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LLOYD A. SMITH, R.S.

September 6, 1985

Mr. Mike McCann
US Nuclear Regulatory Commission
Region III
Glen Ellyn, IL 60137

RE: Control No. 79315
NRC No. 21-G0998-01

Dear Mr. McCann:

After receiving your call on 9-5-85, we would like to have the possession limit increased to 100mc. as you advised since it would be possible for two patients to be under treatment at the same time with the Ir-192 ribbons.

Your suggestion of incorporation of authorized use of Groups I through VI is acceptable with us, but having read our License again, we think this may be a duplication in that this is a Broad License. In any case, would not possession limit changes require an amendment?

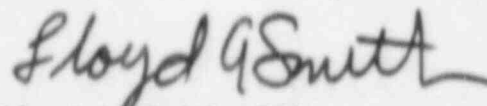
Per our conversation and as is stated in our letter to Dr. Adam on July 22, 1983, we have not and will not do any research that would require approval of the RDRC. We are at present trying to form the above Committee and will notify Region III when it is completed and approved by the FDA.

Very sincerely yours,



Kenneth D. McGinnis, M.D.

LAS:nm



Lloyd A. Smith, RSO

RECEIVED
SEP 11 1985
REGION III

8511180676 851002
REG 3 LIC 30
21-00998-01 PDR

SEP 11 1985

Mount Carmel
MERCY HOSPITAL

DATE: September 6, 1985

TO: Leonard Alexander, M.D., Chairman, Dept. of Internal Medicine
Avis Olson, M.D., Senior Associate, Dept. of Pathology
Peter Reilly, Pharm. D., Pharmacy Department
Lloyd A. Smith, B.S., Radiation Safety Officer

FROM: Kenneth D. McGinnis, M.D.

RE: Formation of a Radioactive Drug Research Committee

At the time of the renewal of our Broad Licensure in 1983, we considered formation of a radioactive drug research committee which must be approved by the FDA through submission of appropriate documents rather than approved by the NRC. We have gone through several steps:

- .. We initially believed the formulation of the Isotope Committee as it exists would be satisfactory for the dual function but it seems a modification of participants is necessary.
- .. We then began to work towards using the Committee already in existence at Wayne University Medical School through our close association with Jack Krohmer, Ph.D., who was an active member of that Committee as well as a member of our Auxillary Medical Staff. However, his unexpected early retirement and the Medical School reorganization seems to make this impractical.
- .. Since our isotope research has been in vitro rather than involving patients, there seemed to be little urgency to forming another committee.

However, there are certain phase four clinical trial, such as Indium labeled white cells for abscess localization, which, if approved, might be of mutual value--to our patients and to the project. It is expected the Committee will meet infrequently upon call when a request is made for a clinical study and that Mr. Smith will gather the information required for review.

We would very much appreciate your agreeing to serve on this Committee. A Curriculum Vitae for submission to the FDA is requested. I am including Section 361.1 of the Federal Register, Vol. 40, No. 144, Friday July 25, 1975 for background information.

nm

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SEP 11 1985

REGION III

CONVERSATION RECORD

TIME

11:18am

DATE

5 September 1985

TYPE

☐ VISIT☐ CONFERENCE☐ TELEPHONE☐ INCOMING☐ OUTGOING

ROUTING

NAME/SYMBOL INT

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT
WITH YOU Lloyd Smith RSOORGANIZATION (Office, dept., bureau,
etc.) Mt Carmel Mercy Hosp
Detroit, MI

TELEPHONE NO.

(313) 927
7741

SUBJECT

C/N 79315

SUMMARY

Agreed to authorizing license for sources
manufacture under Part 32.74

License wants to change license to include
group usage will on license

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION

Mike M. Cam

SIGNATURE

George M. M. Cam

DATE

09/05/85

ACTION TAKEN

SIGNATURE

TITLE

DATE