EXHIBIT 1
Part 1 of 14

Exhibit 2004
05-12237-WGY

IND/NDA SUBSEQUENT SUBMISSIONS REVIEW TRANSMITTAL

1. IND/NDA NUMBER	2. CORRESPONDENCE DATE	3. DATE RECEIVED	4. DOCUMENT IDENTIFICATION
16,234	6-16-88	6-30-88	N(WI)

DELIVER TO LAST ADDRESSEE INDICATED BELOW:

TO: SUPERVISORY TECHNICIAN/CSO	INITIALS	DATE

CSO for Deputy Director

REVIEWER - If this decision is incorrect, notify Group Consumer Safety Officer at once.

	TYPE OF ACTION		
MEDICAL OFFICER	REVIEW	INFO	NAI
[redacted] - FRED		✓	
[redacted]			
CHEMIST	REVIEW	INFO	NAI
[redacted]			
[redacted]			
PHARMACOLOGIST	REVIEW	INFO	NAI
[redacted]		✓	
[redacted]			
STATISTICIAN/MICROBIOLOGIST	REVIEW	INFO	NAI

Deliver to Document Control Desk when this box is checked.	File review. Destroy this form and attached submission.

[redacted] NAI 7/14/88

TRIAL EXHIBIT
2489
97-10814 WGY

TRIAL EXHIBIT
OAA
97-10814 WGY

HMR 935312

FORM FDA 2774 (7/85) PART II - CHEMIST'S COPY

EXHIBIT
Baron 5
on 3/16/07

AM670221946

AM-ITC 01006613

THE UNIVERSITY OF CHICAGO
THE PRITZKER SCHOOL OF MEDICINE

ersity of Chicago ☐
Medical Center
5841 S. Maryland Ave., Box 420
Chicago, Illinois 60637
(312) 702-

Michael Reese Hospital ☐
and Medical Center
Lake Shore Drive at 31st Street
Chicago, Illinois 60616
(312) 791-

Louis A. Weiss ☐
Memorial Hospital
4646 N. Marine Drive
Chicago, Illinois 60640
(312) 878-

June 16, 1988

NOTED, NAI
7/6/88

Department of Medicine
Joint Section of
Hematology/Oncology

Director and Professor
Harvey M. Golomb, M.D.

Professors
Leon O. Jacobson, M.D.
Kenneth C. Robbins, Ph.D.
Janet D. Rowley, M.D.
John E. Ultmann, M.D.
Stanley Yachnin, M.D.

Associate Professors
Joseph M. Baron, M.D.
Jacob D. Bitran, M.D.
Juan Chediak, M.D.
Manuel O. Diaz, M.D.*
Philip C. Hoffman, M.D.
Hans B. Neuwinny, M.D.
Richard L. Schilsky, M.D.
Margaret C. Telfer, M.D.
Nicholas J. Vogelzang, M.D.

Assistant Professors
B. Cohen, Ph.D.*
amliel, Ph.D.*
. Gregory, Ph.D.*
Stuart A. Krauss, M.D.
Richard A. Larson, M.D.
Michelle M. Le Beau, Ph.D.
Mark J. Ratain, M.D.
Ahmad R. Safa, Ph.D.*
Everett E. Vokes, M.D.
June Wencel-Drake, Ph.D.*
Carol A. Westbrook, M.D., Ph.D.

Instructors
Kyung E. Choi, Pharm.D.*
Dawn Magid, Ph.D.*
Stephanie F. Williams, M.D.

Clinical Professor
Charles M. Shapiro, M.D.

Clinical Associate Professors
Rose Catchatourian, M.D.
Richard K. Desser, M.D.

Clinical Assistant Professors
Peter E. Friedell, M.D.
Renee Jacobs, M.D.
Mark F. Kozloff, M.D.*
Marilyn G. Pearson, M.D.
Erwin L. Robin, M.D.

Fellows
Teresa A. Gilewski, M.D.
Raymond J. Hohl, M.D.
Arthur L. Hooberman, M.D.
Lynne S. Kaminer, M.D.
Gary E. Kay, M.D.
Jill A. Moormeier, M.D.
Funmi I. Olopade, M.D.
Jon M. Richards, M.D., Ph.D.
Brian L. Samuels, M.D.
I. Smith, M.D.

h Associate

Ms. Marsha Petersen
Consumer Safety Officer
Division of Gastrointestinal and
Coagulation Drug Product
Office of Drug Evaluation I
Center for Drug and Biologics
Department of Health and Human
Services
Public Health Service
Food and Drug Administration
Rockville, MD 20857

RE: IND 16,234

Dear Ms. Petersen:

Thank you for your letter dated June 3, 1988 regarding the investigational new drug application (IND) submitted pursuant to Section 505(i) of the Federal Food, Drug, and Cosmetic Act for human erythropoietin (16,234).

I would like to request at this time that our IND be put on inactive status. We do not have sufficient supplies of the drug available to carry on anticipated studies at this time and for the immediate foreseeable future. We do wish, however, to have the opportunity to re-open this study by submission of a protocol amendment with proposed investigational plan for the coming year and appropriate protocols as indicated in your letter.

I am grateful to you for your correspondence in this regard and trust that this request will be acceptable at this point. Thank you very much.

Sincerely yours,

Joseph M. Baron, M.D.
Associate Professor of Medicine
Section of Hematology/Oncology

JMB/ajt

CENTER FOR DRUGS AND BIOLOGICS REC'D JUN 30 1988 HFN-130

HMR 935313

AM670221947

AM-ITC 01006614

JUL 6 1988

IND 16,234

Joseph M. Baron, M.D.
The University of Chicago Medical Center
Section of Hematology/Oncology
5841 S. Maryland Avenue, Box 420
Chicago, IL 60637

Dear Dr. Baron:

Please refer to your Investigational New Drug Application (IND) submitted pursuant to section 505(i) of the Federal Food, Drug, and Cosmetic Act for human erythropoietin.

We also refer to your request of June 16, 1988 that this IND be placed on inactive status.

If, in the future, you decide to resume clinical investigations under this IND, it is required that you submit a protocol amendment under 21 CFR 312.30 containing the proposed general investigational plan for the coming year and appropriate protocols. Any additional information supporting the proposed investigation should be submitted in an information amendment. We further remind you that, not withstanding the provisions of 21 CFR 312.30, clinical investigations under an IND on inactive status may only resume (1) 30 days after FDA receives the protocol amendment, unless we notify you that the investigations described in the amendment are subject to a clinical hold, or (2) on earlier notification by us that the clinical investigations described in the protocol amendment may begin.

Sincerely yours,

Stephen B. Fredd, M.D.
Director
Division of Gastrointestinal
and Coagulation Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
IND 16,234
HFD-180
HFD-80
HFD-181/Petersen
akd/7/5/88/1456d 7/6/88

INACTIVE (WI) SF 7/6/88

HMR 935314

AM670221948

AM-ITC 01006615

Lilly N(NL) '11

THE UNIVERSITY OF CHICAGO
THE PRITZKER SCHOOL OF MEDICINE

University of Chicago Medical Center
5841 S. Maryland Ave., Box 420
Chicago, Illinois 60637
(312) 702-

Michael Reese Hospital and Medical Center
Lake Shore Drive at 31st Street
Chicago, Illinois 60616
(312) 791-

Louis A. Weiss Memorial Hospital
4646 N. Marine Drive
Chicago, Illinois 60640
(312) 878-

June 16, 1988

Ms. Marsha Petersen
Consumer Safety Officer
Division of Gastrointestinal and Coagulation Drug Product
Office of Drug Evaluation I
Center for Drug and Biologics
Department of Health and Human Services
Public Health Service
Food and Drug Administration
Rockville, MD 20857

RE: IND 16,234

Dear Ms. Petersen:

Thank you for your letter dated June 3, 1988 regarding the investigational new drug application (IND) submitted pursuant to Section 505(i) of the Federal Food, Drug, and Cosmetic Act for human erythropoietin (16,234).

I would like to request at this time that our IND be put on inactive status. We do not have sufficient supplies of the drug available to carry on anticipated studies at this time and for the immediate foreseeable future. We do wish, however, to have the opportunity to re-open this study by submission of a protocol amendment with proposed investigational plan for the coming year and appropriate protocols as indicated in your letter.

I am grateful to you for your correspondence in this regard and trust that this request will be acceptable at this point. Thank you very much.

Sincerely yours,

Joseph M. Baron, M.D.
Associate Professor of Medicine
Section of Hematology/Oncology

JMB/ajt

CENTER FOR DRUGS AND BIOLOGICS REC'D JUN 30 1988 HFN-130

HMR 935315

AM670221949

AM-ITC 01006616

JUN 3 1988

IND 16,234

Joseph M. Baron, M.D.
The University of Chicago Medical Center
Section of Hematology/Oncology
5841 S. Maryland Avenue, Box 420
Chicago, IL 60637

Dear Dr. Baron:

Please refer to your Investigational New Drug Application (IND) submitted pursuant to section 505(i) of the Federal Food, Drug, and Cosmetic Act for human erythropoietin.

