

UNIVERSITY OF ILLINOIS
AT CHICAGO

School of Public Health (MC 922)
2121 West Taylor Street
Chicago, Illinois 60612-7260

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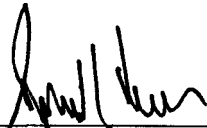
May 30, 2008

Carolyn Kachovec, Director
Division of Dockets Management
Office of Management Programs
Office of Management
Food and Drug Administration
Department of Health & Human Services
Rockville, MD 20857

Dear Ms. Kachovec,

Further to your attached May 21, 2008, letter, I am resubmitting the petition together with copies of the articles or source cited.

Sincerely,



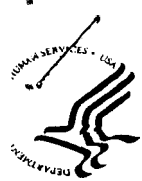
Samuel S. Epstein, M.D.

Enclosures: May 13, 2008 Petition Seeking a Cancer Warning on Cosmetic Talc Products;
Copies of articles or source cited

FDA-2008-P-0309

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

May 21, 2008

Samuel S. Epstein, M.D.
Chairman, Cancer Prevention Coalition
c/o University of Illinois at Chicago
School of Public Health, MC 922
2121 West Taylor Street, Rm. 322
Chicago, IL 60612

Dear Dr. Epstein:

This letter responds to your petition requesting the Food and Drug Administration to seek a cancer warning on cosmetic talc products. Your petition was received by this office on May 15, 2008.

FDA has established procedural regulations that describe the appropriate format for petitions like yours, as well as certain matters on which information must be submitted. The regulations provide that if a petitioner fails to follow the appropriate format, or fails to submit information on a required subject, we cannot accept the petition for filing.

Your petition fails to include the relevant information referenced in your petition, therefore, fails to meet the requirements of 21 CFR 10.20(c). For this reason, your petition is not acceptable for filing.

I am enclosing a copy of the appropriate regulations pertaining to your submission. Please contact Ms. Bigesby at 301/827-6857 if you have questions regarding this regulation.

Should you amend your petition to comply with this regulation, we will accept it for filing. Please note, however, that acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely yours,

Carolyn Kachovec, Director
Division of Dockets Management
Office of Management Programs
Office of Management

Encls.