Note To: License Fee Management Section, ADM

From: Region I

Subject: VOIDED APPLICATION - Abandonment

May 2 I VSK
3P
108759

Control Number 108759

Applicant Biodecision Lab., Inc.

Date Voided 88-09-19

Reason for Void:

Licensee withdrew Amendment request by letter dated 88/09/06.
MS 25 - Abandonment was entered after review

Rebecca J. Brown 88/09/19
Signature Date

Attachment:
Official Record Copy
of Voided Action

OK LPMB - no refund due - withdrawn after review

OFFICIAL RECORD COPY ML18

030-19121
108759

biodecision
laboratories
5900 PENN AVENUE
PITTSBURGH, PENNSYLVANIA 15206-3817
(412) 363-3300

September 6, 1988

John Glenn, Ph.D.
Region I
Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406

RE: License # 37-19699-01

Dear Dr. Glenn:

Due to a recent business decision, we would like to withdraw our license amendment application dated March 30, 1988 signed by Alfred Bacharach.

Thank you for your attention to this matter.

Sincerely,

Monte J. Levitt

Monte J. Levitt, Ph.D.
Vice Chairman and
Scientific Director

MJL:cam

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

MS = 20
P1

AUG 0 8 1988

MEMORANDUM FOR: John E. Glenn, Chief
Nuclear Material Safety Section, RI

FROM: John H. Austin, Acting Chief
Medical, Academic and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: TECHNICAL ASSISTANCE REQUEST: BIODECISION LABORATORIES; CONTROL NUMBER 108759

This is in response to your technical assistance request of June 15, 1988, requesting clarification of our licensing policy for human research to study pharmacokinetics of investigational drugs. You indicated that NRC, in the past, would require approval of each study by a Radioactive Drug Research Committee (RDRC), require administration by a physician, and waive the licensed supplier requirement.

Biodecisions Laboratories of Pittsburgh, Pennsylvania, is requesting an amendment to do human research for pharmaceutical companies to study pharmacokinetics and tracer biodistribution. Biodecisions Laboratories indicated they will study pharmaceuticals that have been labeled by and received from pharmaceutical companies under an active "Notice of Claimed Investigational Exemption for a New Drug" (IND).

The Food and Drug Administration (FDA) was contacted to clarify whether the studies described would be conducted under the FDA's RDRC or IND regulations. The pharmacokinetic and biodistribution studies are a routine part of Phase I of an IND and are not to be authorized by an RDRC.

FDA indicated they may have regulatory concerns with Biodecision Laboratories and other similar companies' participation in the human use phase of an IND. Biodecision Laboratories should request a determination from FDA that their intended participation in pharmacokinetics and biodistribution studies is in accordance with FDA regulations. This information must be presented to NRC before Biodecision Laboratories' license amendment can be approved.

An IND application describes the pharmacy procedures for labeling a pharmaceutical with radioactive material, identifies who labels the pharmaceutical, and identifies who performs the pharmacokinetic and biodistribution tests. The IND also describes human subject selection criteria, informed consent information, and the protocols for the pharmacokinetic and biodistribution tests. If NRC approves Biodecision Laboratories' participation in IND studies, then the licensee will be identified in each IND, and FDA would review its participation in each IND before accepting the IND.

108759
8/22/88

OFFICIAL RECORD COPY ML18

The materials being studied may be either routine pharmaceuticals with a radioactive tag or radiopharmaceuticals. The pharmaceutical company might not be licensed under sections 32.72 or 32.73 and the pharmaceuticals might not be intended for uses identified in sections 35.100, 35.200 or 35.300. Biodecisions Laboratory will need a specific line item to receive byproduct material from a pharmaceutical company for use in IND studies accepted by the FDA.

Information should be obtained from the licensee to assure that proposed equipment and facilities are adequate to protect health and minimize danger to life or property and the applicant is qualified by training and experience to use the material for the purpose requested in such a manner as to protect health and minimize danger to life or property.

Biodecisions Laboratory has not demonstrated they can meet these requirements for their human use research studies. They must have equipment, facilities, and personnel that can immediately respond to a medical emergency. The license should specify that the pharmaceuticals be administered by a physician and the physician be physically present, and ready and available to offer immediate medical care. Ray Kaczur, a consultant to Biodecisions Laboratories, indicated that the physician listed in the license works for Shadyside Hospital and may be a consultant to Biodecisions Laboratories. This should be clarified by the licensee. Further, the training and experience of the other individuals identified in the amendment appears limited to invitro diagnostic kits and does not include administration of radioactive materials to humans.

If you have any questions about this memorandum, please contact Donna-Beth Howe, FTS 492-0636.

John H Austin

John H. Austin, Acting Chief
Medical, Academic and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

Licensee: BIODECISION LAB., INC. License No.: 37-19699-01

TECHNICAL ASSISTANCE REQUEST

DATE: June 15, 1988

TO: VANDY L. MILLER, Chief, Material Licensing Branch, NMSS

_____, Chief, Material Certification and Procedures Branch, NMSS

FROM: JOHN E. GLENN, Ph.D., Chief, Nuclear Materials Safety Section A, Region I

SUBJECT: REQUEST FOR TECHNICAL ASSISTANCE

X Control No. 108759 (enclosed)

_____ Letter dated _____ (enclosed)

_____ Suggested change in licensing procedure (enclosed)

_____ Other (see remarks)

Requested Action:

_____ Custom source/device review

_____ Review and comment

X Provide policy guidance

_____ Other (see remarks)

Remarks: Request for human research to study pharmokinetics of investigational drugs. In the past, we would require approval of each study by an RDRC, administration by a physician, and would have waived the licensed supplier requirement. Please comment on present policy.

To Be Completed by NMSS

DATE: _____

The above request has been received by MLB/MCPB and assigned to _____ (name)

_____ (phone number). Please contact this individual for a status report if a response is not received by _____ (date).

Signature: _____
FCML/FCMC Branch Chief

"OFFICIAL RECORD COPY" ML10