DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 19 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 #5179

Dear Dr. Johnson:

Reference is made to Fujisawa USA Inc.'s (FUSA) Coming Soon ad for Ambisone. The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed this ad and finds it in violation of the Federal Food, Drug, and Cosmetic Act (Act) and the applicable regulations.

DDMAC refers FUSA to the April 1994, guidance letter to industry, which discussed preapproval promotion. As you know, the regulations promulgated pursuant to the Act at 21 CFR 312.7 state, among other things, that an investigational new drug may not be promoted as being safe and effective for the uses under investigation. Therefore, DDMAC usually considers preapproval promotion of drug products to be violative. However, DDMAC has traditionally recognized two methods in which sponsors may discuss products under FDA review, without making promotional claims of safety or efficacy that are prohibited under the Act.

The first method of permissible preapproval promotion is "institutional promotion." Institutional advertisements state that a particular drug company is conducting research in a certain therapeutic area. The advertisement may not suggest any particular drug by name or otherwise suggest that a particular drug will soon be approved for use in the therapeutic area under discussion.

The second method of permissible preapproval promotion is "coming soon" advertisements. Coming soon advertisements announce the name of a new product that will be available soon, but do not make written, verbal, or graphic representations or suggestions concerning the safety, efficacy, or intended use of the product.

Therefore, the statements "AmBisone Coming Soon" and "AmBisone is a joint effort of Fujisawa USA, Inc., a leader in the discovery critical care pharmaceuticals and NeXstar Pharmaceuticals, Inc., the innovators of liposomal pharmaceutical products" renders this advertisement as neither a coming soon or an institutional advertisement because it makes a representation about FUSA's and NeXstar's areas of research and a specific product.

In order to address this objection, DDMAC recommends that FUSA take the following actions:

1. Immediately discontinue the use of the above referenced journal ad, and any and all other promotional materials or advertising that make the same or similar representations.

2. Provide to DDMAC, in writing, FUSA's intent to comply with number one above.

FUSA's response should be received by April 2, 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 #5179, in addition to the NDA number.

Sincerely,

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