STATE OF CALIFORNIA

RESEARCH ADVISORY PANEL
6000 STATE BUILDING
SAN FRANCISCO, CALIFORNIA 94102

February 8, 1977

Alexander T. Shulgin, Ph.D.
1483 Shulgin Road
Lafayette, California 94549

Re: Revised Application #7739 -
"The Biosynthesis of
Marijuana Components"

Dear Doctor Shulgin:

Reference is made to your amended research protocol, dated December 7, 1976, which was submitted in response to the Panel's letter of November 23, 1976. The Panel has reviewed the material you have submitted and is unable to approve your protocol because of its major deficiencies.

Moreover, in view of violation of the controlled substances act and failure to obtain Panel approval for recently completed non-marijuana Schedule I drug research, the Research Advisory Panel hereby withdraws its approval of your marijuana project - "The Origin and Potencies of Marijuana," which was authorized in March 1970. Thus, it should be noted that henceforth you do not have authorization to conduct research with any Schedule I controlled substances in the State of California. The Drug Enforcement Administration is being apprised of this action by a carbon copy of this letter. The detailed findings of the Panel's review are presented below.

Supplying of a Schedule I controlled substance to a non-registered individual and without an official order form.

It has come to the Panel's attention that you supplied mescaline for a research project at the University of California at San Diego. This Schedule I substance was supplied to non-registered individuals and without an official federal order form. You are well aware of the State and Federal statutes and regulations, including the need for prior Research Advisory Panel approval of research protocols involving mescaline and

other hallucinogenic drugs. This deliberate violation of the law (c.f. Hadorn, D. et al, Behavioral Biology 17: 403-9, 1976, footnote #1) leaves the Panel with serious questions about the propriety of your handling of drugs with abuse potential.

Conduct of Schedule I drug research (other than marijuana) without Panel approval.

Along with your brief amended research application for marijuana, you submitted an extensive bibliography. Some of the recent publications (e.g., Pharmacology 10: 12-18, 1973; Neuropharmacology 14: 165-74, 1975) report research work with Schedule I hallucinogenic substances that has never been submitted to the Panel, nor approved by this body as required by State law. Your published activities document violation of State laws regarding controlled substance research.

A further aspect of this violation is the unauthorized use of human subjects for research with a investigational new drug. Since this matter is primarily the concern of the Federal Food and Drug Administration, a copy of this letter is being forwarded to FDA for follow-up and appropriate action.

Failure to submit an annual report for 1976.

In its letter of November 23, 1976 the Panel requested that you submit an annual progress report of your research project. Annual reports, as in the past, were due by December 31st. No report was received from you by, nor since, the deadline. This report is still required, but rather than a progress report it should be a comprehensive final project report. Pursuant to Section 11480 of the California Health and Safety Code the nature of research projects and their conclusions are to be reported to the State legislature.

Deficiencies in amended protocol.

The deficiencies in the amended research protocol are referred to by section number.

2.b The purpose of the experiment is unnecessarily vague with regard to "several of the organic chemicals which are present in the intact plant." You must specify which substances you are interested in studying. Moreover, the scientific merit of this proposed investigation is not clear from your protocol. What is the value of such a study?

2.c In the protocol you indicate that you are uncertain whether tetrahydrocannabinol or cannabinol will be needed, and that you have these substances on hand anyway. It is

required that the amounts of these substances that are on hand be reported.

Marijuana will be planted, grown and harvested as part of this experiment. You have not provided estimates of yield of psychoactive or potentially psychoactive substances. The protocol is vague as to how much marijuana will be grown. You have not disclosed the source of the seeds. Also required is your current inventory of seeds, growing plants, harvested plant parts, and extracted resin material.

2.d It is required that your capabilities for characterization of the tetrahydrocannabinols and their sulfur analogs be described. This information is applicable.

2.e The description of the facilities is cursory and inadequate. A floor plan of the chemical laboratory is required and a full description of the equipment therein contained (if not included in 2.d above). Where will the marijuana plants be grown?

2.f It is not sufficient to state that the storage facilities for the controlled substances are DEA approved. The storage arrangements must be described. Regarding the inventory of controlled substances, the precise information recorded in your laboratory notebook, including documentation of use, must be described in the protocol.

Summary.

It is the Panel's policy that anyone can apply to the State to conduct specific research projects with Schedule I controlled substances and, moreover, that applicants who have had their approvals withdrawn can reapply. In addition to following the requirements and procedures of the Panel, should you wish to resubmit an application, it would be required that you submit a protocol for all of your research with Schedule I drugs, and that you provide a suitable explanation for the publicly disclosed violations cited above.

It is required that all Schedule I controlled substances held for research purposes be turned over to the Drug Enforcement Administration at this time for disposition. If you intend to reapply to the Panel, your supplies of Schedule I controlled substances may be held until final action is taken on your reapplication, or until June 30, 1977, whichever comes first.

Very truly yours,

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Chairman

(b)(7)(C) Pharm.D.
Executive Secretary

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