



January 31, 1995

T93-0078

John L. Lewis, M.D.
Chairman, Institutional Review Board
Memorial Sloan-Kettering Cancer Center
1275 York Avenue
New York, New York 10021

RE: Protocol # 93-105

Dear Dr. Lewis:

You will find appended to this covering letter an amended version of the approved IRB protocol # 93-105, entitled "Phase II Study of Antineoplastons A10 and AS2-1 in Patients with Advanced Recurrent Malignant Gliomas". Further amendments, as described below, have been made at the request of NCI.

The minor textual changes expand the pool of eligible patients, thus permitting us to recruit patients more rapidly; however, they do not otherwise alter the overall design of the protocol.

1. In Sections 1.1-b) and 6.1-i) the permissible Karnofsky Performance Status Score has been lowered from 70% to 60%.
2. In Sections 1.1-k) and 6.2-a) the exclusion criteria have been changed.

The statement:

"Patients with tumors > 5 cm in diameter, multifocal tumors, or with leptomeningeal or systemic metastases are excluded"

has been replaced by the statement:

"There will be no exclusion based on tumor size, multifocality, or leptomeningeal or systemic metastases".

I thank you for your assistance in this matter.

Sincerely,

Mark Malkin, M.D.

cc Jerome Posner, M.D., Charles Young, M.D.
Mario Sznol, M.D. (NCI)