

BROOKHAVEN NATIONAL LABORATORY

MEMORANDUM

DATE: Oct. 14, 1965

TO: Dr. H. Atkins

FROM: Comm. on Clinical Investigations

SUBJECT: CIRC #24

The Committee approves in principle your proposal "Evaluation of Tc^{99m} Fe-Ascorbic Acid Complex for Renal Scanning. However, we feel that the proposal would be greatly strengthened if the following points were made clear: 1) The Committee did not understand what the symbol "rads/m Ci" means. 2) We would appreciate receiving a guess as to what degree of diminution of the radiation dose you would expect by frequent urination. Is it not possible to force fluids on such patients? 3) We have been concerned with the problem of pyrogens since the intravenous route would be used. Pyrogen testing can be done commercially and the Committee will feel much reassured if some of your preparations were so tested.

These reservations can obviously be met and do not subtract from the quality of your proposal.

George C. Cotzias

George C. Cotzias, M.D.
Chairman

- 1) rads/mCi = rads per millicurie.
- 2) The average amount in the bladder is about 10%. Approximately 60% is excreted in 24 hours. The radiation dose to the bladder is probably 1/10 of that estimated in the application.
- 3) Pyrogen testing has been done. See enclosed reports.

The Medical Research Center
Brookhaven National Laboratory
Upton, L. I., New York

REPOSITORY Records Holding Area Bldg. 494
COLLECTION Committee - Clinical Investigations
and use of Radioisotopes
BOX No. 4
FOLDER CIRC #24

1180011

The Committee on Clinical Investigations and Use of Radioisotopes
hereby approves the program with the following title:

EVALUATION OF Tc^{99m}-Fe-ASCORBIC ACID COMPLEX FOR RENAL SCANNING

CIRC # 24 has been assigned to this program.

George C. Cotzias

George C. Cotzias, M.D., Chairman

Lewis M. Schiffer

Lewis M. Schiffer, M.D.

Knud D. Knudsen

Knud D. Knudsen, M.D.

Walton W. Shreeve
Walton W. Shreeve, M.D., Ph.D. (ex officio)

Date: OCT 6 1966
~~October, 1965~~

Place: Medical Research Center
Brookhaven National Laboratory
Upton, New York

1180012

Hospital of the Medical Research Center
Brookhaven National Laboratory
Upton, New York 11973
Area Code 516 Yaphank 4-6262

CONSENT FOR PROCEDURE, STUDY, OR
DRUG UNDER CLINICAL INVESTIGATION

Unit No:
Pavilion:
Date:

OP

CIRC 24

I understand that the physicians at the Hospital of the Medical Research Center, Brookhaven National Laboratory, are engaged in research and study of the nature of diseases and of new methods of diagnosis and treatment. I have been informed of the anticipated duration of hospitalization and the nature of the procedure, study, or drug under clinical investigation known as: ^{99m}Tc - iron ascorbate for kidney scanning.

I understand that the nature of this procedure, study, or drug is experimental, and that at the present time no assurance can be given that my participation will be directly beneficial to me. I have been informed that the timing and sequence of these studies may not be revealed to me. I understand that in the opinions of the investigators responsible for this project, and of the review board (Clinical Investigations Committee), I should be informed of the following possible hazards and inconveniences before agreeing to this clinical investigation: The compound cannot be tested for sterility or pyrogens before use.

I have been informed of the above. I have also been informed of customary procedures. These may, or may not, be used. I have been offered the opportunity for further discussion of this procedure, study, or drug with the attending physician.

I voluntarily consent to participate in the above studies with an understanding of the known possible effects or hazards that might occur in the course thereof, and with the further understanding that not all effects of such procedure, study, or drug are known.

PATIENT'S NAME: _____

SIGNED BY: _____
(Patient or Legal Guardian)

WITNESS: _____

I, the undersigned, herewith affirm that I have explained the above to Mr. (Mrs.) (Miss) _____ and I am willing to answer further inquiries.

