DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FDA

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

Ron Lapre
Director, Regulatory Affairs
Oclassen Pharmaceuticals, Inc.
311 Bonnie Circle
Corona, California 91720

APR 28 1998

RE: **NDA # 50-641**
Monodox (doxycycline monohydrate) 100mg Capsules
MACMIS ID # 6521

Dear Mr. Lapre:

The Division of Drug Marketing, Advertising, and Communications (DDMAC), as part of its routine monitoring and surveillance program, has reviewed materials used to promote Oclassen Pharmaceuticals, Inc.'s (Oclassen) product, Monodox. This material included brochure #G11021331 submitted under cover of FDA Form 2253 on February 16, 1998. DDMAC finds this brochure to be false or misleading, in violation of the Federal, Food, Drug, and Cosmetic Act (Act) and the applicable regulations. Specifically, DDMAC objects to the following:

Failure to Provide Fair Balance

Brochure #G11021331 is misleading because it fails to disclose any information about the risks associated with the use of Monodox. Specifically, the brochure contains several promotional claims regarding the effectiveness of Monodox, such as, "Proven efficacy equal to minocycline;" "Saves your patients significant dollars over the leading brand of minocycline;" "May be taken with food or dairy products with no major effect on total absorption; etc.," without disclosing any risk information about the product. For example, the brochure fails to disclose that Monodox is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines (which includes doxycycline); that photosensitivity has been observed in some individuals taking tetracycline, and that treatment should be

discontinued at the first evidence of skin erythema, etc.

Cost Claims

. **"Saves your patients significant dollars over the leading brand of minocycline"**

The above statement is misleading because it fails to reveal material facts concerning the cost of Monodox and the cost of the leading brand of minocycline to which Monodox is being compared. In addition, cost minimization claims should clearly identify the source of cost data in the body of the promotional material. If the source of information is the Average Wholesale Price data, or similar wholesale data, an additional disclosure should be made that the data may not reflect final costs paid by the pharmacy or the consumer. Failure to include this information renders the above statement misleading.

In order to address the above violations, DDMAC recommends that Oclassen take the following actions:

1. Immediately discontinue the use of the referenced brochure and other promotional materials for Monodox that contain the same or similar claims or presentations.

2. Provide a written response to DDMAC of your intent to comply with the above request, and a list of promotional materials containing the misleading presentations that will be discontinued.

Oclassen's response should be received by May 12, 1998. If Oclassen 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.

DDMAC reminds Oclassen that only written communications are considered official.

Ron Lapre
Oclassen Pharmaceuticals, Inc.
NDA# 50-641

In all future correspondence regarding this particular matter, please refer to MACMIS ID #6521 in addition to the NDA number.

Sincerely,

JoAnn Spearmon, Pharm.D., M.P.A.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications