



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 16 2000

TRANSMITTED VIA FACSIMILE

Gregory T. Brophy, Ph.D.
Director, U.S. Regulatory Affairs
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

RE: NDA #18-936
Sarafem (fluoxetine HCl) Tablets
MACMIS # 9523

Dear Dr. Brophy:

This letter concerns a 60-second Direct-to-Consumer (DTC) television broadcast advertisement ("Shopping Cart" ID# SA 18116) that Eli Lilly and Company (Lilly) has disseminated for Sarafem (fluoxetine HCl) Tablets. As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed this advertisement and concluded that it is misleading, lacking in fair balance, and therefore in violation of the Federal Food, Drug, and Cosmetic Act and its applicable regulations.

Specifically, DDMAC objects to the following issues in the DTC broadcast advertisement:

Inadequate Presentation of Indication

The graphics of the advertisement show a frustrated woman trying to pull her shopping cart out of its interlocked lineup in front of a store. The concurrent audio states "Think it's PMS? It could be PMDD." The imagery and audio presentation of the advertisement never completely define or accurately illustrate premenstrual dysphoric disorder (PMDD) and there is no clear distinction between premenstrual syndrome (PMS) and PMDD communicated. Consequently, the overall message broadens the indication and trivializes the seriousness of PMDD, a disorder whose hallmarks include a markedly depressed mood, anxiety or tension, affective lability, and persistent anger or irritability. For a diagnosis of PMDD, these and other symptoms must markedly interfere with work, school, usual social activities, and relationships.

Fair Balance

The advertisement is lacking fair balance because the graphics accompanying the audio presentation of the risk information are very distracting and minimize the important risk information. The distractions include competition from the imagery, scene changes, camera shots, and concurrent supers.

Adequate Provision

The elements of adequate provision in the advertisement appear as supers that lack prominence and readability. Specifically, the font size is too small and the color lends insufficient contrast to the graphics in each scene. Therefore, the advertisement does not fulfill the requirements for adequate provision of the approved product labeling.

Requested Action

DDMAC requests that Lilly immediately cease using this broadcast advertisement and all other promotional materials for Sarafem that contain the same or similar issues. Lilly should submit a written response to DDMAC on or before November 30, 2000, describing its intent and plans to comply with the above. In its letter to DDMAC, Lilly should include a list of all promotional materials that were discontinued and the date(s) of discontinuation.

If you have any further questions or comments, write to me at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, 5600 Fishers Lane, HFD-042, rm. 17B-17, Rockville, MD 20857.

DDMAC reminds you that only written communications are considered official. In all future correspondence regarding this matter, please refer to MACMIS #9523 in addition to the NDA number.

Sincerely,

/s/

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

ELI LILLY AND COMPANY

Sarafem™ "Shopping Cart"

:60 TV Commercial

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Sarafem is a trademark of Eli Lilly and Company. Prozac is a registered trademark of Eli Lilly and Company

	<u>VIDEO</u>		<u>AUDIO</u>
1	OPEN ON ESTABLISHING SHOT OF GROCERY STORE WITH SHOPPING CARTS LINED UP IN FRONT	MUSIC:	UP AND UNDER THROUGHOUT
		SFX:	(AMBIENT GROCERY STORE SOUNDS UNDER)
2	CUT TO WOMAN IN GROCERY STORE TRYING TO PULL OUT A SHOPPING CART FROM A LINE OF THEM	AVO:	It's that week before your period.
			The irritability
	SUPER: IRRITABILITY	SFX:	(DING!)
3	WOMAN CONTINUES TO STRUGGLE WITH CART	AVO:	Mood swings
		SFX:	(DING!)
4	SHE STRUGGLES SOME MORE	AVO:	Bloating.
		SFX:	(DING!)
5	CUT TO TITLE CARDS: THINK IT'S PMS? IT COULD BE PMDD.	AVO:	Think it's PMS? It could be PMDD--
6	CUT BACK TO WOMAN GROWING INCREASINGLY IRRITATED.	AVO:	Premenstrual Dysphoric Disorder – those intense mood and physical symptoms the week before your period.
	SUPER: PREMENSTRUAL DYSPHORIC DISORDER		
7	CUT TO SARAFEM™ LOGO AND THE WORD "NEW"	AVO:	Introducing Sarafem. The first and only prescription medication
8	CUT BACK TO WOMAN, IRRITATED AT CART	AVO:	for both the mood and physical symptoms of PMDD.
	SUPER: AVAILABLE BY PRESCRIPTION ONLY		
9	CUT TO CLOSE UP OF WOMAN'S HANDS AS SHE TRIES TO TUG AT HANDLE OF CART	AVO:	Sarafem can help bring relief. If you develop a rash or hives while taking Sarafem, call your doctor right away because this can be a sign of a serious medical condition.
	WOMAN LOOKS AROUND AS IF EMBARRASSED BEFORE TUGGING AT SHOPPING CART AGAIN		

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|----|---|------|---|
| 10 | WOMAN CONTINUES TO BE IRRITATED.
SUPER: SEE OUR PRINT AD IN REDBOOK
SUPER: CONTAINS FLUOXETINE HYDROCHLORIDE, THE SAME ACTIVE INGREDIENT FOUND IN PROZAC® | AVO: | People treated with MAO inhibitors or thioridazine should not take Sarafem. Tell your doctor about any medications you're taking or if you're pregnant, nursing or plan to become pregnant. |
| 11 | ANOTHER WOMAN APPROACHES AND EASILY PULLS OUT A SHOPPING CART

SUPER: 1-800-602-PMDD | AVO: | Some women may experience side effects such as tiredness, upset stomach, nervousness, dizziness and difficulty concentrating. |
| 12 | FIRST WOMAN LOOKS EXHASPERATED AND MOVES TO ANOTHER SHOPPING CART THAT SHE IS ABLE TO PULL OUT

SUPER: WWW.SARAFEM.COM | AVO: | Sarafem can help. |
| 13 | CUT TO SARAFEM LOGO

SUPER: ASK YOUR DOCTOR TODAY | AVO: | Ask your doctor today if Sarafem is right for you. |
| 14 | LILLY LOGO COMES UP WITH CLOSE UP OF SHOPPPING CART WITH A "BUM" WHEEL | AVO: | Why live this way another month? |