DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FOI

AUG 11 1998

TRANSMITTED BY FACSIMILE

Hana B. Moran, Ph.D.
Sr. Vice President
Regulatory Affairs and Quality Assurance
SangStat Medical Corporation
1505-B Adams Drive
Menlo Park, CA 94025

Re: ANDA 64195
Cyclosporine Oral Solution
MACMIS # 6843

Dear Dr. Moran:

This letter concerns promotional materials for SangStat Medical Corporation's (SangStat) cyclosporine oral solution. The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed a journal advertisement (9025-4101-0398) as part of its monitoring program, and has determined that SangStat is promoting this drug in interstate commerce prior to its approval for marketing by the Food and Drug Administration. The promotion of drugs prior to their approval for marketing is in violation of the Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder.

Specifically, SangStat is promoting its cyclosporine product in the journal Transplantation (65 Transplantation No.s 11, 12 (June 15, 1998; June 27, 1998)). The advertisement states, "[C]yclosporine coming soon from SANGSTAT The Transplant Company™." As a whole, this advertisement represents the use of SangStat's cyclosporine product for an indication for which it is currently under investigation. Therefore, this advertisement constitutes pre-approval promotion and is in violation of 21 C.F.R. § 312.7(a).

Moreover, although reminder advertisements that call attention to the name of the product without making representations about the product's use are permitted for some products, they are not permitted for drugs whose product labeling carries a boxed warning relating to a serious hazard associated with the product's use (21 C.F.R. § 202.1(e)(2)(i)). If approved, SangStat's cyclosporine product labeling is likely to have a boxed warning. Therefore, DDMAC objects to SangStat's use of the "coming soon" reminder type advertisement for its cyclosporine product.

SangStat should acknowledge receipt of this letter and its plans to discontinue use of this journal advertisement and similar violative promotional activities by August 25, 1998. SangStat should direct its response to the undersigned by facsimile at (301) 594-6771, or by written communication 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 SangStat that only written communications are considered official.
In all future correspondence regarding this matter, please refer to MACMIS ID #6843, in addition to the ANDA number.

Sincerely,

/S/

Sherrie Shade, R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications