DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 20 1997

TRANSMITTED VIA FACSIMILE

Jerry Johnson, Ph.D.
Vice President, Regulatory Affairs
Fujisawa USA Inc.
Parkway North Center
Three Parkway North
Deerfield, Illinois 60015-2458

RE: NDA 50-740
AmBisone (liposomal amphotericin B)
MACMIS ID #5227

Dear Dr. Johnson:

The Division of Drug Marketing, Advertising and Communications (DDMAC) has received and reviewed materials that suggest that FUSA and/or NeXstar Pharmaceuticals may be promoting AmBisone prior to its approval. (See attached). If so, this activity would be in violation of the Federal Food, Drug, and Cosmetic Act (Act) and the applicable regulations.

Specifically, DDMAC has obtained a copy of a mailing to physicians and pharmacists that solicits their input into the treatment of systemic fungal infections during a telephone conversation with a research company The materials provided to participants request information about their specialty, institution, percent of patients treated with certain fungal infections, current protocols for treating certain fungal infections, the availability of liposomal amphotericin products on their institution's formulary, and their clinical experience with these products, including AmBisone. The materials also include a number of "Scenarios" that describe various attributes of liposomal amphotericin products, including AmBisone.

DDMAC is concerned about the scenarios that describe AmBisone. For example, these scenarios provide suggested indications, safety data, and efficacy data in treating specific fungal infections. We are concerned that this information states or suggests that AmBisone has clinical utility in fungal infections that may be beyond the scope of the indications and labeling that may be approved for Ambisone.

Also, the scenarios provide clinical success and bacteriologic eradication rates for AmBisone and other liposomal products. These comparisons of efficacy rates state or suggest that AmBisone may be more clinically active than the other liposomal products.

Finally, the materials ask participants to provide product attribute ratings for the liposomal products, including AmBisone. However, it is not clear how physicians and pharmacists could have sufficient experience with AmBisone, since it is not yet commercially available, to be able to rate their experience with the product.

In order to address these concerns, DDMAC requests that FUSA provide the following information:

1. Provide the sampling strategy for identifying and selecting physicians and pharmacists for participation in the telephone interviews.

2. Provide a list of all physicians and pharmacists who were mailed the telephone interview invitation letter, their specialties, and their geographic locations.

3. Provide a list of all physicians and pharmacists who participated in the telephone interviews with the research firm and provide a list of all teleconference dates and times.

4. Provide copies of all documents (e.g., handouts, announcements, agendas, questionnaires, etc.) given or shown to physicians and pharmacists during or for purposes of the aforementioned teleconferences.

5. Provide the script used by the research firm during the telephone interviews and copies of all audiotapes and transcripts pertaining to the aforementioned teleconferences.

6. Provide the contents of the "envelope" that participants were instructed not to open until the phone interviews. If all the envelopes did not contain the same information, provide copies of all materials that were disseminated to participants in these envelopes.

7. Provide the name of all person(s) and organizations that were involved in the development of the product scenarios.

8. Provide the amount of renumeration, if any, provided to physicians and pharmacists who participated in the telephone interviews.

9. Provide copies of all data and information supporting any and all claims or statements (including comparative claims or claims of superiority) pertaining to AmBisone.

FUSA's response should be received by April 3, 1997. If FUSA has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or in writing at DDMAC, HFD-40, Room 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

In all correspondence related to this matter, please refer to MACMIS ID #5227, in addition to the NDA number.

Sincerely,

Russell Fleischer, PA-C, MPH
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications

Attachments