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PETITION SEEKING A CANCER WARNING ON COSMETIC TALC PRODUCTS

May 13, 2008

Mike Leavitt
Secretary of Health and Human Services
U.S. Department of Health and Human Services

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs

Dockets Management Branch
Food and Drug Administration, Room 1601
5630 Fishers Lane
Rockville, MD 20852

Citizen Petition

The undersigned submits this May 13, 2008, Citizen Petition on behalf of: Samuel S. Epstein, M.D., Chairman, Cancer Prevention Coalition (CPC), and Professor emeritus Occupational and Environmental Medicine, University of Illinois at Chicago School of Public Health; Peter Orris, M.D., Professor and Chief of Service, University of Illinois at Chicago Medical Center; Quentin Young, M.D., Chairman, Health and Medicine Policy Research Group, Chicago; Rosalie Bertell, Ph.D., International Association for Humanitarian Medicine, Scientific Advisor to the International Institute of Concern for Public Health, Toronto, and the International Science Oversight Board of the Organic Consumers Association, Washington, D.C.; and Ronnie Cummins, National Director of the Organic Consumers Association.

This Petition, submitted 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, requests the Commissioner of Food and Drugs to require that all cosmetic talc products bear labels with a warning such as, "Frequent application of talcum powder in the female genital area substantially increases the risk of ovarian cancer."

A. AGENCY ACTION REQUESTED

This Petition requests FDA to take the following action:

- (1) Immediately require cosmetic talcum powder products to bear labels with a prominent warning such as: "Frequent talc application in the female genital area is responsible for major risks of ovarian cancer."
- (2) Pursuant to 21 CFR 10.30 (h) (2), a hearing which will be held at which time we can present scientific evidence in support of this Petition.

B. STATEMENT OF GROUNDS

On November 17, 1994, the Cancer Prevention Coalition and the New York Center for Constitutional Rights submitted a Citizen Petition to the Commissioner of the FDA, "Seeking Carcinogenic Labeling on all Cosmetic Talc Products." The Petition was endorsed by Quentin Young, M.D., Chairman of The Health and Medicine Policy Research Group, Peter Orris, M.D., Director of Health Hazard Evaluation, Cook County Hospital, and Professor of Medicine, University of Illinois Medical School, Chicago, Nancy Nelson, Chair of the Ovarian Cancer Early Detection and Prevention Foundation, and subsequently by Senator Edward Kennedy. In a 1997 statement to the Senate, he requested the FDA to place a cancer warning on the label of talc products, besides other products containing known carcinogens. However, over a decade later his warning remains ignored.

The 1994 Petition was supported by 15 scientific publications. These included nine, from 1983 to 1992, on the major risks of ovarian cancer from the frequent application of brand or generic talc "baby powder" to the genital area of women without any warning of the risks involved. Two of these publications also reported that the genital application of talc could result in its translocation to the ovary.

The scientific basis of the 1994 Petition was further supported by J. Mande, Acting Associate Commissioner for Legislative Affairs of the Department of Health and Human Services. On August 25, 1993, he admitted that "We are aware that there have been reports in the medical literature between frequent direct female perineal talc dusting over a protracted period of years, and an incremental increase in the statistical odds of subsequent development of certain ovarian cancers . . . (However) at the present time, the FDA is not considering to ban, restrict or require a warning statement on the label of talc containing products."

The scientific basis of the 1994 Petition was also admitted by the industry. In an August 12, 1982, article in the *New York Times*, Johnson & Johnson, the manufacturer and retailer of talc dusting powder, stated it was aware of a publication which concluded that frequent genital application of talc was responsible for a three-fold increased risk of ovarian cancer. Warnings of these risks were emphasized by the Cancer Prevention Coalition in November 19, 1994, in letters to Mr. Ralph Larsen, CEO of Johnson & Johnson, and Mr. C.R. Walgreen, Chairman and CEO of Walgreens. Johnson & Johnson was urged to substitute cornstarch, a safe organic

carbohydrate, for talcum powder products, and also to label its products with a warning on cancer risks.

In spite of the scientific evidence, and admission by Johnson & Johnson, the Petition was denied by Dr. John Bailey, FDA's Director of the Office of Cosmetics and Colors, on the basis of the "limited availability" (of Agency resources) and on alleged scientific grounds. Dr. Bailey is currently Director of the industry's Personal Care Products Council.

Evidence for the May 2008 Petition is supported by Edward Kavanaugh, President of the industry's Cosmetic Toiletry and Fragrance Association. In 2002, he admitted that talc is "toxic," that it "can reach the human ovaries," and that prior epidemiological investigations concluded that its genital application increased the risk of ovarian cancer. Further evidence for this Petition is based on 12 publications since 1995, cited below. These confirm the causal relation between genital application of talc and ovarian cancer, and the protective effect of tubal ligation or hysterectomy, preventing the translocation of talc to the ovary.

As Dr. Andrew C. von Eschenbach, former Director of the National Cancer Institute, is aware, the mortality of ovarian cancer for women over the age of 65, has escalated dramatically since 1975, by 13% for white and 47% for black women (1). There are about 15,300 deaths from ovarian cancer each year. This makes it the fourth most common fatal cancer in women after colon, breast and lung.

A case-control study, the largest to date, confirmed the relation between the perineal use of talc and ovarian cancer (2). This has also been confirmed by other reports (3-7). In view of the strength of this evidence, "formal public health warnings" were urged in 1999 (8). An analysis of 16 pooled studies confirmed a statistically significant 33% increased risk of ovarian cancer associated with the perineal use of talc (9). A report by 19 scientists in eight nations worldwide, under the auspices of the International Agency for Research on Cancer, concluded that eight publications confirmed a 30-60% increased risk of ovarian cancer following the perineal application of talc (10). This risk has been confirmed in other reports (11, 12).

The protective effects of tubal ligation or hysterectomy, preventing the translocation of talc from the perineum to the ovary, have also been confirmed (2, 3, 4, 7).

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 his best knowledge and belief, 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.

This petition is submitted by:

Samuel S. Epstein, M.D.
Chairman, Cancer Prevention Coalition
Professor emeritus Occupational and Environmental Medicine
University of Illinois School of Public Health, Chicago

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