_____ M. D. DATE: _____

1180013

BROOKHAVEN NATIONAL LABORATORY

MEMORANDUM

DATE: July 3, 1973

TO: H.L. Atkins

FROM: E.P. Cronkite *E.P. Cronkite*

SUBJECT: Use of Technetium-99m Iron Hydroxide

Approval of further use of ^{99m}Tc -iron hydroxide will require a routine CIRC application which should be accompanied with a statement from Diagnostic Isotopes Incorporated that IND 8946 is currently active, and whether or not there have been any unusual reactions noted to date.

EPC/ck

1180014

Central X

Survey old log book

1. Certify of current status
of 5046 being in use.

2. Best Application to
CIRC in various fashion.

From Eric

To H Allen

Subject:

Since there is no CIRC
approval for ^{99m}Tc iron hydroxide
your request is disapproved.
Submit CIRC for said
material for approval

~~Mr. Allen~~

approval of use of ^{99m}Tc iron hydroxide
will require a written CIRC application which should
be reviewed and either returned from Des Moines, Iowa or
FD-302b is currently active, and which must then be
submitted to the relevant authority.

1180016

BROOKHAVEN NATIONAL LABORATORY
MEMORANDUM

DATE: 18 June 1973

TO: CIRC COMMITTEE
FROM: Harold L. Atkins, M.D. *HA*
SUBJECT: IND Form 1573

Enclosed is IND Form 1573 which I recently filled out for the investigator, Diagnostic Isotopes Incorporated. The Committee acted on my request to use this material, Technetium-99m Iron Hydroxide, some time back, but did not require the filing of any forms for this procedure. We have used the material on 10 patients within the last fiscal year. We do not contemplate at this time doing any further patients, but would like to reserve the approval to use the agent should the need arise.

cfh
Enclosure

1180017

STATEMENT OF INVESTIGATOR

TO SUPPLIER OF DRUG (Name and Address)

Diagnostic Isotopes, Inc.
123 Pleasant Avenue
Upper Saddle River, NJ 07458

NAME OF INVESTIGATOR (Print or Type)

HAROLD L. ATKINS, M. D.

DATE

June 18, 1973

NAME OF DRUG

Technetium-99m Iron Hydroxide

Dear Sir:

(IND NO. 8946)

The undersigned, HAROLD L. ATKINS, M. D., submits this statement as required by section 505(i) of the Federal Food, Drug, and Cosmetic Act and §130.3 of Title 21 of the Code of Federal Regulations as a condition for receiving and conducting clinical investigations with a new drug limited by Federal (or United States) law to investigational use.

1. THE FOLLOWING IS A STATEMENT OF MY EDUCATION AND EXPERIENCE:

- a. Colleges, universities, and medical or other professional schools attended, with dates of attendance, degrees, and dates degrees were awarded.

Sue IND # 5375

- b. Postgraduate medical or other professional training: Dates, names of institutions, and nature of training.

- c. Teaching or research experience: Dates, institutions, brief description of experience.

- d. Experience in medical practice or other professional experience: Dates, institutional affiliations, nature of practice, or other professional experience.

- e. Representative list of pertinent medical or other scientific publications: Titles of articles, names of publications and volume, page number, and date.

(If this information has previously been submitted to the sponsor, it may be referred to and any additions made to bring it up to date.)

2. IF ANY HOSPITAL, INSTITUTIONAL, AND CLINICAL LABORATORY FACILITIES, ETC., ARE AVAILABLE AND WILL BE EMPLOYED IN CONNECTION WITH THE INVESTIGATION, AN IDENTIFICATION OF EACH FOLLOWS:

(If this information has previously been submitted to the sponsor, reference to the previous submission will be adequate.)

3. THE INVESTIGATIONAL DRUG WILL BE USED BY THE UNDERSIGNED OR UNDER HIS SUPERVISION IN ACCORDANCE WITH THE PLAN OF INVESTIGATION DESCRIBED AS FOLLOWS: (Outline the plan of investigation, including approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be undertaken prior to, during, and after administration of the drug; the estimated duration of the investigation; and a description or copies of report forms to be used to maintain an adequate record of the observations and tests, results obtained. This plan may include reasonable alternates and variations, and should be supplemented or amended when any significant change in direction or scope of the investigation is undertaken.)

Dose: 2-4 mCi/70 kg patient - Administration i. v.

Purpose: (1) Detection of pulmonary embolism, (2) Differential diagnosis of pulmonary embolism and myocardial infarction, (3) Evaluation of therapy in pulmonary embolism, (4) Evaluation of regional pulmonary arterial blood flow.

Number of Patients Studied: Fifty (no pregnant or lactating women)

Duration of Investigation: Six months.

Age Range: Over 18 years unless unusual circumstances exist (as determined by physician)

Adverse Reactions: Immediate; time of scan; and 24 hours if possible. Any will be immediately reported to company and regulatory authorities.

Consent will be obtained.

Summary Report: Within 6 months of completion of investigation.

4. THE UNDERSIGNED UNDERSTANDS THAT THE FOLLOWING CONDITIONS, GENERALLY APPLICABLE TO NEW DRUGS FOR INVESTIGATIONAL USE, GOVERN HIS RECEIPT AND USE OF THIS INVESTIGATIONAL DRUG:

- a. The sponsor is required to supply the investigator with full information concerning the preclinical investigations that justify clinical trials, together with fully informative material describing any prior investigations and experience and any possible hazards, contraindications, side-effects, and precautions to be taken into account in the course of the investigation.
- b. The investigator is required to maintain adequate records of the disposition of all receipts of the drug, including dates, quantities, and use by subjects, and if the investigation is terminated to return to the sponsor any unused supply of the drug.
- c. The investigator is required to prepare and maintain adequate and accurate case histories designed to record all observations and other data pertinent to the investigation on each individual treated with the drug or employed as a control in the investigation.
- d. The investigator is required to furnish his reports to the sponsor of the drug who is responsible for collecting and evaluating the results obtained by various investigators. The sponsor is required to present progress reports to the Food and Drug Administration at appropriate intervals not exceeding 1 year. Any adverse effect that may reasonably be regarded as caused by, or probably caused by, the new drug shall be reported to the sponsor promptly, and if the adverse effect is alarming, it shall be reported immediately. An adequate report of the investigation should be furnished to the sponsor shortly after completion of the investigation.
- e. The investigator shall maintain the records of disposition of the drug and the case histories described above for a period

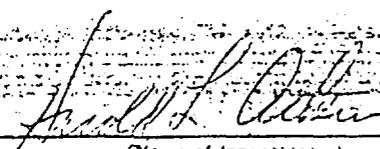
of 2 years following the date a new-drug application is approved for the drug; or if the application is not approved, until 2 years after the investigation is discontinued. Upon the request of a scientifically trained and properly authorized employee of the Department, at reasonable times, the investigator will make such records available for inspection and copying. The subjects' names need not be divulged unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual cases studied, or do not represent actual results obtained.

- f. The investigator certifies that the drug will be administered only to subjects under his personal supervision or under the supervision of the following investigators responsible to him,

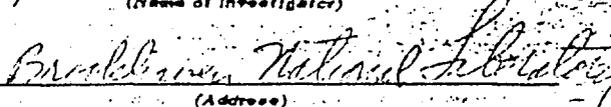
and that the drug will not be supplied to any other investigator or to any clinic for administration to subjects.

- g. The investigator certifies that he will inform any subjects, including subjects used as controls, or their representatives, that drugs are being used for investigational purposes, and will obtain the consent of the subjects, or their representatives, except where this is not feasible or, in the investigator's professional judgment, is contrary to the best interests of the subjects.

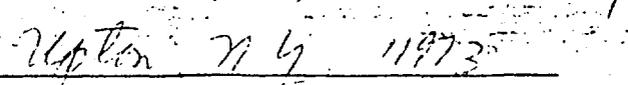
Very truly yours,



(Name of Investigator)



(Address)



BROOKHAVEN NATIONAL LABORATORY

MEMORANDUM

DATE: 5/5/72

TO: CIRC Committee
FROM: H.L. Atkins, M.D. *HA*
SUBJECT: CIRC Proposal # 24

Please be advised that as of 5/5/72 CIRC #24 entitled "Evaluation of Tc^{99m}-Fe-Ascorbic Acid Complex for Renal Scanning" by H.L. Atkins, IND#5375, Patient Consent Form # 41 has been declared inactive.

HLA/ck
cc: Dr. L. Schiffer
Dr. Robertson
Dr. Dahl
Dr. Cronkite
A. Harrison
C. Kerr
W. Finn

1180020

HOSPITAL OF THE MEDICAL RESEARCH CENTER,
BROOKHAVEN NATIONAL LABORATORY
Upton, New York 11973

NAME

UNIT NO.

-41-
CONSENT FOR PROCEDURE, STUDY, OR
DRUG UNDER CLINICAL INVESTIGATION

PAVILION

OP

I understand that the physicians at the Hospital of the Medical Research Center, Brookhaven National Laboratory are engaged in research and study of the nature of diseases and of new methods of diagnosis and treatment. I have been informed of the anticipated duration of hospitalization and the nature of the procedure, study, or drug under clinical investigation known as:

^{99m}Tc-iron ascorbate for kidney scanning

I understand that the nature of this procedure, study, or drug is experimental, and that at the present time no assurance can be given that my participation will be directly beneficial to me. I have been informed that the timing and sequence of these studies may not be revealed to me. I understand that in the opinion of the investigators responsible for this project and of the Review Board (Clinical Investigations Committee), I should be informed of the following possible hazards and inconveniences before agreeing to this clinical investigation:

The compound cannot be tested for sterility or pyrogens before use.

Discontinue
H. L. G. [Signature] M.D.
5/5/72

I have been informed of the above. I have also been informed of the customary procedures. These may or may not be used. I have been offered the opportunity for further discussion of this procedure, study, or drug with the attending physician.

I voluntarily consent to participate in the above studies with an understanding of the known possible effects or hazards that might occur in the course thereof, and with the further understanding that not all effects of such procedure, study, or drug are known.

PATIENT'S NAME _____

SIGNED BY: _____
(Patient or Legal Guardian)

WITNESS: _____

I, the undersigned, herewith affirm that I have explained the above to Mr. (Mrs.) (Miss) _____ and I am willing to answer further inquiries.

_____ M.D. DATE _____

1180021

HOSPITAL OF THE MEDICAL RESEARCH CENTER,
BROOKHAVEN NATIONAL LABORATORY
Upton, New York 11973

NAME

UNIT NO.

-41-

CONSENT FOR PROCEDURE, STUDY, OR
DRUG UNDER CLINICAL INVESTIGATION

CIRC 24

PAVILION

OP

I understand that the physicians at the Hospital of the Medical Research Center, Brookhaven National Laboratory are engaged in research and study of the nature of diseases and of new methods of diagnosis and treatment. I have been informed of the anticipated duration of hospitalization and the nature of the procedure, study, or drug under clinical investigation known as:

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PATIENT'S NAME _____

SIGNED BY: _____
(Patient or Legal Guardian)

WITNESS: _____

I, the undersigned, herewith affirm that I have explained the above to Mr. (Mrs.) (Miss) _____
and I am willing to answer further inquiries.

M.D. DATE _____

1180022

Minutes CIRC Meeting

8 November 1971

Present: G.C. Cotzias, H.R. Connell, R.A. Love, E.A. Popenoe, G.A. Price,
N.P. Rathvon, Jr.

