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SAN FRANCISCO MEDICAL CENTER: SCHOOL OF MEDICINE

September 22, 1971

R. Curtis Morris, M.D.
Chairman
Human Use Subcommittee of
the Committee on Research
of the Academic Senate
1203 M

Dear Dr. Morris:

I am enclosing a protocol for a study I would like to carry out on four patients with atopic dermatitis who will be hospitalized on our dermatology ward to investigate the absorption, distribution in skin and excretion of a new topical antifungal agent. The amounts and concentrations to be applied are safe from a toxicologic standpoint as well as radiologically. The patients will be fully informed of the nature of the study so that, I believe, the patient's rights are being adequately protected. We have also applied for clearance to use the radioactive compound from the Radiation Safety Committee. Since the radioactive isotope is S^{35} which has a limited half-life, I would appreciate a speedy review of this protocol so that we may initiate the study. If there are any problems or any potential difficulties, please call me. I stress the short half-life of the radioactive material.

Thank you for your cooperation.

Very sincerely yours,

Bill Epstein

William L. Epstein, M.D.
Professor and Acting Chairman
Department of Dermatology

WLE:jam

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PROTOCOL:
TOPICAL ABSORPTION STUDIES
WITH PYRIDNETHIONE DISULFIDE

AIM: To determine the absorption kinetics, skin distribution and excretion pattern of a new topical antifungal agent, pyridnethione disulfide, utilizing an S³⁵ labeled preparation.

METHOD OF STUDY: Four patients with atopic dermatitis or infected eczema will be hospitalized on the dermatology service and will receive a single topical exposure in a 2 centimeters square area of pyridnethione disulfide³⁵ (10 to 40 microcuries) in a 0.5% concentration which will be kept in place with a bandage for a period of 8 hours. The site will then be washed clean with detergent and water and the wash saved for scintillation counting. After the wash, a punch biopsy will be secured, one half to be processed for autoradiography and the other for scintillation counting. For the next four days all urine and stool specimens will be collected and counted and, in addition, periodic blood specimens will be secured for counting.

COMMENT: Pyridnethione disulfide is chemically related to the active ingredient in Head and Shoulders Shampoo, zinc omadine. It is being supplied under an IND. The disulfide has been studied for topical toxicity in laboratory animals, including monkeys and is relatively nontoxic. In addition, it has been applied to man in concentrations up to 10% with no untoward effects, although it is generally applied in an 0.5% concentration which will be used in this study. Absorption studies on sodium pyridnethione have been reported (Parekh, Food and Cosmetic Toxicology 8:147, 1970, and Minn et al, Food and Cosmetic Toxicology 8:161, 1970).

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FOLDER NAME	Comm. Human Experimentation Final Action
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Laboratory and initial human studies indicate the compound is considered safe for topical application; the amount of radioactivity being utilized is small; and the studies being carried out will be clearly presented to the patients who will be considered research subjects. A patient consent form is included.

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PATIENT CONSENT FORM

Date: _____

Time: _____

I authorize and direct the following members of the University of California, San Francisco, namely, Dr. William L. Epstein and his associates to perform and carry out on me the following research procedure:

Topical application of a sulfur³⁵ labeled antifungal agent to be followed by a skin biopsy. In addition, blood, urine and stool specimens will be collected for a period of four days to determine the absorption, distribution in skin and excretion of this new drug.

Dr. _____ has explained to me and I fully understand the purpose, extent and nature of the experimental procedure described above. I understand that the S³⁵ labeled compound is a radioactive substance which produces a small amount of radiation for a short period of time and that the amount applied will be very small. I understand that this is an experimental procedure which may have adverse effects and may not directly benefit my care. I thereby request topical application of the S³⁵ labeled compound plus the skin biopsy and collection of specimens and hereby release Dr. Epstein and his associates from any and all responsibility for any adverse effects arising during the course of or as a consequence of the procedure.

I recognize that during the course of this research unforeseen conditions may necessitate additional or different clinical procedures than that set forth above. I therefore authorize and request that the above named investigator, his assistants or designees perform such procedures as are deemed in their professional judgment to be necessary and desirable.

_____ Patient
 _____ Other(if required)
 _____ Investigator
 _____ Witness

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