

**Harcon Division**  
**HEALTH-CHEM CORPORATION**

Research & Development Laboratories  
200B Corporate Court, Middlesex Business Center, So. Plainfield, N.J. 07080  
(201) 755-7730 Telex: 4992962 HCHEM

29-20767-01

June 6, 1985

Dr. Jack Davis  
Nuclear Materials Section A  
Division of Engineering and Technical Programs  
U.S. Nuclear Regulatory Commission  
Region 1, 631 Park Ave  
King of Prussia, PA 19406

Application	06245
Check	4/20-3/11
Amendment	7/11/85
Date	7/11/85
Resubmit	Jackman

Ref: 6/006/SN

Dear Dr. Davis:

Your approved NRC material license dated December 18, 1984 to Health-Chem Corporation Harcon Division has been received.

However, Dr. Bret Berner, who was the Radiation Safety Officer, has left the company. Therefore we would like to make the following changes:

1. Ms. Prafulla Amin will be our Radiation Safety Officer. Ms. Amin has 16 years of experience in working with a variety of isotopes using  $\beta$  and  $\gamma$  radiation. The maximum amount of radiation that she ever dealt with was 30 mCi. Her resume is included.
2. In item 6 of the application form we will delete the following people.
  - a. Dr. Agis F. Kydonieus/Executive Vice President
  - b. Dr. Bret Berner/Director of Pharmaceutical Research
  - c. Ms. Barbara Kelly/Research Scientist

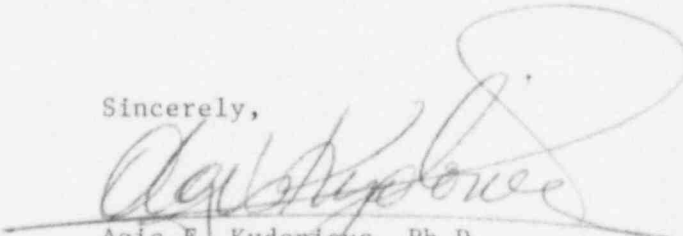
Instead we will add the following people:

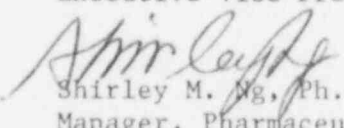
- a. Dr. Shirley Ng/Manager, Pharmaceutical Research (resume is included)
  - b. Ms. Prafulla Amin/Sr. Research Scientist
  - c. Mr. Taras Sochan/Research Scientist (resume is included)
3. Item 10 of the application form; In addition to the Beckman model, we would like to add Packard model or its equivalent.

If you have any questions, please call!

Thank you very much!

Sincerely,

  
Agis F. Kydonieus, Ph.D.  
Executive Vice President

  
Shirley M. Ng, Ph.D.  
Manager, Pharmaceutical Research

"OFFICIAL RECORD COPY"

ML10 03937

JUN 10 1985

RECEIVED BY LFMS
Date 6/17/85
Log June Pg 12 - I
By Jacques
Orig To
Action Compl. 7/11/85

8510280076 850816  
REG1 LIC30  
29-20767-01 PDR

TARAS YURI SOCHAN  
53 BRINKERHOFF STREET  
JERSEY CITY, NEW JERSEY 07304  
TELEPHONE (201) 434-1017

### Education

Bachelor of Arts, New York University, Oct. 1983

Broad physics background: Thermal and statistical physics, Dynamics, Electronics for scientists, Modern physics I, II, III; Physics I, II III.

BASIC and PL/1 programming languages.

Calculus I, II, III; General Chemistry I, II.

Fine Arts minor, NYU men's volleyball team.

### Work experience

#### Hercon Division

11/84-present

Research Scientist, Researched & developed transdermal delivery systems, performed in vitro drug permeation studies.

#### Diamond West Energy Corp. 11/83 - 7/84

Chemical engineering research assistant.

Petroleum coke desulfurization, gold ore pretreatment.

Research conducted at The Cooper Union, NYC.

Responsible for reactor operation and physical analysis of samples, AA & GC experience.

#### SVOBODA Ukrainian daily 1/78 - 6/83

Newspaper production, proofreading, darkroom.

### Personal

NYU scholarship recipient.

Foreign languages: German, fluent Ukrainian.

Hobbies: amateur radio (FCC Advanced class license), photography, backpacking, tennis, ice hockey.

Single, excellent health.

### References

On request.