It is required that the sponsor of an IND forward an annual report of progress of the investigation within 60 days of the anniversary date that the IND went into effect. Such reports aid us in the evaluation of the safety and effectiveness of the drug with respect to the plan of study. Your IND does not contain this information. We request that you report within 30 days.

Your report should be in triplicate, reference the above IND number, and be addressed to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Gastrointestinal and
Coagulation Drug Products, HFD-180
Attention: Document Control Room 10-74
5600 Fishers Lane
Rockville Maryland 20857

In the event the study has been discontinued or completed, we should be notified promptly. If you plan no further studies at this time you should request withdrawal or inactivation of your IND. If the IND is withdrawn, it may not be reinstated. It must be refiled in its entirety as a new IND. Such request should include the reason the study was discontinued; assurance that all investigators have been informed; and steps taken with respect to disposition of unused supplies of the drug.

A request for inactivation of the IND will relieve you of the responsibility of annual reporting. Should you decide to resume studies after the IND has been inactivated, you must submit a protocol amendment containing the proposed general investigational plan for the coming year and appropriate protocols. If, on the other hand, your IND remains inactive for 5 years or more it may be terminated by the Agency under 21 CFR 312.44.

HMR 935316

Withdrawal of an IND does not constitute abandonment of the Application as used in 21 CFR 314.430(g). A determination concerning abandonment is only made when a request is made under the Freedom of Information Act for information in the withdrawn IND and after consultation with the sponsor.

Should you have any questions, please call me at 301-443-0487.

Sincerely yours,

Marsha Petersen
Consumer Safety Officer
Division of Gastrointestinal
and Coagulation Drug Product
Office of Drug Evaluation I
Center for Drug and Biologics

Enclosure

cc: Orig IND
HFD-180
HFD-180/CSO
HFD-180/MGould/5/31/88
ajj/5/31/88/1230d

REPORT REQUEST — RR

HMR 935317

AM670221951

AM-ITC 01006618

NCK-please file

IND ASSIGNMENT

1.1 C

THE UNIVERSITY OF CHICAGO
THE PRITZKER SCHOOL OF MEDICINE

University of Chicago
Medical Center

5841 S. Maryland Ave., Box 420
Chicago, Illinois 60637
(312) 702-

Michael Reese Hospital
and Medical Center

Lake Shore Drive at 31st Street
Chicago, Illinois 60616
(312) 791-

February 11, 1987

Ms. Bonnie Bodo
Application Examiner
Center for Drugs and Biologics
HFN-110
5600 Fishers Lane
Rockville, MD 20857

RE: IND #16,234

Attention: Document Control Room
168-30

Dear Ms. Bodo:

Thank you for your letter of January 30, 1987. There have been no additional clinical investigations with the experimental drug, human erythropoietin, since my last report to you. However, we are not finished with our studies of this material and anticipate additional investigations of it when sufficient quantities once again become available for our use. I appreciate your keeping this Claimed Investigational Exemption open for our continued studies.

Sincerely yours,

Joseph M. Baron

Joseph M. Baron, M.D.
Associate Professor
Department of Medicine
Section of Hematology/Oncology

RECEIVED
FEB 19 1987
HFD-110
BUREAU OF DRUGS

JMB/ajt

HMR 935318

AM670221952

AM-ITC 01006619

IND 16,234

Joseph M. Baron, M.D.
The University of Chicago
Medical Center
Section of Hematology/Oncology
5841 S. Maryland Avenue, Box 420
Chicago, IL 60637

Dear Dr. Baron:

Please refer to your notice of claimed investigational exemption for human erythropoietin.

The sponsor of an IND is required to forward progress reports for clinical investigations at reasonable intervals not exceeding a year. These reports aid us in the evaluation of the safety and effectiveness of the drug with respect to the plan of study. Your IND does not contain this information.

If your study was discontinued, we should have been notified promptly. Notification of discontinuance should include the reason, assurance that investigators have been informed and steps taken with respect to the unused supplies of the drug.

We request that you send within thirty (30) days either a report or a notice of discontinuance and your final progress report in triplicate identified with IND number 16,234 to the following address:

Center for Drugs and Biologics, HFN-110
Attention: DOCUMENT CONTROL ROOM #16B-30
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, please contact:

Ms. Bonnie Bodo
Application Examiner
(301) 443-0313

Sincerely yours,

Bonnie Bodo
for
Natalia A. Morgenstern
Chief, Project Management Staff
Division of Cardio-Renal Drug Products
Office of Drug Research and Review
Center for Drugs and Biologics

cc:
Original IND
~~HFN-110~~
HFN-110/CSO
HFN-110/JMazzitti
HFN-110/BBodo/1/22/87 BBodo 1-30-87
bjb/1/22/87/0167D/p11

REPORT REQUEST

HMR 935319

PROGRESS REPORT P

THE UNIVERSITY OF CHICAGO
THE PRITZKER SCHOOL OF MEDICINE

ORIGINAL

University of Chicago
Medical Center

5841 S. Maryland Ave., Box 420
Chicago, Illinois 60637
(312) 962-6114

Michael Reese Hospital
and Medical Center

Lake Shore Drive at 31st Street
Chicago, Illinois 60616
(312) 791-

October 2, 1985

Department of Medicine
Joint Section of
Hematology/Oncology

Director and Professor
Harvey M. Golomb, M.D.

Professors
Clifford W. Gurney, M.D.
Leon O. Jacobson, M.D.
Janet D. Rowley, M.D.
John E. Ultmann, M.D.
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Richard L. Schilsky, M.D.
Nicholas J. Vogelzang, M.D.
Carol A. Westbrook, M.D., Ph.D.

Research Associates
Bernard H. Brownstein, Ph.D
Manuel O. Diaz, M.D.
Harriet Davidson, Ph.D.
Michelle M. LeBeau, Ph.D.
Denise Oleske, Ph.D.
Joseph A. Sinkule, Pharm.D.

Clinical Faculty
Arthur Billings, M.D.
Charles Shapiro, M.D.
Richard Desser, M.D.
Peter Friedell, M.D.
Mark Korloff, M.D.
Erwin Robin, M.D.

Natalia A. Morgenstern
Supervisory Consumer Safety Officer
Division of Cardio-Renal Products
Office of Drug Research and Review
Center for Drugs and Biologics
Department of Health
and Human Services
Food and Drug Administration
Rockville, Maryland 20857

RECD 10/15/85

Dear Ms. Morgenstern:

Thank you for your letter of September 12, 1985, regarding IND #16,234. There have been no further studies performed under this claimed investigational exemption since our last report to you. These follow-up studies have been delayed because of lack of availability of sufficient amounts of purified human urinary erythropoietin to permit us to carry out the investigations. We expect that adequate amounts of the hormone will be forthcoming witin the next several months and that we will be able to continue studies undertaken as described in earlier reports to you. We have not discontinued our study and we wish to have the IND continued until such time as we will be able to complete the intended investigations.

Thank you very much for your help in this regard.

Sincerely yours,

Joseph M. Baron, M.D.
Associate Professor of Medicine
Section of Hematology/Oncology

JMB:ss

HMR 935320

IND 16,234

SEP 12

Joseph M. Baron, M.D.
The University of Chicago
Box 420
950 East 59th Street
Chicago, IL 60637

Dear Dr. Baron:

Please refer to your notice of claimed investigational exemption for human erythropoietin.

The sponsor of an IND is required to forward progress reports for clinical investigations at reasonable intervals not exceeding a year. These reports aid us in the evaluation of the safety and effectiveness of the drug with respect to the plan of study. Your IND does not contain this information.

If your study was discontinued, we should have been notified promptly. Notification of discontinuance should include the reason, assurance that investigators have been informed and steps taken with respect to the unused supplies of the drug.

We request that you send within thirty (30) days either a report or a notice of discontinuance and your final progress report in triplicate identified with IND number 16,234 to the following address:

Center for Drugs and Biologics, HFN-110
Attention: DOCUMENT CONTROL ROOM #16B-30
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, please contact:

Ms. Josephine Mazzitti
Application Examiner
(301) 443-4730

Sincerely yours,

9/12/85

Natalia A. Morgenstern
Supervisory Consumer Safety Officer
Division of Cardio-Renal Drug Products
Office of Drug Research and Review
Center for Drugs and Biologics

cc:
Original IND
HFN-110
HFN-110/CSO
HFN-110/JMazzitti
HFN-110/NMorgenstern/9/10/85
sb/9/11/85/1919s

REPORT REQUEST

HMR 935321

AM670221955

AM-ITC 01006622