

April 1995

RECEIVED MANAGEMENT DIVISION

95 APR 12 PM 12:52

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

Dear Dr. Kessler:

This letter is in support of the petition submitted by the Cancer Prevention Coalition, Inc. (CPC); docket number 94P-0420/CP 1, filed on 11/17/94. This petition requests that the Commissioner of Food and Drugs 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 genitalia area increases the risk of ovarian cancer."

There is a very large amount of literature on the research that has been done this topic. Current research indicates a strong association between the use of talcum powder in the female genitalia area and ovarian cancer, despite the lack of a conclusive, direct link, as "proven" by research. With such a vast literature on the subject, I am astounded that talc is still being used in products, such as feminine deodorant sprays and powders, as well as many brands of condoms. While talc is still being used in these types of products, despite existing literature, that repeatedly links genital talc use and ovarian cancer, I find it absolutely negligible that these products carry no warnings as to the danger of talc.

It is the right of women to be warned of the possible association, and I hope that you will strongly consider this citizen's petition.

Sincerely,

Julie Rae E. Temby
Julie Rae E. Temby
3430 N. Elaine Place #11
Chicago, IL 60657

cc: Samuel M. Epstein, M.D.
Cancer Prevention Coalition
520 N. Michigan Avenue
Chicago, IL 60610

94P-0420

C1

5 April 1995

Marion Merrill Dow
Clomid Marketing Department
9300 Ward Parkway
P.O. Box 9627
Kansas City, MO 64134-0627

To Whom it May Concern:

This letter is regarding my request for any consumer and medical information on the product known as Clomid, from your organization. I am a graduate student at the School of Public Health, University of Illinois at Chicago, and I am looking into the association between clomiphene citrate, and ovarian cancer. I called your organization, with my requests, at the end of March, and upon explaining my intentions, I was directed to the employees who could provide me the information I was seeking. I was treated with courtesy and respect, and was assured that the relevant information would be sent to me.

I want to commend your polite and professional staff, and thank you for your cooperation. Please consider this letter a formal request for any information you can provide, on your product, Clomid, that might assist me in my research on this very important topic.

Your diligent attention and cooperation are greatly appreciated.

Sincerely,



Julie Rae E. Temby
3430 N. Elaine Place #11
Chicago, IL 60657

cc: Samuel M. Epstein, M.D.
Cancer Prevention Coalition

David A. Kessler, M.D.
Commissioner, Food and Drug Administration

5 April 1995

Robert Lederer
Vice President, Marketing
Serono Laboratories
100 Longwater Circle
Norwell, MA 02061

Dear Mr. Lederer:

This letter is regarding my attempts to attain some consumer and medical information on the product known as Serophene, from your organization. I am a graduate student at the School of Public Health, University of Illinois at Chicago, and I am looking into the association between clomiphene citrate, and ovarian cancer. I started my inquiries, by phone, during the middle of March, 1995. Upon explaining my intentions, and requesting any available information, and/or further reference resources, I was transferred to several different people, one of which was Mr. Steve Eby. Mr. Eby was to have directed my inquiries to an employee who could provide the information I was requesting, however, I have not heard from any Serono employee since my last conversation with Mr. Eby in March.

Please consider this letter a formal request for any information you can provide, on your product, Serophene, that might assist me in my research on this very important topic.

Your diligent attention and cooperation are greatly appreciated. -

Sincerely,

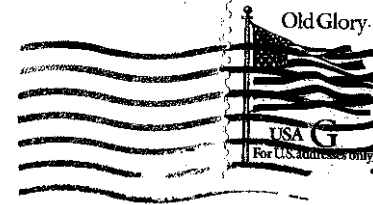
Julie Rae E. Temby

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3430 N. Elaine Place #11
Chicago, IL 60657

cc: Samuel M. Epstein, M.D.
Cancer Prevention Coalition

David A. Kessler, M.D.
Commissioner, Food and Drug Administration

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DAVID A. KESSLER, M.D.
COMMISSIONER
FOOD AND DRUG ADMINISTRATION, ROOM 1-23
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