SHIRLEY MEIKING NG

8 Brian Drive  
Bridgewater, N.J. 08807

Home: 201-231-9542  
Work: 201-755-7730

EDUCATION

Ph.D. Division of Pharmaceutics and Pharmaceutical Chemistry,  
College of Pharmacy, The Ohio State University. GPA  
3.52 on a 4.0 scale. Title of Dissertation: 'In Vitro  
Drug Release from Multiple Emulsion.' Major advisor:  
Dr. Sylvan G. Frank

Program of study includes the following coursework:  
Physical pharmacy, Concepts of pharmaceutical research,  
Biopharmaceutics, Pharmacokinetics, Design and development  
of pharmaceutical dosage forms, Drug stability, Isolation  
techniques, Radioisotope tracer techniques, Physical  
chemistry, Organic chemistry, Physical methods in organic  
chemistry, Chromatographic methods in drug assays,  
Chemical kinetics and thermodynamics.

B.S. (Cum Laude) School of Pharmacy, The University of Connecticut (Honors  
program)

Honor's Thesis was entitled 'An In Vitro Investigation  
of Sustained Release Formulations of Cephalexin.'

EXPERIENCE

Feb. 1985-present Manager of Pharmaceutical Research, Hercon Div. Health-Chem Corp.  
Manager of Pharmaceutical research. Functional responsibilities  
involve: developing stable therapeutic transdermal  
delivery systems, managing the research activities  
of three professionals, coordinating activities between  
the client companies and Hercon R&D.

1983-1985 Senior Research Chemist, Colgate-Palmolive.  
Project leader of two current therapeutic oral products.  
Responsibilities include: developing stable marketable  
products, scaling up of pilot batches, coordinating  
activities in various area of the projects, assisting  
the filing of an IND, and supervising a technician.

1980-1983 Senior Scientist, Group Leader, Elizabeth Arden Research  
and Development, Eli Lilly and company. Functional  
responsibilities included: developing, planning, conducting

and supervising research programs and new formulation systems; evaluating product stability; oral and written communications; successful coordination of activities among different groups, and supervising two chemists.

1976-1980

Graduate Research Associate at The Ohio State University, College of Pharmacy. Research involved the development of multiple emulsions as a potential prolonged release oral drug delivery systems, a project sponsored by Dorsey Laboratories, Division of Sandoz, Inc.

1975-1976

Teaching Associate for the junior class at The Ohio State University, College of Pharmacy.

Various part-time work and volunteer experiences including those of student medical technician and pharmacy technician.

#### PUBLICATIONS

1. "Preliminary Investigation of Phase Equilibrium of Peanut Oil-Span 80-Tween 20-Water System" by Ng, S.M. and Frank, S.G. Abstracts of the 9th Annual Graduate Student Pharmaceutics Research Meeting, University of Kentucky, Lexington, Kentucky, June 15, 1977.
2. "Formulation of Multiple Emulsions Under Dynamic Equilibrium Conditions in a Four-Component System Containing Nonionic Surfactants" by Ng, S.M. and Frank, S.G. Abstracts of the 29th National Meeting of the Academy of Pharmaceutical Sciences, San Antonio, Texas, November, 1980.
3. "In Vitro Studies of a Multiple Emulsion for Oral Administration" by Ng, S.M. and Frank, S.G. Abstracts of the 31st National Meeting of the Academy of Pharmaceutical Sciences, Orlando, Florida, November, 1981.
4. "Formulation of Multiple Emulsions in a Four-Component System Containing Nonionic Surfactants" by Ng, S.M. and Frank, S.G., Journal of Dispersion Science and Technology, 3, 217-231, 1982.

5. "In Vitro Studies of a Multiple Emulsion for Oral Administration" by Ng, S.M. and Frank, S.G. (Submitted to the International Journal of Pharmaceutics).

PATENTS

Two Invention Records have been filed at Colgate-Palmolive for the stabilization of one of the current products.

PERSONAL DATA

Honors:

Rho Chi recognition certificate for high scholastic achievement in 1973..

University of Connecticut Honor Scholar since 1973.

Professional  
Affiliation:

Member of Rho chi Honor Society since 1974.  
Elected Secretary of Rho Chi Alpha Gamma Chapter at University of Connecticut 1974-1975.

Member of the Academy of Pharmaceutical Sciences and the American Pharmaceutical Association since 1976.

Co-Chairperson of the Public Affair Discussion Group at Eli Lilly and Company 1981-1982.

Immigration  
Status:

U.S. permanent resident (A22585009)

REFERENCES

Available upon request

RESUME  
of  
Prafulla Amin

253 Tabb Avenue  
Piscataway, NJ 08854  
Phone (201) 968-3654  
WOLX (201) 755-7730

**OBJECTIVE**

A position as a Bioanalytical Chemist in research or clinical industry or health related research institute. Prefer growth oriented organization where advancement and remuneration are based upon abilities.

**EXPERIENCE**

June 1985-present

Hercon Division, Health-Chem Corporation

Position: Sr. Research Scientist

Analysis of Pharmaceutical products from Skin permeation studies in Vitro with HPLC and data processing equipment.

Oct. 1984 to May, 1985

Ortho Pharmaceutical Corp., Raritan, N.J. 08869

**Position: Associate Scientist**

Analysis of biological samples, involving in vivo studies of drug (IND) in humans. To evaluate bioavailability and pharmacokinetics. Analytical method with HPLC and data processing equipment.

1976 to 9/14/84

Montefiore Hospital, University of Pittsburgh, Pittsburgh, PA 15213

**Position: Senior Research Assistant**

Full technical responsibility for developing methodology involving extraction, analysis, quantification of steroids, both bile acids and neutral steroids and their metabolites from biological materials, from human and animal experimentation. Vast experience in various chromatographic techniques, GLC, TLC, Ion-exchange, absorption and HPLC. Synthesis of bile acid conjugates and its purification. Enzymatic methods for analysis of neutral steroids. Experienced in variety of Isotopes in metabolic studies using  $\beta$  and  $\gamma$  radiation and physiological doses administered intravenously and steady state perfusion.

1969 to 1976

Montefiore Hospital, University of Pittsburgh Medical School, Pittsburg, PA 15213

**Position: Research Assistant**

Nutrition related studies mainly involving protein, peptide and amino acid metabolism in humans and animal experiments, in vivo and in vitro. Studies were geared to accomplish better understanding of protein malnutrition diseases and caloric deprivation in obese subjects and a broader application of parental nutrition.

1967 to 1969

St. Cecilia's College, Nyeri, Kenya, East Africa

**Position: Tutor**

Trained teachers for Elementary school programs using environment around children as a teaching aid.

**EDUCATION**

M.S. degree in Biochemistry, 1967

B.S. degree in Chemistry (with honors), 1965

**SPECIAL SKILLS**

1. Experience with HPCL and data processing equipment, amino acid analyzer, gas liquid chromatograph, radioactive scanner, biological material oxidizer.
2. Surgical techniques with rats and hamsters. Experience with monkeys in restraining capacity.

**PERSONAL**

Marital Status: Single  
Citizenship: Citizen of the United States  
Health: Excellent

**SALARY**

Negotiable. Willing to relocate or travel providing position merits.

**REFERENCES**

Furnished upon request.

