloe, mineral oil, magnesium stearate, silica, benzethonium chloride, fragrance.

Vaginex Feminine Powder (Schmid Laboratories, Sarasota, FL)

Contains: Zinc oxide, cornstarch, fragrance, 6-hydroxquinoline, 8-hydroxquinoline sulfate, isostearic acid, PPG-20, methyl glucose ether, TALC.

Summer's Eve Feminine Powder (CB Fleet Co., Lynchburg, VA)

Contains: Cornstarch, tricalcium phosphate, oxoxynol-9, benzethonium chloride, fragraence.

FDS Feminine Deodorant Spray (Alberto Culver, Melrose Park, IL)

Contains: isobutane, isopropyl myristate, cornstarch, mineral oil, fragrance, lanolin alcohol, hydrated silica, magnesium stearate, benzyl alcohol.

APPENDIX II:
DESCRIPTION OF PETITIONERS

Cancer Prevention Coalition, Inc., located at 520 North Michigan Avenue, Suite 410, Chicago, Illinois 60611, is a 501 (c)(3) organization, functioning under the fiscal umbrella of Citizen Fund, also a 501 (c)(3) organization. CPC is a unique coalition of leading independent experts in cancer prevention and public health, together with citizen activists and representatives of organized labor, public interest, environmental and women's health groups. Our goal is to reduce cancer rates through a comprehensive strategy of outreach, public education, advocacy and public policy initiatives to establish prevention as the nation's foremost cancer policy.

Nancy Nehls Nelson, 720 N. Washington St., Naperville, Illinois 60563, 708-355-1406. Activist and Member of Ovarian Cancer Early Detection and Prevention Foundation.

Peter Orris, M.D., Director of the Division of Occupational Medicine, Cook County Hospital, 720 South Wolcott, 13th Floor, Chicago, Illinois 60612, 312-633-5310.

Quentin Young, M.D., Hyde Park Medical Association, 5872 South Blackstone, Chicago, Illinois 60637, 312-493-8212.

CANCER PREVENTION COALITION

520 North Michigan Avenue Suite 410

Chicago, Illinois 60611

Cancer prevention through reduction of carcinogens in air, water, food,
consumer products and the workplace.



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