The meeting was held in the Small Conference Room of the Medical Research Center.

Dr. Cotzias opened the meeting at 1400.

The following proposals, presented for annual recertification, were approved:

CIRC #24, #26, and combined #27-27A.

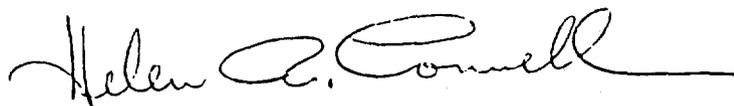
A discussion followed concerning the jurisdiction of the Committee in such cases as the experiment proposed in CIRC #73.

Mr. Rathvon reported that he attended a meeting with Dr. Bond and Dr. Cronkite at which a proposed Standard Operating Procedure for Non-Medical Department Research was discussed. The Standard Operating Procedure would be that whenever any experiment concerning human beings was proposed the Director of the Laboratory would form a select committee to study the proposed experiment and make recommendations.

It was concluded at that meeting that the CIRC Committee should not be used for this purpose. It would be more desirable if the Director appoint an ad hoc committee, the appointees being chosen with a view to the particular problems involved. The flexibility of this kind of committee yields advantages not available in the use of a standing committee such as CIRC.

The meeting was adjourned at 1445.

Respectfully submitted,



Helen R. Connell

cc: CIRC Committee
Mr. Finn
Dr. Aronson
File

1180023

CLINICAL INVESTIGATION AUTHORIZATION FORM

Purpose of Review: Initial Revision Continuing Addendum

Title: EVALUATION OF Tc^{99m}-F₂-ASCORBIC ACID
COMPLEX FOR RENAL SCANNING

CIRC# <u>24</u>
Assigned on (date) <u>10/6/66</u>

To Chairman, CIRC,

The proposal for clinical investigation identified by the above CIRC number and title is forwarded herewith for review and recommendation.

ANNUAL RECERTIFICATION

E.P. Cronkite 12 Oct 71
E.P. Cronkite, M.D., President of Staff Date

To President of Staff,

The Clinical Investigation and Uses of Radiosotopes Committee reviewed the above identified proposal on 4 and recommends that it be with the following modifications:

Recertified.

<u>J.S. Robertson, Chairman</u>	<u>George C. Cotzias</u> G.C. Cotzias, Alt. Chairman	<u>Helen R. Connell</u> H.R. Connell
<u>S.H. Cohn</u>	<u>Edwin A. Popenoe</u> E.A. Popenoe, Alternate	<u>R.A. Love</u> R.A. Love
<u>G. Price</u>	<u>J.F. Klopper</u>	<u>N.P. Rathvon, Jr.</u>
<u>S.E. Duby, Alternate</u>	<u>A.P. Wolf, Alternate</u>	

To Drs. Atkins and Robertson

The above titled and numbered proposal is Approved subject to the following:
Investigational Consent #44 has been established for this CIRC

E.P. Cronkite 9 Nov 71
E.P. Cronkite, M.D., President of Staff Date

1180024

BROOKHAVEN NATIONAL LABORATORY
MEMORANDUM

DATE: 11/2/71

TO: CIRC Committee (Cotzias Comm.)
FROM: R. B. Aronson, Ph.D. *RBA*
SUBJECT: Agenda for CIRC Meeting to be held
8 November 1971 at 2:00 PM

Since the Committee was unable to obtain a quorum for the October 18th meeting it was cancelled. CIRC proposals 24, 26 and combined 27-27A will be presented for annual recertification.

CIRC 26 is to be reviewed again due to conflict of interest because of Dr. Robertson's and Dr. Klopper's attendance.

All necessary papers required for the above have been previously distributed.

1180025

BROOKHAVEN NATIONAL LABORATORY

MEMORANDUM

DATE: 10/14/71

TO: CIRC Committee (Cotzias Comm.)

FROM: R.B. Aronson, Ph.D. *R. Aronson*

SUBJECT: Agenda for CIRC Meeting to be held 18 October 1971

CIRC proposals 24, 26 and combined 27-27A will be presented for annual recertification.

CIRC 26 is to be reviewed again due to conflict of interest because of Dr. Robertson's and Dr. Klopper's attendance.

1180026

BROOKHAVEN NATIONAL LABORATORY

MEMORANDUM

DATE: 29 Sept 1971

TO: H.L. Atkins, M.D.

FROM: R.B. Aronson, Ph.D.

SUBJECT: CIRC Proposal 24

In compliance with recent FDA and HEW notices requiring periodic reviews of clinical research projects, your CIRC proposal, number 24 is scheduled for review soon. Please indicate at the bottom of the page if this proposal should be continuing or placed on the inactive list.

This proposal was last reviewed and approved by the Committee on Oct 6 1966. Do you wish to make any substantive changes in your proposal?

Have you noticed any adverse effects during the experimental program which have not already been reported to the Department Chairman's Office? NO. Please include the nature and frequency of such effects.

Approximately how many patients have been submitted to the experimental regime since the last approval? 25

The Sponsoring Physician on this proposal is JS Robertson. Has there been a change of Sponsoring Physician or Responsible Investigators? Yes
Dr Schiffer no longer affiliated

5375 If you have obtained IND numbers from the FDA in connection with this proposal please list on a separate sheet the compounds and corresponding IND numbers, and attach.

Please attach to this sheet copies of any reports submitted to the FDA, HEW, or other Granting Agency (in connection with this proposal and the IND numbers given above), since the last CIRC approval date.

Please add any additional information which may be of use to the Committee in its deliberations. Include a copy of the Patient Consent Form now in use for this study.

CIRC PROPOSAL NUMBER 24 IS: Continuing

Inactive

Signed Harold L. Atkins 9/29/71
Date

1180027 Please return this completed form to Dr. R.B. Aronson as soon as possible.

Hospital of the Medical Research Center
Brookhaven National Laboratory
Upton, New York 11973
Area Code 516 Yaphank 4-6262

CONSENT FOR PROCEDURE, STUDY, OR
DRUG UNDER CLINICAL INVESTIGATION

Unit No:
Pavilion:
Date:

OP

CIRC 24

I understand that the physicians at the Hospital of the Medical Research Center, Brookhaven National Laboratory, are engaged in research and study of the nature of diseases and of new methods of diagnosis and treatment. I have been informed of the anticipated duration of hospitalization and the nature of the procedure, study, or drug under clinical investigation known as: ^{99m}Tc - iron ascorbate for kidney scanning.

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I voluntarily consent to participate in the above studies with an understanding of the known possible effects or hazards that might occur in the course thereof, and with the further understanding that not all effects of such procedure, study, or drug are known.

PATIENT'S NAME: _____

SIGNED BY: _____
(Patient or Legal Guardian)

WITNESS: _____

I, the undersigned, herewith affirm that I have explained the above to Mr. (Mrs.) (Miss) _____ and I am willing to answer further inquiries.

M. D. DATE: _____

1180028

The Committee on Clinical Investigations and Use of Radioisotopes
hereby approves the program with the following title:

EVALUATION OF Tc^{99m}-Fe-ASCORBIC ACID COMPLEX FOR RENAL SCANNING

CIRC # 24 has been assigned to this program.

George C. Cotzias

George C. Cotzias, M.D., Chairman

Lewis M. Schiffer

Lewis M. Schiffer, M.D.

Knud D. Knudsen

Knud D. Knudsen, M.D.

Walton W. Shreeve, M.D., Ph.D. (ex officio)

Date: OCT 6 1966
~~October, 1965~~

Place: Medical Research Center
Brookhaven National Laboratory
Upton, New York

1180029

BLOKHAVEN NATIONAL LABORATORY

.....19.....

Memo to.....Dept.....

Status 6/30 - # 24

CIRC Ret'd to Athens
for changes.

from.....Dept.....

FORM NO 112-A
UPTON N. Y. 2-57-180M

1180030

BROOKHAVEN NATIONAL LABORATORY

MEMORANDUM

DATE: Oct. 14, 1965

TO: Dr. H. Atkins

FROM: Comm. on Clinical Investigations

SUBJECT: CIRC #24

The Committee approves in principle your proposal "Evaluation of Tc^{99m} Fe-Ascorbic Acid Complex for Renal Scanning. However, we feel that the proposal would be greatly strengthened if the following points were made clear: 1) The Committee did not understand what the symbol "rads/m Ci" means. 2) We would appreciate receiving a guess as to what degree of diminution of the radiation dose you would expect by frequent urination. Is it not possible to force fluids on such patients? 3) We have been concerned with the problem of pyrogens since the intravenous route would be used. Pyrogen testing can be done commercially and the Committee will feel much reassured if some of your preparations were so tested.

These reservations can obviously be met and do not subtract from the quality of your proposal.

George C. Cotzias

George C. Cotzias, M.D.
Chairman

- 1) rads/mCi = rads per millicurie.
- 2) The average amount in the bladder is about 10%. Approximately 60% is excreted in 24 hours. The radiation dose to the bladder is probably 1/10 of that estimated in the application.
- 3) Pyrogen testing has been done. See enclosed reports.

1180031



LEBERCO LABORATORIES

123 HAWTHORNE STREET - ROSELLE PARK, N. J. 07204

DIAL 201 245 1933

BIOLOGICAL ASSAY
FOR
PYROGENIC SUBSTANCES

DATE: November 12, 1965

SUBMITTED TO: **Brookhaven National Laboratory
Associated Universities, Inc.
Upton, Long Island, New York**

ASSAY NUMBER: **60923**

DATE RECEIVED: **November 10, 1965**

TEST MATERIAL: **1 vial Amber Liquid labeled #1**

METHOD OF ASSAY: U. S. P. XV II (1 ml. per kg.)

RESULTS:

Animal Number	Control Temperature	Weight of animal in kilograms	Amount injected in cc	Temperature after injection			Change in Temperature
				One hour	Two hours	Three hours	
925	39.6	3.1	3.1	39.8	39.8	39.8	0.2
926	39.8	3.0	3.0	40.0	39.8	40.0	0.2
927	39.6	3.2	3.2	39.9	39.9	39.9	0.3

CONCLUSIONS: Since the total temperature rise did not exceed 1.4°C the test material is PYROGEN-FREE.

LEBERCO LABORATORIES

Irving Levenstein, Ph. D.
Director

1180032 IL:mr



LEBERCO LABORATORIES

123 HAWTHORNE STREET - ROSELLE PARK, N. J. 07204

DIAL 201 245 1933

BIOLOGICAL ASSAY
FOR
PYROGENIC SUBSTANCES

DATE: November 12, 1965

SUBMITTED TO: Brookhaven National Laboratory
Associated Universities, Inc.
Upton, L. I., New York

ASSAY NUMBER: 60970

DATE RECEIVED: November 10, 1965

TEST MATERIAL: 1 vial Amber Liquid labeled #2

METHOD OF ASSAY: U. S. P. XV II (1 ml. per kg.)

RESULTS:

Animal Number	Control Temperature	Weight of animal in kilograms	Amount injected in cc	Temperature after injection			Change in Temperature
				One hour	Two hours	Three hours	
928	39.7	3.2	3.2	40.0	40.0	40.0	0.3
929	39.8	3.4	3.4	40.2	40.2	40.2	0.4
930	39.6	3.1	3.1	39.9	39.9	39.9	0.3

CONCLUSIONS:

Since the total temperature rise did not exceed 1.4°C the test material is PYROGEN-FREE.

LEBERCO LABORATORIES

Irving Levenstein, Ph. D.
Director

1180033 IL:mr