**PUBLICATIONS**

1. Alteration in the urinary excretion rate of amino acids and nitrogen by dietary means in obese and normal human subjects. The Journal of Lab and Clinical Medicine. Vol 77 1971, pg 278-289. Siamak A. Adibi, Pittsburgh, PA (with technical assistance of Emile D. Livi and Prafulla M. Amin.)
2. Interrelationships between level of amino acids in plasma and tissues during starvation. American Journal of Physiology. Vol 221 (2) 1971, pg 829-838. Siamak A. Adibi (with technical assistance of Emile L. Morse and Prafulla M. Amin) Pittsburgh, PA.
3. Amino acid levels in plasma, liver and skeletal muscle during protein deprivation. Siamak A. Adibi, Thomas A. Modisto, Emile L. Morse and Prafulla M. Amin. American Journal of Physiology. Vol 225 1973, pg 408-414. Pittsburgh, PA
4. Oxidative energy metabolism in the skeleton muscle: biochemical and ultrastructural evidence for adaptive changes. The Journal of Lab and Clinical Medicine. Vol 83 1974, pg 548-562. Siamak A. Adibi, Barbara A. Krzysik, Emile L. Morse and Prafulla Amin, Pittsburgh, PA, and E. Raworth Allen, New Orleans, LA
5. Role of insulin and glucose in the induction of hypaminoacidemia in man: Studies in normal, juvenile diabetic and insuloma patients. The Journal of Lab and Clinical Medicine. Vol 86 1975, pg 395-409. Siamak A. Adibi, Emile L. Morse and Prafulla Amin. Pittsburgh, PA
6. Evidence for two different modes of tripeptide disappearance in human intestine. Uptake by peptide carrier systems and hydrolysis by peptide hydrolysis. The Journal of Clinical Investigation. Vol 56 1975, pg 1355-1363. Siamak A. Adibi, Emile L. Morse, Stanley S. Masilamani and Prafulla M. Amin. Pittsburgh, PA
7. Use of simple enzymatic assay for cholesterol analysis in human bile. Journal of Lipid Research. Vol 21 1980, pg 259-261. Hans Fromm, Prafulla Amin, Heidi Klein and Ingeborg Kupke. Pittsburgh, PA
8. Metabolism in man of 7 ketolitholic acid; Precursor of chenodeoxycholic and ursodeoxycholic acids. American Journal of Physiology. Vol 239 1980, pg G161-166. Hans Fromm, G.L. Carlson, A.F. Hofman, S. Farivar and Prafulla Amin, Pittsburgh, PA
9. Factors in the mechanism of diarrhea in bile acid malabsorption: Fecal pH - A key determinant. Gastroenterology. Vol 80 1981, pg 1454-1464. B. McJunkin, H. Fromm, R.P. Sarva and P. Amin, Pittsburgh, PA
10. Comparative sensitivity of eight and 24-hour bile acid breath tests and Schilling test in ileopathies. American Journal of Gastroenterology. Vol 76 no 5 1982, pg 432-437. Rajendra P. Sarva, Sirus Farivar, Hans Fromm, Franco Bazzoli, Arnold Wald and Prafulla M. Amin, Pittsburgh, PA
11. Effects of jejunoileal bypass on the enterohepatic circulation of bile acids, bacterial flora in the upper small intestine, and absorption of Vitamin B<sub>12</sub>. Metabolism. Vol 32 No. 12 1983, Hans Fromm, Rajendra P. Sarva, Mark M. Ravitch, Brittain McJunkin, Sirus Farivar, and Prafulla Amin. Pittsburgh, PA



**ACKNOWLEDGEMENTS FOR TECHNICAL ASSISTANCE**

1. Tests for bile acid and vitamin B metabolism in ileal and Crohn's disease. American Journal of Clinical Pathology. Vol 83, 1980.
2. Sensitivity of bile acid breath test in the diagnosis and bacterial overgrowth in the small intestine with and without the stagnant (blind) loop syndrome. The American Journal of Digestive Diseases. Vol 24, 1979.
3. Protein digestion in human intestine and reflected in luminal, mucosal and plasma amino acid concentrations after meals. The Journal of Clinical Investigation. Vol 52, 1973.
4. Dietary regulation of liver and muscle transport of amino acid. American Journal of Physiology. Vol 230, 1976.
5. Functional characterization of dipeptide transport system in human jejunum. The Journal of Clinical Investigation. Vol 53, 1974.
6. Relationship between serum and biliary bile acids as an indicator of chenodeoxycholic and ursodeoxycholic acid induced hepatotoxicity in the rhesus monkey. Digestive Diseases and Sciences. Vol. 27, 1982.
7. Comparative formation of lithocholic acid from chenodeoxycholic and ursodeoxycholic acids in the colon. Gastroenterology. Vol 83, 1982.
8. Relationship between serum and biliary bile acids as an indicator of chenodeoxycholic and ursodeoxycholic acid-induced hepatotoxicity in the rhesus monkey. Digestive Diseases and Sciences. Vol 27, No. 5, 1982.



BETWEEN: William O. Miller, Chief  
License Fee Management Branch  
Office of Administration -

John E. Glenn, Chief  
Nuclear Materials Section B  
Division of Engineering and  
Technical Programs

LICENSE FEE TRANSMITTAL

A. REGION I

Fee Needed

1. APPLICATION ATTACHED

Applicant/Licensee: Health-Chem Corporation

Application Dated: 6/6/85

Control No.: 03937

License No.: 29-20767-01

2. FEE ATTACHED

Amount: 0

Check No.: 0

3. COMMENTS

Signed Brenda Platchek

Date 6/11/85

12/89

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 3M - 1/20

2. Correct Fee Paid. Application may be processed for:

Amendment ✓

Renewal \_\_\_\_\_

License \_\_\_\_\_

Signed 6 Jackson

Date 7/11/85