DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 19 1999

TRANSMITTED VIA FACSIMILE

Priya Jambhekar
Director, Regulatory Affairs
Baxter Pharmaceutical Products, Inc.
110 Allen Road
Liberty Corner, NJ 07938-0804

RE: NDA 20-118
Suprane (desflurane, USP)
MACMIS ID #7846

Dear Ms. Jambhekar:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of promotional materials for Suprane (desflurane), disseminated by Baxter Pharmaceutical Products, Inc. (Baxter), that are in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. DDMAC specifically refers to a professional journal advertisement entitled "Get your anesthesia performance on the fast track" that appears in the premiere issue of *Inspirations – The Anesthesia Residents Quarterly.* DDMAC has reviewed this journal advertisement, submitted under cover of Form FDA 2253 on February 25, 1999 (Item # 742256), and finds it to be in violation of the Act for the following reasons:

Lack of Fair Balance

Promotional materials are misleading if they fail to present information relating to adverse consequences associated with the use of the advertised drug and fail to include appropriate reference to warnings, precautions, and contraindications. Such disclosures should be presented with a prominence and readability reasonably comparable with the information relating to the effectiveness of the drug. The journal ad for Suprane fails to present information relating to side effects and contraindications with a prominence and readability that is reasonably comparable with the presentation relating to effectiveness, taking into account all implementing factors and techniques apt to achieve emphasis. Baxter's presentation of risk information in this ad is limited to three statements, presented in very small type face, that are placed below the list of references and directly above the brief summary. Moreover, none of the adverse reactions derived from controlled clinical trials with Suprane are presented in the ad.

In order to address these objections, DDMAC recommends that Baxter take the following actions:

1. Immediately discontinue the use of these, and all other promotional materials for Suprane that contain the same or similar violations.

2. Provide to DDMAC, in writing, Baxter's intent to comply with #1 above. Your response should be received by May 3, 1999.

3. This response should include a list of all similarly violative promotional materials and Baxter's method for discontinuing their use.

If you have 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. DDMAC reminds you that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #7846 in addition to the NDA number.

Sincerely,

Mark W. Askine, R.Ph.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications