



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

March 27, 2006

FILE COPY

Ellen L. Stovall, President & CEO
National Coalition for Cancer Survivorship
1010 Wayne Avenue – 7th Floor
Silver Spring, MD 20910

Sandra J. Horning, M.D., President
American Society of Clinical Oncology
1900 Duke Street – Suite 200
Alexandria, VA 22314

Dear Ms. Stovall and Dr. Horning:

Your petition requesting the Food and Drug Administration to issue Guidance for Industry outlining procedures and standards for initiating an “expanded access program” for unapproved drugs was received by this office on 03/27/2006. It was assigned docket number 2006P-0135/CP1 and it was filed on 03/27/2006. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the 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,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2006P-0135

ACK 1