



MAR -9 1998

TRANSMITTED VIA FACSIMILE

Eloise R. Scott, D.V.M.
Associate Director, U.S. Regulatory Affairs
Smithkline Beecham Pharmaceuticals
1250 Collegeville Road
P.O. Box 5089
Collegeville, PA 19426-0989

RE: NDA #20-031
Paxil (paroxetine HCl) Tablets
MACMIS #6383

Dear Dr. Scott:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of promotional activities by Smithkline Beecham Pharmaceuticals (SKB) for Paxil (paroxetine HCl) Tablets that are false, misleading, and in violation of the Federal Food, Drug, and Cosmetic Act. DDMAC refers to a T-shirt that was distributed by, or on behalf of, SKB during a Health Fair function at the Children's Advocacy Center of Brevard in Brevard, Florida. The front of the T-shirt bears the logo and name of the Children's Advocacy Center, while the back of the T-shirt bears the claim "Multiple Symptoms, One Solution" followed by the Paxil logo and the proprietary name.

Specifically DDMAC has the following objections to the distribution of this T-shirt:

1. The distribution of this T-shirt at an affair focused on children's health, along with the combination of the Children's Advocacy Center logo and the Paxil advertisement on the same T-shirt, implies that Paxil is a product that is useful in children. However, the safety and effectiveness of Paxil in the pediatric population has not been established. Thus, the T-shirt is violative because it is promoting an unapproved use of Paxil.
2. The claim "Multiple Symptoms, One Solution" is misleading because it is too broad and it lacks contextual information regarding the indications for Paxil. Further, Paxil is not indicated for multiple "symptoms," it is indicated for several disorders (i.e., major depression, obsessive-compulsive disorder, and panic disorder). It is

neither indicated for symptoms that are non-specific, nor any other disorders.

3. The T-shirt is not a reminder advertisement because it makes representation of the product by its broad efficacy claim and by the profile of the head. Thus, the advertisement lacks fair balance because it has no risk information about Paxil.
4. The T-shirt would be violative because the established name does not accompany the proprietary name.

To address these objections, DDMAC recommends that SKB do the following:

1. Immediately discontinue the promotional use of this T-shirt and all other materials that contain the same or similar presentations.
2. Respond to this letter, in writing, by March 20, 1998. This response should include SKB's intent to comply with the above, a list of all violative promotional materials that include the same or similar issues, and SKB's methods for discontinuing their use.

If SKB has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #6383 in addition to the NDA number.

Sincerely,

Lisa L. Stockbridge, Ph.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications