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October 31, 1997

By Hand

Dockets Management Branch
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

2268 97 OCT 31 P 4:16

Re: **Pharmanex, Inc. *Petition for Stay of Action***
(filed by Stuart M. Pape, Patton Boggs, L.L.P. on October 29, 1997)
(Filing Stamp 2261 -- Docket # Not Yet Assigned)

Dear Sir or Madam:

Enclosed please find the following documents for inclusion in the above-referenced Docket:

- ♦ *Statement of Wm. James Howard, M.D.* (addition to *Petition* Attachment 28);
- ♦ *Curriculum Vitae* of Sanford A. Miller, Ph.D. (addition to *Petition* Attachment 6); and
- ♦ Test Results for Red Yeast Rice Sample #4 (New York) (addition to *Petition* Attachment 21).

If you have any questions, please do not hesitate to call.

Sincerely,



Daniel A. Kracov

97P-0441

Supl

STATEMENT OF WM. JAMES HOWARD, M.D.

I, Wm. James Howard, M.D., state as follows:

1. I am the Senior Vice President and Medical Director, Washington Hospital Center, Washington, D.C., and Professor of Medicine, Department of Medicine, George Washington University, School of Medicine and Health Sciences. A copy of my curriculum vitae is attached.

2. I received my medical degree from the University of Pennsylvania School of Medicine, and have been certified as a specialist in endocrinology and internal medicine. I am the President Elect of the American Heart Association, Nation's Capital Affiliate, and have been a member of the American Heart Association Affiliate's Board of Directors since 1989, and previously served as Vice President of the American Heart Association Affiliate from 1984 through 1995.

3. At the Washington Hospital Center, in addition to serving as Medical Director, I maintain a clinical practice that involves treating patients with elevated cholesterol levels. I have also conducted numerous studies and written numerous articles regarding hypercholesterolemia, dietary fat, blood cholesterol, coronary heart disease and related subjects. A listing of my publications is included in the attached curriculum vitae.

4. I have been asked to provide my opinion with regard to certain cholesterol-related issues. Based on my professional experience and training, and familiarity with the relevant scientific and academic literature, I hold the following opinions:

- a. Total serum cholesterol levels in the range of 200-239 mg/dL are not considered to represent a disease, as indicated by the National Cholesterol Education Program (NCEP). Cholesterol levels in this range could be characterized as "borderline high," and could be considered to be a non-disease form of hypercholesterolemia. Desirable or "ideal" levels of cholesterol would be under 200 mg/dL. Cholesterol levels above 239 mg/dL may constitute a disease stage of hypercholesterolemia.
- b. Individuals with cholesterol levels under 240 mg/dL should not normally be treated with drugs, absent the presence of coronary heart disease or other significant risk factors for coronary heart disease.
- c. In fact, some individuals with hypercholesterolemia and very high levels of total serum cholesterol may not be suffering from a disease. For

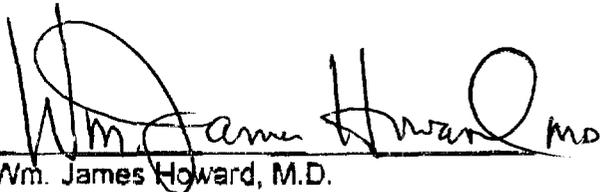
example, if their hypercholesterolemia is due to elevated levels of "HDL," then these individuals could actually have a lower risk of heart disease than patients without hypercholesterolemia.

- d. Individuals with cholesterol levels in the range of 200-239 mg/dL should be treated with a regimen that encourages greater exercise, the consumption of complex carbohydrates, high fiber foods, such as fruits and vegetables, avoidance of red meats and high fat food items, the consumption of fish and appropriate foods or dietary supplements. This program would help promote more desirable cholesterol levels.
- e. Finally, it is not appropriate to directly equate cholesterol levels with the disease atherosclerosis or arterial build-up. The build-up of plaque on artery walls is diagnosed as a disease when it produces some functional abnormalities such as stroke, angina, circulatory problems, etc., but it must be evaluated separately from cholesterol levels.

5. In conclusion, it is my opinion that, in general, it is desirable and healthy to bring total cholesterol levels under 200 mg/dL where possible. For generally healthy individuals whose cholesterol levels are within the range from 200-239 mg/dL, it is appropriate to recommend a regimen based on diet and exercise. In the absence of other evidence or risk factors, I would not diagnose individuals within the 200-239 mg/dL range as suffering from hypercholesterolemia at a disease stage, atherosclerosis, arterial build-up or other form of coronary heart disease. For such individuals, lowering cholesterol levels below 200 mg/dL involves a shift from a "borderline" condition to a more desirable one. I would not view cholesterol reduction of this nature as the direct treatment, prevention or mitigation of a disease.

Date:

10/28/97


Wm. James Howard, M.D.

CURRICULUM VITAE

WM. JAMES HOWARD, M.D.

PERSONAL

Date and Place of Birth:

[REDACTED]

Citizenship:

U.S.A.

Marital Status:

[REDACTED]

Social Security Number:

[REDACTED]

Office Address:

Washington Hospital Center
106 Irving Street, N.W.
Physicians' Office Building, #121
Washington, D.C. 20010

Phone:

(202) 877-5284

Facsimile:

(202) 877-3375

Internet Address:

[REDACTED]

Home Address:

[REDACTED]

Home Phone:

[REDACTED]

EDUCATION

1960

B.A., Chemistry, Haverford College, Haverford, Pennsylvania

1964

M.D., University of Pennsylvania, School of Medicine,
Philadelphia, Pennsylvania

POSTGRADUATE TRAINING

1964-1965

Intern in Medicine, Department of Medicine, Hospital of the University of
Pennsylvania, Philadelphia, Pennsylvania

1965-1966

Resident in Medicine, Department of Medicine, Hospital of the University of
Pennsylvania, Philadelphia, Pennsylvania

1966-1967

Fellow in Metabolic Diseases, Laboratory of James B. Wyngaarden, M.D.,
Department of Medicine, Hospital of the University of Pennsylvania,
Philadelphia, Pennsylvania

1967-1968 Fellow in Metabolic Diseases, Laboratory of James B. Wyngaarden, M.D., Department of Medicine, Duke University Medical Center, Durham, North Carolina

1968-1969 Fellow in Clinical Endocrinology, Department of Medicine, Duke University Medical Center, Durham, North Carolina

MILITARY SERVICE

1969-1972 Major, Medical Corps, United States Army, Walter Reed Army Medical Center, Washington, D.C.

FACULTY APPOINTMENTS

1972-1976 Assistant Professor, Department of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania

1976-1982 Adjunct Associate Professor, Department of Medicine, University of Arizona Health Sciences Center, Tucson, Arizona

1982-1988 Clinical Professor, Department of Medicine, University of Arizona Health Sciences Center, Tucson, Arizona

1990-1992 Clinical Professor, Department of Medicine, George Washington University School of Medicine & Health Sciences

1991-present Adjunct Assistant Professor, Department of Medicine, Baylor College of Medicine, Houston, Texas

1992-present Professor of Medicine, Department of Medicine, George Washington University School of Medicine & Health Sciences

HOSPITAL AND ADMINISTRATIVE APPOINTMENTS

1969-1972 Director, Endocrine-Metabolic Outpatient Clinic, Walter Reed General Hospital, Walter Reed Army Medical Center, Washington, D.C.

Research Internist and Head of the Section of Metabolism, Department of Endocrinology and Metabolism, Division of Medicine, Walter Reed Army Institute of Research, Walter Reed Army Medical Center, Washington, D.C.

1972-1976 Assistant Director, General Clinical Research Center, Philadelphia General Hospital, Philadelphia, Pennsylvania

1972-1976 Chief, Endocrine Section, University of Pennsylvania Medical Service, Philadelphia General Hospital, Philadelphia, Pennsylvania

- 1973-1975 Assistant Chief, University of Pennsylvania Medical Service, Philadelphia General Hospital, Philadelphia, Pennsylvania
- 1973-1976 Director of House Staff Training, University of Pennsylvania Medical Service, Philadelphia General Hospital, Philadelphia, Pennsylvania
- 1975-1976 Associate Chief, University of Pennsylvania Medical Service, Philadelphia General Hospital, Philadelphia, Pennsylvania
- 1976-1981 Director, Medical Residency Program, Good Samaritan Medical Center, Phoenix, Arizona
- 1980-1988 Director, of Transitional Residency Program, Good Samaritan Medical Center, Phoenix, Arizona
- 1980-1981 Acting Director of Medical Education, Good Samaritan Medical Center, Phoenix, Arizona
- 1981-1988 Director of Medical Education, Good Samaritan Medical Center, Phoenix, Arizona
- 1984-1988 Senior Administrator, Good Samaritan Medical Center, Phoenix, Arizona
- 1988-1992 Director of Clinical Research, Medlantic Research Foundation, Washington, D.C.
- 1988-1992 Medical Director, Medlantic Prevention & Research Clinics, Washington, D.C.
- 1990-1992 Chief, Section of Endocrinology, Washington Hospital Center, Washington, D.C.
- 1991-1992 Vice President of Medical Programs, Medlantic Research Foundation, Washington, D.C.
- 1992- Senior Vice President & Medical Director, Washington Hospital Center, Washington, D.C.

PROFESSIONAL ORGANIZATIONS AND COMMITTEES

- 1973-1976 House Staff Committee, Medical Staff, Philadelphia General Hospital, Philadelphia, Pennsylvania
- 1973-1976 Pharmacy and Therapeutic Committee, Medical Staff, Philadelphia General Hospital, Philadelphia, Pennsylvania
- 1973-1976 Research and Publications Committee, Philadelphia General Hospital, Philadelphia, Pennsylvania

- 1974-1976 Chairman, Patient Care Committee, Medical Staff, Philadelphia General Hospital, Philadelphia, Pennsylvania
- 1974-1976 Long Range Planning Committee of the Medical Staff, Philadelphia General Hospital, Philadelphia, Pennsylvania
- 1976-1980 Medical Committee, Good Samaritan Medical Center, Phoenix, Arizona
- 1976-1985 Program Directors' Subcommittee, Good Samaritan Medical Center, Phoenix, Arizona
- 1981-1985 Chairman, Program Directors' Subcommittee, Good Samaritan Medical Center, Phoenix, Arizona
- 1977-1988 Medical Education Committee, Good Samaritan Medical Center, Phoenix, Arizona
- 1977-1988 Board of Directors Arizona Affiliate, American Heart Association
- 1984-1988 Chairman, Program Directors' Subcommittee, Good Samaritan Medical Center, Phoenix, Arizona
- 1978-1980 Chairman, Professional Education Committee, Arizona Affiliate, American Diabetes Association
- 1979-1987 Research and Publication Committee, Good Samaritan Medical Center, Phoenix, Arizona
- 1980-1988 Research and Development Committee, Veterans Administration Medical Center, Phoenix, Arizona
- 1981-1983 President Elect, Arizona Affiliate, American Diabetes Association
- 1983-1985 President, Arizona Affiliate, American Diabetes Association
- 1984-1988 Chairman, Medical Education Committee, Greater Phoenix Affordable Health Care Foundation
- 1984-1988 Member, Board of Directors, Central Arizona Chapter, American Red Cross
- 1985-1988 Executive Committee - Medical Staff, Good Samaritan Medical Center, Phoenix, Arizona
- 1985-1988 Chairman, Board of Directors, Palms Clinic and Hospital Corporation

- 1986-1988 Chairman, Greater Phoenix Alliance of Medical Educators, Phoenix, Arizona
- 1987-1988 Governor Elect, Arizona Region, American College of Physicians, Phoenix, Arizona
- 1988- Graduate Medical Education Committee, Washington Hospital Center, Washington, D.C.
- 1989- Board of Directors, Nation's Capital Affiliate, American Heart Association, Washington, D.C.
- 1990- Ethics Committee, Washington Hospital Center, Washington, D.C.
- 1990-1992 Associate Editor, *Diabetes Care*
- 1991-1994 Education Program Review Panel, American Diabetes Association
- 1991-1993 Institutional Review Board, Medlantic Research Institute, Washington, D.C.
- 1991-1993 Medlantic Research Institute Research Committee
- 1992- Board of Directors, Washington Regional Transplant Consortium, Washington, D.C.
- 1992- Executive Committee, American Heart Association, Nation's Capital Affiliate
- 1992-1995 Chairperson, Medical and Community Education Programs Committee, American Heart Association, Nation's Capital Affiliate
- 1992- Executive Committee, Washington Hospital Center Medical and Dental Staff, Washington, D.C.
- 1992- Professional Affairs/Quality Assurance Committee, Medlantic Healthcare Group Board of Directors, Washington, D.C.
- 1992- Strategic Planning Committee, Medlantic Healthcare Group Board of Directors, Washington, D.C.
- 1992- Credentials Committee, Washington Hospital Center, Medical and Dental Staff
- 1993- Executive Committee of the Medical Staff, National Rehabilitation Hospital, Washington, D.C.
- 1994-1996 Vice President, American Heart Association, Nations Capital Affiliate
- 1994- Continuing Medical Education Committee, Washington Hospital Center, Washington, D.C.

- 1994- Medical Director's Forum, District of Columbia Hospital Association, Washington, D.C.
- 1994- Program Committee, Washington D.C. Chapter, American College of Physicians
- 1994- Member, Governor's Council, Washington D.C. Chapter, American College of Physicians
- 1994-1996 Co-chair, Diversity Committee, Washington D.C. Chapter, American College of Physicians
- 1995- Editorial Board, *Endocrinology & Metabolism*
- 1995- Board of Directors, Alliance of Independent Academic Medical Centers
- 1995- Board of Directors, Physician-Hospital Organization, Washington Hospital Center
- 1995-1996 Chairperson, Programs/Site Based Management Committee, American Heart Association, Nation's Capital Affiliate
- 1995- Continuing Medical Education Committee, Medical Society of the District of Columbia
- 1996- President Elect, Board of Directors, American Heart Association, Nation's Capital Affiliate
- 1996- Membership Committee, Medical Society of the District of Columbia
- 1996- President, Board of Directors, Alliance of Independent Academic Medical Centers
- 1996- GRA Work Group on GME Sizing, Association of American Medical Colleges
- 1997- Continuing Medical Education Committee, Medical Society of the District of Columbia
- 1997-2000 Member, Clinical Affairs Committee, Council on Arteriosclerosis, American Heart Association
- 1997- Review Committee, EM Documentation Illustrations Project, Association of American Medical Colleges
- 1997- Bioethics Committee, Medical and Dental Staff, Washington Hospital Center

SPECIALTY CERTIFICATION

- 1972 Internal Medicine, American Board of Internal Medicine
1972 Endocrinology, American Board of Internal Medicine

LICENSURE

Arizona, District of Columbia

AWARDS, HONORS AND MEMBERSHIPS IN HONORARY SOCIETIES

- 1956-1960 National Merit Scholar
1960-1964 National Foundation Scholar
1964 Priestly Prize for Undergraduate Medical Student, Research, University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania
1964 Lillie M. Erk Prize, Commencement Exercises of the University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania
1964 Alpha Omega Alpha
1976 Fellow, American College of Physicians
1992 Teaching Award, Department of Medicine, Washington Hospital Center, Washington D.C.

MEMBERSHIPS IN PROFESSIONAL AND SCIENTIFIC SOCIETIES

The American Diabetes Association
The Endocrine Society
The American College of Physicians
The American Heart Association
The Academy of Medicine, Washington, D.C.
The Association for Hospital Medical Education
The Alliance of Independent Academic Medical Centers
The District of Columbia Hospital Association
The Medical Society of the District of Columbia

COMMUNITY ACTIVITIES

- 1978-1979 President, Parents Booster Club, All Saints Episcopal Day School, Phoenix, Arizona
1979-1982 Board of Governors, All Saints Episcopal Day School, Phoenix, Arizona

- 1980-1981 Vice Chairman, Board of Governors, All Saints Episcopal Day School, Phoenix, Arizona
- 1981-1982 Chairman, Board of Governors, All Saints Episcopal Day School, Phoenix, Arizona
- 1980-1988 Camelback Kiwanis Club, Phoenix, Arizona
- 1980-1981 Chairman, Key Club Committee, Camelback Kiwanis Club, Phoenix, Arizona
- 1981-1983 Pack Committee, Cub Scout Pack #107, All Saints Episcopal Day School, Phoenix, Arizona
- 1993- Loaves and Fishes Committee

PUBLICATIONS

Original Papers:

1. Schoenberg, H.W., Beisswanger, P., and Howard, W.J. Effect of Lower Urinary Tract Infection Upon Ureteral Function. *J. of Urology* 92:107, 1964
2. Howard, W.J., Kerson, L.A. and Appel, S.H. Synthesis *de novo* of Purines in Slices of Rat Brain and Liver. *Journal of Neurochemistry* 17:121-123, 1970
3. Males, J.L., Howard, W.J., Mask D.R., Townsend J.L., Snow J.B. and McPherson H.T. Primary Hyperparathyroidism Presenting as a Giant Cell Tumor of the Maxilla. *Arch. of Int. Med.* 132:107-111, 1973
4. Dimond, R.C., Brammer, S.R., Atkinson, R.L., Howard, W.J., and Earll, J.M. Chlorpromazine Treatment and Growth Hormone Secretory Response in Acromegaly. *J. Clin. Endo. & Metab.* 36: 1189-1195, 1973
5. Shore, R.N., Howard, B.V., Howard, W.J., and Shelley, W.B. Lipoid Proteinosis: Demonstration of Normal Lipid Metabolism in Cultured Cells. *Arch. Dermatol.* 110:591-594, 1974
6. Howard, B.V., Howard, W.J., and Bailey, J.M. Acetyl Coenzyme A Synthetase and the Regulation of Lipid Synthesis from Acetate in Cultured Cells. *J. Biol. Chem.* 249(24):7912-7921, 1974
7. Atkinson, R.L., Jr., Dimond, R.C., Howard, W.J. and Earll, J.M. Unsuccessful Treatment of Acromegaly with Medroxyprogesterone Acetate. *Acta Endocrinologica* 77:19-25, 1974
8. Emerson, C.H., Anderson, A.J., Howard, W.J. and Utiger, R.D. Serum Thyroxine and Triiodothyronine Concentrations During Iodine Treatment of Hyperthyroidism. *J. Clin. Endo. & Metab.* 40(1):33-36, 1975

9. Howard, B.V., Howard, W.J., de la Llera, M. and Kefalides, N.A. Triglyceride Accumulation in Cultured Human Fibroblasts: The Effects of Hypertriglyceridemic Serum. *Atherosclerosis* 23:521-534, 1976
10. Howard, B.V., Howard, W.J. and Kefalides, N.A. Regulation of Lipid Synthesis from Acetate in Diploid Fibroblast Cultures - Variation with Passage Level and Stage of Cell Growth. *J. Cell Physiol.* 89:325-336, 1976
11. Howard, B.V., de la Llera, M. and Howard, W.J. A New Method for the Establishment of Diploid Fibroblast Cell Cultures from Human Foreskins. *Proceedings of the Society for Experimental Biology and Medicine* 153:280-283, 1976
12. Persky, H., O'Brien, C.P., Fine, E., Howard, W.J., Khan, M.A. and Beck, R.W. The Effect of Alcohol and Smoking on Testosterone Function and Aggression in Chronic Alcoholics. *Amer. J. Psych.* 134:621-625, 1977
13. Howard, W.J. and Savage, P.J. Oral Hypoglycemic Drugs: Should They Be Used? Two Views. *Ariz. Med.* 35:549-551, 1978
14. Howard, B.V., Mott, D.M., Hidaka, H., Fields, R.M., Katzeff, H., Howard, W.J. and Bennett, P.H. Cell Culture Studies of a Patient with Congenital Lipotrophic Diabetes - Normal Insulin Binding with Alterations in Intracellular Glucose Metabolism and Insulin Action. *Metabolism* 30(9): 845-852, 1981
15. Howard, W.J. The Enigma of Mild Hypertension - Who, When and How to Treat. *Samaritan Medicine*, 1(4):21-32, 1983
16. ✓ Howard, W.J. and Brown, W.V. Pharmacologic Therapy of Hypercholesterolemia. *Curr. Opin. in Card.*, 3:525-541, 1988
17. Howard, W.J. Therapeutic Management of Dyslipidemias. *Osteopathic Medical News*, 6:21-27, 1989
18. Howard, W.J. How Would You Treat . . . A Man with Moderate Hypercholesterolemia? *Drug Therapy*, 19:66-71, 1989
19. ✓ Brown, W.V. and Howard, W.J. Treatment of Lipoprotein Disorders. *Cardiovas. Clin.*, 20(3):157, 1990
20. Howard, W.J. Dietary Fat, Blood Cholesterol, and Coronary Heart Disease. *Prev. Card.*, 3:1, 1989
21. Howard, W.J. Cholesterol: Should We Test? Whom Should We Test? *Institute on Critical Issues in Health Laboratory Practice: Improving the Quality of Health Management through Clinician and Laboratorian Teamwork.* DuPont, 49, 1991
22. Howard, Wm. James. Aspetti Clinici della Cardiopatia Ischemica nel Paziente Diabetico. *Il Diabete*, 263, 1993

23. ✓ Hunninghake, D.B., Miller, V.T., LaRosa, J.C., Kinoshian, B., Brown, V., Howard, W.J., DiSerio, J.J., and O'Connor, R.R. Hypocholesterolemic Effects Of A Dietary Fiber Supplement. *Am. J. Clin. Nutr.*, 59(5):1050-1054, 1994
24. Howard, B.V. and Howard, W.J. Dyslipidemia in Non-Insulin-Dependent Diabetes Mellitus. *Endocrine Reviews*, 15(3):263-274, 1994
25. Hunninghake, D.B., Miller, V.T., LaRosa, J.C., Kinoshian, B., Jacobson, T., Brown, V., Howard, W.J., Edelman, D. and O'Connor, R.R. Long-Term Treatment of Hypercholesterolemia with Dietary Fiber. *Am. J. Med.*, 97(6):504-508, 1994
26. Pan, X.R., Chen, C., Li, G.W., Hu, Y.H., Howard, B.V., Bennett, P.H. and Howard W.J. Relation of Insulin and Blood Pressure - Does the Effect of Insulin on Elevating Blood Pressure Start in Younger Non-Obese People with Normal Glucose Tolerance? The Da Qing IGT Study, submitted for publication, 1994
27. Howard, B.V., Hannah, J., Heiser, C.C., Jablonski, K.A., Paidi, M.C., Alarif, L., Robbins, D.C., and Howard, W.J. Polyunsaturated Fatty Acids Result in Greater Cholesterol Lowering and Less Triacylglycerol Elevation than do Monounsaturated Fatty Acids in a Dose-response Comparison in a Multiracial Study Group, *Am. J. Clin. Nutr.*, 62(2):392-402, 1995
28. Howard, B.V., Lee, E.T.; Cowan, L.D.; Fabsitz, R.R.; Howard, W.J.; Oopik, A.J.; Robbins, D.C.; Savage, P.J.; Yeh, J.L.; and Welty, T.K. Coronary Heart Disease Prevalence and its Relation to Risk Factors in American Indians: The Strong Heart Study. *Am. J. Epidemiology*, 142(3):254-268, 1995
29. Yamane, K.; Kataoka, S.; Le, N.A.; Paidi, M.; Howard, W.J.; Hannah, J.S.; and Howard, B.V. Binding Affinity and Particle Size of LDL in Subjects with Moderate Hypercholesterolemia. Relationship with In Vivo LDL Metabolism. *Journal of Lipid Research*, 37:1646-1654, 1996
30. ✓ Weingand, K.W.; Le, N.; Kuzmak, B.R.; Brown, W.V.; Daggy, B.P.; Miettinen, T.A.; Howard, B.V.; Howard, W.J. Effects of Psyllium on Cholesterol and Low-Density Lipoprotein Metabolism in Subjects with Hypercholesterolemia. *Endocrinology and Metabolism*, 4:141-150, 1997
31. Lee, E.T., Cowan, L.D., Welty, T.K., Sievers, M., Howard, W.J., Oopik, A., Wang, W., Yeh, J., Devereux, R.B., Rhoades, E.R., Fabsitz, R.R., Go, O., Howard, B.V. All-Cause Mortality and Cardiovascular Disease Mortality in Three American Indian Populations, Aged 45-74 Years, 1984-88: The Strong Heart Study. Submitted for publication to the American Journal of Epidemiology, July 1997

Abstracts:

1. Schoenberg, H.W., Beisswanger, P., Howard, W.J., et al. Effect of Lower Urinary Tract Infection Upon Ureteral Function. *Surgical Forum* 14:483-484, 1963

2. Howard, W.J. and Appel, S.H. Control of Purine Biosynthesis: FGAR Amidotransferase. *Clin. Research* 16:344, 1968
3. Atkinson, R.L., Howard, W.J., Dimond, R.C., et al. Treatment of Acromegaly with Medroxyprogesterone. *Clin. Research* 19:649, 1971
4. Dimond, R.C., Brammer, S., Howard, W.J., Atkinson, R.L. and Earll, J.M. Chlorpromazine Treatment of Acromegaly. *Clin. Research* 20:424, 1972
5. Howard, B.V. and Howard, W.J. Stimulation of Lipid Biosynthesis in WI-38 Cells. Different Passage Levels in Lipid-Free Medium in the Presence and Absence of Delipidized Serum Protein *in vitro*. *Proceedings of the Tissue Culture Association* 9:370, 1974
6. Howard, W.J., Howard, B.V. and Kefalides, N.A. The Influence of Hypertriglyceridemic Serum on Triglyceride Metabolism in Cultured Human Fibroblasts. *Clin. Research* 23:323, 1975
7. Hannah, J.S.; Heiser, C.C.; Jablonski, K.A.; Paidi, M.C.; Robbins, D.C.; Howard, W.J.; Howard, B.V. Effects of monounsaturated (MONO) and polyunsaturated (POLY) fat on HDL and triglycerides in moderate hypercholesterolemia. Presented at Atherosclerosis X, Montreal, October, 1994, pp. 77
8. Hannah, J.S.; Heiser, C.C.; Jablonski, K.A.; Paidi, M.C.; Robbins, D.C.; Howard, W.J.; Howard, B.V. Effects of Obesity on the Response to a Low Fat Diet. *Circulation*, 90;4:I-236, Part 2, October 1994
9. Weingand, K.W.; Howard, B.V.; Le, N.A.; Kuzmak, B.R.; Miettinen, T.; Daggy, B.; Albrecht, H.; Allgood, L.; Brown, V.; Howard, W.J. Effects of Psyllium on Serum Lipoproteins and Cholesterol Metabolism in Hypercholesterolemic Patients. Accepted for presentation at the American Heart Association's Scientific Conference on the Efficacy of Hypocholesterolemic Dietary Interventions. Texas, 1995
10. Anderson, J.; Weingand, K.W.; Allgood, L.D.; Davison, M.; Blonde, L.; Brown, W.V.; Howard, W.J.; Ginsberg, H.N. Psyllium Therapy Adjunctive to American Heart Association Step One Diet for Hypercholesterolemic Subjects Sustains Reduction of Low-Density Lipoprotein Cholesterol for 26 Weeks. Submitted for presentation at the American College of Cardiology Meeting, 1996

Editorials:

1. Howard, W.J. Financing Medical Education. *Samaritan Medicine* 1(4):3-5, 1983
2. Howard, W.J. Is the Good Samaritan Medical Center an Endangered Species? *Samaritan Medicine* 3(4):3-6, 1985
3. Howard, W.J. Ruminations of An Ex-DME. *Samaritan Medicine* 6(1):3, 1988

4. Howard, B.V. and Howard, W.J. The Compelling Case for Smoking Cessation in Diabetics. *Circulation* 82:299-301, 1990
5. Howard, W.J. When to Treat? A Workshop to Address the Threshold of Treatment of Hypertension in Diabetes. *Diabetes Care*, 14(11) Supplement 4:1-3, November 1991
6. Howard, W.J. Is It Time for a Clinical Trial of Dietary Fish Oil Supplementation in Individuals with NIDDM? *Annals of New York Academy of Sciences*, 683:341-342, 1993

Chapters and Reviews:

1. Howard, B.V. and Howard, W.J. Lipid Metabolism in Cultured Cells. In: Adv Lipid Res, Vol. 12, eds. Paoletti, R. and Kritchevsky, D., pp. 51-90, 1974
2. Howard, B.V. and Howard W.J. Lipids in Normal and Tumor Cells in Culture. In: Lipids in Tumors, ed. Carroll, K.K., *Prog. Biochem. Pharm.*, Vol. 10, pp. 136-166, 1975
3. Brown, W.V., Howard, W.J. and Field, L. Nicotinic Acid and its Derivatives. Drug Treatment of Hyperlipidemia, edited by Rifkind, B., Marcel Dekker, New York, New York, pp. 189-213, 1991
4. Howard, B.V. and Howard W.J. The Pathophysiology and Treatment of Lipid Disorders in Diabetes Mellitus. Joslin's Diabetes Mellitus, 13th Edition, CR Kahn and GC Weir, eds Lea and Febiger, pp. 372-396, 1994
5. Ratner, R.E.; Howard, B.V.; and Howard, W.J. Lipid Abnormalities in Diabetes Mellitus. In: Principles and Practice of Endocrinology and Metabolism, Ed. Kenneth Becker, J.B. Lippincott, p.p 1402-1409, 1995

1970-1983 Professor of Nutritional Biochemistry;
Director
Training Program in Oral Science, M.I.T.

1965-1970 Associate Professor of Nutritional
Biochemistry, Department of Nutrition and
Food Science, M.I.T.

1963-1985 Visiting Lecturer in Nutrition
Tufts University School of Dental Medicine,
Boston University School of Medicine.

1963-1987 Harvard University School of Medicine

1959-1965 Assistant Professor of Nutritional
Biochemistry, Department of Nutrition and
Food Science, M.I.T.

1957-1959 Research Associate, Department of Food
Technology, M.I.T.

1955-1957 Teaching Assistant, Physiology and
Biochemistry, Rutgers University

1953-1954 Assistant to Chief Toxicologist, Army Medical
Center, Washington, D.C.

1952 Chemist, Applied Research Branch, Army
Chemical Center, Maryland

1951 Junior Chemist, Electronics Branch, Army
Chemical Center, Maryland

SOCIETIES AND PROFESSIONAL ORGANIZATIONS

Academy of Toxicology
American Association for the Advancement of Science
Animal Care Panel
American Chemical Society
American Institute of Dental Research
American Institute of Nutrition
American Society for Clinical Nutrition
Institute of Food Technologists
Mark L. Morris Animal Care Panel, Honorary Fellow
New York Academy of Sciences
Perinatal Research Society
Sigma Xi
Society for Pediatric Research
Society for Teratology
Toxicology Forum

SPECIAL RESEARCH AND ADMINISTRATIVE INTERESTS

Research Interests

General - regulation and control of metabolism, nutrition and toxic phenomena; nutrition, food science and public policy.

Specific - perinatal development of the infant with particular reference to dietary effects; development of oral tissues; relationships among diet, metabolic energy and structure of dietary energy sources; synthetic dietary energy sources and other unique sources of nutrients, e.g., single cell protein; food additives toxicology; diet and development of the central nervous system; adolescent nutrition.

Teaching Interests

Physiological and nutritional biochemistry; mammalian nutrition, nutrition, growth and development, food toxicology and food policy.

HONORS/AWARDS

Sep 1989	The Sterling B. Hendricks Memorial Lecture, American Chemical Society
Jun 1989	Glenn W. Kilpatrick Memorial Address, Association of Food and Drug Officials
May 1988	Esther Peterson Consumer Service Award, Food Marketing Institute
Sep 1987	Award of Merit, Institute of Food Technologists, Washington, D.C. Section
Jun 1987	Award of Merit, Food and Drug Administration
Dec 1986	Senior Executive Service Salary Bonus
Jun 1983	Distinguished Service Award, DHHS
Aug 1982	Samuel W. Johnson Memorial Lecture, Connecticut Agricultural Experiment Station
Apr 1982	Public Health Service Superior Service Award

- May 1982 The Braverman Memorial Lecture at the Technion-Israel Institute of Technology in Haifa, Israel
- 1981 Conrad A. Elvehjem Award, American Institute of Nutrition
- 1975 Outstanding Teacher of the Year Award, Department of Nutrition and Food Science, M.I.T.

MEMBERSHIP ON COMMITTEES

Membership Advisory Groups:

- 1990 W.H.O. Commission on Health and Environment, Panel on Food and Agriculture
- 1990 Chairman, WHO/FAO Joint Food Safety Committee
- 1990 Chairman, FAO/WHO World Food Conference Planning Commission
- 1990 Chairman, WHO/FAO Joint Commission on Biotechnology
- 1990 Member, U.S. Nestle Advisory Board
- 1988-1992 National Advisory Environmental Health Sciences Council of NIH
- 1988-1991 Chairman, AIN/ASCN Public Affairs Committee
- 1988-present Southwest Research Institute, Board of Trustees
- 1988-present National Medical Fellowships, Inc.
- 1987-present The Food and Drug Law Institute, Board of Trustees
- 1985-present Member and Chairman, Joint FAO/WHO Expert Advisory Panel on Food Safety
- 1979-present Toxicology Forum, Director
- 1978-present Food Update Board of Governors, The Food and Drug Law Institute
- 1973-1981 Committee on Contraceptive Steroids, NICHD
- 1973-1978 Advisory Committee on Nutrition, NIDR
- 1973-1977 Committee on Maternal and Child Health, NICHD

1972-1978 Board of Scientific Advisors, FDA
1972-1978 Expert Committee on GRAS (Generally
Recognized as Safe) Substances, FASEB
1972-1976 Committee on Growth and Development, NICHD
1972 Chairman, Ad Hoc Committee on Nutrition,
NINDS
1969 Committee on Food Safety, White House
Conference on Food and Nutrition
1969 Division of Space Medicine, NASA Manned Space
Flight Center
1963-1968 Advisory Committee on Nutrition, Animal Care
Panel

UTHSCSA Committees:

1989 Co-Chairman, University of Texas Genome
Project
1988-to date Chairman, University of Texas Institute of
Biotechnology Building Committee
1988-to date University of Texas Institute of
Biotechnology Search Committee
1988-to date Chairman, Presidential Lecture Series
1987-to date Chairman, Graduate Faculty Council
1987-to date South Texas Medical Center Research Building
Committee
1987-1988 Chairman, University Presence in the Park
Committee

FDA/DHHS Committee Functions:

1986-1987 Interagency Committee on Human Nutrition
Research (ICHNR) Subcommittee on Technology,
Nutrition, and Food Production
1986-1987 Interagency Committee on Human Nutrition
Research (ICHNR) Subcommittee on Research and
the RDAs

1985-1987 Chairman, Subcommittee on Governmental Affairs, CCEHPR

1985-1987 Council, Committee to Coordinate Environmental Health and Related Programs (CCEHRP)

1984-1987 USDA/Food Safety and Inspection Service Technology Assessment Steering Committee (TASC)

1984-1987 Alternate member of the Subcommittee on Research of the Working Group on Future Food and Agriculture Policy of the Cabinet Council on Food and Agriculture

1984-1987 Co-chairman of the Cancer Risk Assessment Task Force

1983-1987 DHHS Nutrition Policy Board

1983-1985 USDA/DHHS Dietary Guidelines Advisory Committee

1982 FDA Conflict of Interest Review Board

1982-1987 Coordination of Nutrition Initiatives for the Public Health Service

1982-1984 Chairperson, PHS Task Force on the National Academy of Sciences Report on "Diet, Nutrition, and Cancer"

1980-1987 Co-chairman of USDA/FDA Working Group on Food Safety Legislation

1979-1987 Steering Committee on FDA Residue Programs

1979-1983 FDA Performance Review Board

1978-1987 Commissioner's Policy Board

1978-1987 National Center for Toxicological Research (NCTR) Policy Board

1978-1987 FDA Long-Term Training Committee

Other Activities:

1990-1992 Member, IFT's Regional Communicators

1986-to date Consultant to OECD in Food Safety and
 Nutrition, Paris, France

1984-1987 Member, Policy Board, International Program
 in Chemical Safety

1984-1987 Deputy U.S. Coordinator for Codex
 Alimentarius

1981-to date Editorial Board, DRUG-NUTRIENT INTERACTIONS

1980-to date Advisory Committee to the Pediatric Pulmonary
 Center on Nutrition Matters, Dept. of
 Pediatrics, Georgetown University Hospital,
 Wash., D.C.

1979-to date Life Member, Corporation of The Culinary
 Institute of America

1979 E.V. McCollum Commemorative Committee

1978-1987 Official FDA Liaison Representative to the
 Food and Nutrition Board, National Academy of
 Sciences

Offices Held:

1989-1990 Chairman, AIN/ASCN Public Affairs Committee

1977-1978 Chairman, Fellows Committee, American
 Institute of Nutrition

1977 Program Committee, Western Hemisphere
 Nutrition Congress

1973 Chairman, Gordon Research Conferences

1973 Chairman, FASEB Conference

1972 Vice Chairman, Gordon Research Conferences

1972 Meetings Committee, Federation of American
 Societies for Experimental Biology (FASEB)

1970-1971 Chairman, Northeast Section, Institute of
 Food Technologists

1969-1972 National Chairman, Committee on Nutrition
 Education, Institute of Food Technologists

1969-1970 Vice-Chairman, Northeast Section, Institute
 of Food Technologists

- 1968-1969 Secretary, Northeast Section, Institute of Food Technologists
- 1967-1972 Member, National Program Committee, American Institute of Nutrition
- 1967-1969 Chairman, Comm. on Biochemical Nutrition American, Institute of Nutrition
- 1966-1969 National Councilor, Institute of Food Technologists

PUBLICATIONS

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- Miller, S.A. (Jan. 1990) "The FDA in the 1980s: The Center for Food Safety and Applied Nutrition," Food Drug Cosmetic Law Journal.
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- Miller, S.A. (in press) "Scientific Decisionmaking from a National Policy Perspective," Food Drug Cosmetic Law Journal.
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- Miller, S.A. (in press), "FDA In The 80's: The Center for Food Safety and Applied Nutrition," (Presented at Institute of Food Technologists, Chicago, IL, June 1989)

Miller, S.A. (in press), "The Regulatory Climate and What's Ahead," (Presented at Institute of Food Technologists, Chicago, IL, June 1989)

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PUBLIC SPEAKING

"Circling the Wagons: The Internationalization of Food Safety," Presented at the International Conference on Issues in Food Safety and Toxicology, Michigan State University, East Lansing, Michigan, May 31, 1990.

"FDA, Politics, and the Evolution of Food Safety,"
Presented at the International Conference on Issues in Food
Safety and Toxicology, Michigan State University, East
Lansing, Michigan, May 31, 1990.

"The Products of Janus: Risks and Benefits of Nutrient
Substitutes", Presented at the World Sugar Research
Organization and National Institute of Nutrition
International Dietary Guidelines Symposium, The University
of British Columbia, Vancouver, B.C., Canada, May 12, 1990

"Pesticides in Our Foods - Risk/Benefit vs. Delaney",
Presented at the Mid-Continental Association of Food and
Drug Officials Annual Training Conference, LeBaron Hotel,
Dallas, Texas, March 28, 1990

"Prioritization of Issues: The Consumer Viewpoint on
Prioritization and Recommendations on Issues Raised in
Management Session", Presented at The ESCA Genetics
Corporation Conference on Food Safety and Quality in the
1990's, Westin Hotel O'Hare, Chicago, Illinois, March 27,
1990.

"Current Issues In Food Safety", Presented at the 86th
Annual Convention and Exposition of The United Fresh Fruit
and Vegetable Association, San Antonio Convention Center,
San Antonio, Texas, February 12, 1990

"Health Claims Labeling: A Case of Regulatory
Schizophrenia", Keynote Address given at the National
Institute of Nutrition Forum on Health Claims in Food
Marketing: The Imminent Challenges, Hotel Admiral, Toronto,
Canada, February 1, 1990.

"Food Labeling and Biotechnology", Presented at the FDA,
Dallas District Conference, Colony-Parke Hotel, Dallas,
Texas, November 8, 1989.

"Chemicals and the Apple Industry: A Case Study in the Food
Safety Debate", Presented at The American Institute of Wine
and Food Seventh International Conference on Gastronomy,
Chicago, IL, November 3, 1989.

"The Future of Nutrition and Food Regulation", Presented at
CERES Conference, Global Food and technology Issues in the
21st Century, Williamsburg, VA, October 24, 1989.

"Quest for Safe Food: Knowledge and Wisdom," Presented at
USDA/ARS before the American Chemical Society, Miami Beach,
FL, September 11, 1989

"The Production of Safe Food," Presented at Texas A&M University Beef Industry Conference, College Station, TX, August 14, 1989.

"FDA In the 80's: The Center for Food Safety and Applied Nutrition", Presented at IFT, Chicago, IL, June 28, 1989

"The Regulatory Climate and What's Ahead", Presented at IFT, Chicago, IL, June 27, 1989

"Food Safety and Nutrition", Presented at IFT, Chicago, IL, June 28, 1989

"Interesting Times", The Glenn Kilpatrick Memorial Address, Presented at AFDO, Hyatt Regency, Louisville, KY, June 26, 1989

"The Regulation of Artificial Sweeteners", Presented at AADR, San Francisco, CA, March 19, 1989

"The Problems Associated With The Establishment of Maximum Nutrient Limited Infant Formula", Presented at the Symposium on Upper Limits of Nutrients in Infant Formulas, Holiday Inn, Iowa City, IA, Nov. 7, 1988

"Principles of Food Regulation," Presented to the Toxicology Forum at the Chinese Academy of Preventive Medicine in Beijing, China, October 17, 1988

"The Saga of Health Claims Labeling: A Modern Fable," Presented at the AACC 73rd Annual Meeting, San Diego Marriott Hotel, San Diego, CA, October 13, 1988

"New Foods - Old Problems," Presented at the Tenth International Congress on Dietetics, Paris, France, July 7, 1988.

"Internationalization of Food Science and Safety," Presented at the IFT 1988 Annual Meeting and Food Expo, New Orleans Convention Center, New Orleans, LA, June 21, 1988.

"Risk-Risk Decision Making: The Need to Evaluate All of the Associated Risks," Presented at the 1988 IFT-IUFoST Basic Symposium, Sheraton New Orleans Hotel, New Orleans, LA, June 18, 1988.

"Delaney vs De Minimis Risk: Are There Solutions?," Presented to the ILSI Risk Science Institute Brookings Institution, Washington, D.C., May 31, 1988.

"Food Safety: Fact and Fancy," Presented at the 1988 Editors' Briefing Program, FMI Annual Convention '88, May 9, 1988.

"Public Policy Implications of Supplement Risk/Benefit Analysis," Presented at the AIN/FASEB meeting, Symposium on "Nutrient Supplementation: Risk/Benefit Analysis," May 4, 1988.

"The Regulatory Impact of New Analytical and Safety Testing Techniques," Presented to the Cosmetic Toiletry and Fragrance Association, Arlington, VA, April 25-26, 1988.

"Intellectual Integration: A Plea For a Neo-Renaissance in the Food and Nutritional Sciences," Presented to Food Update '88, Rancho Bernardo, San Diego, CA, April 20, 1988.

"Basic Science and Transitional Research," Presented at the Academic/Industry Joint Conference 1988, Wyndham Hotel, San Antonio, TX, March 16, 1988.

"Regulatory Environment and Issues At FDA," Plastics Institute of America, Inc., FoodPlas IV '86/'87, Orlando, FL, March 3, 1988.

"Safety and Risk/Benefits of Irradiation," The AMA/IFT Symposium on "Safety of the Food Supply in the Twenty-First Century: Concerns and Challenges," Arlington, VA, March 3, 1988.

"Overview - A Regulatory Perspective," The 1988 Annual Winter Toxicology Forum, Bethesda, MD, February 1988.

"Legislative and Regulatory Control of Irradiation," The 14th Annual Meeting & Scientific Sessions of The American College of Nuclear Physicians, Scottsdale, AZ, February 1988.

"Certainty and Uncertainty: The Science of Regulating Health," The American Industrial Health Council Annual Meeting, "Identifying and Regulating Chronic Health Risks: The Challenge of the Future," Washington, D.C., December 1987.

"The Renaissance Medical Scientist: The Debate Over Joint M.D./Ph.D. Degrees," (prepared by Miller, S.A. and T.M. Mikiten), The Council of Graduate Schools in the United States 27th Annual Meeting, Washington, D.C., December 1987.

"Scientific Decision Making From A National Policy Perspective," The Food and Drug Law Institute seminar on "The Scientific Issues Raised by Proposition 65," Washington, D.C., November 1987.

"Responding to Today's Food Safety Concerns," The American Association of Cereal Chemists, "To Your Health: A Forum on Food Safety, Nutrition and Policy," Nashville, TN, November 1987.

"Science, Scientists and the Regulatory Process: The Mobius Interaction," Teratology Society Annual Meeting-Public Affairs Forum on "The Impact of Scientific Societies on the Legislative and Regulatory Process," Palm Springs, CA, June 1987.

"Public Health Considerations in Communicating Health Claims," (prepared by Miller, S.A. and M.G. Stephenson), Institute of Food Technologists Short Course: "Designing and Promoting Foods for Health," Las Vegas, NV, June 1987.

"High Technological Food Preservation and The Law--National and International," Food: Liability, Reliability and Product Safety, University of Wisconsin-Madison, Madison, WI, June 1987.

"The Saga of Chicken Little and Rambo," Keynote address at the 71st Annual Conference of the Central Atlantic States Association of Food and Drug Officials, Baltimore, MD, May 1987.

"How Mergers Have Affected FDA Regulation With Regards To Research And Development, Quality Assurance Programs, And Distribution," (prepared by Miller, S.A. and K. Skinner), Food and Drug Law Institute Food Update, Wesley Chapel (Tampa), FL, April 1987.

"High Technological Food Preservation and the Law--National and International," International Seminar on Food Safety Towards the 21st Century, London, England, April 1987.

"Noncaloric Sweeteners in the Diabetic Diet: Saccharin," (prepared by Miller, S.A. and V.P. Frattali), Conference on Sweeteners in Diabetes, San Francisco, CA, March 1987.

"Present and Future of Food Analysis," (prepared by Miller, S.A. and A.E. Pohland), 100th Anniversary Celebration of the Municipal Laboratories of Barcelona, Barcelona, Spain, March 1987.

"Food Control Policies in the United States," 100th Anniversary Celebration of the Municipal Laboratories of Barcelona, Barcelona, Spain, March 1987.

"America's Changing Consumer Habits: Where Are They Headed?" (prepared by Miller, S.A., and M.G. Stephenson), Presented at the Celebration of the Signing of the Hatch Act of 1987 Creating the State Agriculture Experiment Station System, National Academy of Sciences, Washington, DC, March 1987.

"Wine and Health," American Wine Society Conference, Baltimore, MD, November 1986.

"Emerging Food Safety Issues," (prepared by Miller, S.A. and K. Skinner), University of Guelph Workshop on "Food Research 2000: Challenges and Opportunities," Ontario, Canada, October 1986.

"Food Safety: The Fight for Priorities," (prepared by Miller, S.A. and K. Skinner), Association of Food and Drug Officials Annual Conference, Williamsburg, VA, June 1986.

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"Remarks on the Future of Codex Alimentarius," (prepared by Miller, S.A. and C.W. Cooper), Government/Industry Codex Meeting sponsored by the Food and Drug Law Institute, Arlington, VA, May 1986.

"Technology, Innovation and Regulation," (prepared by Miller, S.A. and K. Skinner), Food and Drug Law Institute, Food Update, La Quinta, CA, April 1986.

"Reflections on Food Safety," (prepared by Miller, S.A. and J.E. Kvenberg), National Food Processors Association (NFPA) Conference entitled, "Avoiding Pesticide, Environmental Contaminant, and Food Additive Crises," Atlanta, GA, February 1986.

"Issues in Establishing Health Claims Policy," (prepared by Miller, S.A. and M.G. Stephenson), Public Voice for Food and Health Policy and the Council for Responsible Nutrition Conference on "Health Claims for Foods: Current Policy Issues," Washington, DC, January 1986.

"Technical Barriers to Trade," (prepared by Miller, S.A. and F.M. MacKeith), Food and Drug Law Institute (FDLI) 29th Annual Education Conference, Washington, DC, December 1985.

"Public Health and Its Relation to Agriculture Policy," (prepared by Miller, S.A. and J.J. Kozak), National Milk Producers Federation Dairy Summit Convention, Orlando, FL, December 1985.

"Dietary Guidelines for Health Promotion and Disease Prevention," (prepared by Miller, S.A. and M.G. Stephenson), American Public Health Association 113th Annual Meeting, Washington, DC, November 1985.

"Views on U.S. - Japan Cosmetic Regulatory Affairs," (prepared by Miller, S.A. and J.A. Wenninger), International Conference on Cosmetic Regulation, Tokyo, Japan, November 1985.

"Foods and Health-Related Research Needs," (prepared by Miller, S.A. and C. Mapes) Institute for Comparative and Environmental Toxicology-Symposium II entitled "The American Food Supply: Are We At Risk?," Cornell University, Ithaca, NY, October 1985.

"Nutrition Quackery; What Are the Hazards?" (prepared by Miller, S.A. and F.S. Linde), Second Annual Symposium on Nutrition Quackery: A Health Hazard, University of California, Davis, CA, October 1985.

"Regulation and Innovation -- An Uneasy Alliance Revisited," Annual Meeting of the Agricultural Research Institute, Arlington, VA, October 1985.

Regulating Applications of Biotechnology in the Food Processing Industry," Regulatory Affairs Professionals Society (RAPS) Educational Seminar--Biotechnology Update 1985, San Francisco, CA, October 1985.

"Toxicology, Food Safety and Agricultural Policy," Toxicology and Technological Development Conference sponsored by the Toxicology Forum and The Canadian Center for Toxicology, Ottawa, Canada, September 1985.

"Food Safety and Health: A Scientific and Legislative Perspective," XIII International Congress of Nutrition, Brighton, U.K., August 1985.

"Toxicology and Food Safety Regulations," Inter-American Conference on Food Protection, Washington, DC, August 1985.

"Food Safety: The State of the Art," USDA/FDA Food Editors Conference: Food Safety and Nutrition, San Francisco, CA, July 1985.

"Food Irradiation," 89th Annual Association of Food and Drug Officials Conference, Madison, WI, June 1985.

"Risk Assessment and U.S. Food Safety Policy," Finnish Society of Toxicology Symposium on Food and Nutrition Toxicology in Helsinki, Finland, May 1985.

"The Future and FDA: Science, Technology and the Consumer," Finnish-American Seminar on Finnish Food Exports to the U.S., Helsinki, Finland, May 1985.

"Nutrition at the Crossroads: Science, Politics and Policy," Keynote Address to the Japanese Society for Nutrition and Food Science 39th Annual Meeting, Tokyo, Japan, April 1985.

"A Contemporary Approach to Food Safety by the U.S. Food and Drug Administration: A Critical Evaluation," Food Additive Association, Osaka, Japan, April 1985.

"Excess Intake of Vitamins and Minerals - Real or Imaginary," 26th Meeting of the Federation of Netherlands Medical Biological Societies, Amsterdam, Netherlands, April 1985.

"New Policy Directions at FDA," National Food Processors Association Annual Convention, San Francisco, CA, February 1985.

"A Commencement Address," Annual Meeting of the Food and Nutrition Liaison Committee of the Nutrition Foundation-International Life Sciences Institute, Naples, FL, January 1985.

"Regulation and Innovation - An Uneasy Alliance," 28th Annual Education Conference by the Food and Drug Law Institute in cooperation with FDA, Washington, DC, December 1984.

"Science, Scientists and Society: A Need For a Cannon of Ethics," Fifth Annual Meeting of the American College of Toxicology, Arlington, VA, November 1984.

"Risk Assessment and U.S. Food Safety Policy" and "The Uncertainty of Certainty - The Art and Science of Risk Assessment," International Life Sciences Institute International Symposium on Safety Assessment, Kasumigaseki, Chiyoda-Ku, Japan, November 1984.

"Human Health and Safety in This Biotechnical Age," Meeting of the Food and Agriculture Forum of the National Planning Association, Des Moines, IA, November 1984.

"Food Risks: Is Eating Hazardous to Your Health?," MIT Lecture Series, Washington Seminar, Washington, DC, November 1984.

"A Contemporary Approach to Food Safety by the U.S. Food and Drug Administration: A Critical Evaluation," French Nutrition Foundation colloquium, Food Toxicological Risk and Problems of Technological Innovation, Paris, France, September 1984.

"The Role of Government in Providing Dietary Guidelines to Reduce Risk of Cancer," Conference on Nutrition and Cancer Prevention: Science Policy and Ethics, University of California Berkeley Extension Conference Center, San Francisco, CA, September 1984.

"To Supplement or Not to Supplement: That is the Question," 17th Annual Meeting of the Society for Nutrition Education, Philadelphia, PA, July 1984.

"Safety of Novel -- Microbiologically Derived -- Foods," International Development Research Centre, Ottawa, Canada, June 1984.

"Public Health and Food Safety Control," keynote speech to the Symposium on Postharvest Technology of Agricultural Produce, Taipei, Taiwan, January 1984.

"When Do Foods Become Drugs?," Stokley-Van Camp Annual Symposium, at the University of Tennessee, Knoxville, TN, May 1983.

"The Leap of Faith: Public Science, Public Policy and Public Health," Boston University School of Public Health Commencement Exercise, Boston, MA, May 1983.

"Changing Times: FDA, The Food Industry and the American People," 12th Annual Meeting of the Whey Products Institute & the 58th Annual Meeting of the American Dry Milk Institute, Rosemont, IL, April 1983.

"Food Safety Laws: Delaney and Other Dilemmas," Boston University School of Public Health Conference, Washington, DC, September 1982.

"Food Safety and Public Expectation," (Samuel W. Johnson Memorial Lecture), Connecticut Agricultural Experiment Station Plant Science Day, New Haven, CT, August 1982.

"Science and the Law: The Basis for New Food Safety Legislation," Food and Nutrition Committee of the American Health Foundation International Conference, New York, NY, April 1982.

"Nutrition at the Crossroads," Ohio Nutrition Council Meeting, Columbus, OH, March 1982.

"The Wish and The Reality: Science, Legislation and Food Safety," Food and Drug Law Institute (FDLI), Scottsdale, AZ, April 1981.

"Revolution and Evolution," National Food Processors Convention, San Francisco, CA, February 1981.

"The Evolution of American Food Law," Third Annual International Seafood Conference, Rome, Italy, November 1980.

"Public Policy and the Kinetics of Dietary Change," American Dental Association Fourth Annual Workshop Conference, Chicago, IL, October 1980.

"Nutrition Labeling, Public Policy and Self Interest: The Voice of the Turtle," Lillian Fountain Smith Conference for Nutrition Educators, Colorado State University, Denver, CO, July 1980.

"Public Health, Politics, and PCBs: A Case Study in Science and Policy," 1980 National Environmental Health Assn. Annual Education Conference on Toxic and Hazardous Substances, Milwaukee, WI, July 1980.

"Development of FDA Labeling Concepts and Proposed New Legislation," FDA-Embassy Diplomatic Corp Briefing, Department of State, Washington, DC, June 1980.

"The Control of a Non-Lethal Hazard: The Limits of Government," International Association for Dental Research, 8th International Conference on Oral Biology, Tokyo, Japan, June 1980.

"Pro Bono Publicam," National Food Processors Association Annual Conference, St. Louis, MO, February 1980.

"The Voice of the Turtle," National Food Processors Association Annual Conference, St. Louis, MO, February 1980.

"Portent of Things to Come: Regulation, Food and Society," Annual Convention of the International Food Service Executives Association, Las Vegas, NV, August 1979.

"Current Trends at The Bureau of Foods," Embassy Diplomatic Corps Briefing, Washington, DC, June 1979.

"A 20th Century Conflict Between Pragmatism and Protection: Implementation of Food Safety Policy," Food Safety Policy Conference, New York, NY, March 1979.

"Nutrition at the Crossroads: A 20th Century Conflict," Third Clinical Congress of the American Society of Parenteral & Entereal Nutrition, Boston, MA, February 1979.

"The Meaning of Zero and Other Absolutes," Washington Journalism Center, Washington, DC, January 1979.

"Preservation and Protection -- The Conflict In Food Science," R&D Association Fall Meeting, scheduled for the Army Natick R&D Command, Natick, MA, November 1978.

"Sugar, Oral Health and Regulation: A Strategy for Prevention of Oral Disease," American Dental Association Health Foundation Conference, Chicago, IL, October 1978.

"The Wise Use of Chemicals in Foods," 176th American Chemical Society National Meeting, Miami, FL, September 1978.

"Science, Technology and Regulation Industry's Contribution to the Public's Need," Industrial Liaison Panel, Food and Nutrition Board, National Academy of Sciences, Chicago, IL, July 1978.

"The FDA Program in Nutrition," NIH Conference, The Biomedical and Behavioral Basis of Clinical Nutrition -- A Projection for the 1980's, Bethesda, MD, June 20, 1978.

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1. 项目背景与意义

随着信息技术的飞速发展，企业面临着日益激烈的市场竞争。为了提高企业的核心竞争力，必须加强信息化建设，提升管理效率。

本项目旨在通过引入先进的管理理念和技术手段，构建一套完善的信息化管理体系，实现企业运营的数字化转型。

项目的实施将有助于企业优化资源配置，降低运营成本，提高客户满意度，从而在激烈的市场竞争中脱颖而出。

本项目的成功实施将对企业的长远发展产生深远影响，是企业实现可持续发展的关键举措。

项目的主要目标是实现业务流程的自动化和智能化，提升决策的科学性和准确性。

项目将采用先进的云计算技术和大数据分析技术，确保系统的安全性和稳定性。

项目团队将严格按照项目计划推进各项工作，确保项目按时高质量完成。

项目将建立完善的沟通机制，定期向管理层汇报项目进展，确保信息畅通。

项目将注重人才培养和团队建设，提升员工的信息化素养和技能水平。

项目将建立科学的考核评价体系，对项目成果进行客观公正的评估。

项目将建立完善的售后服务体系，确保系统长期稳定运行。

项目将建立完善的文档管理制度，确保项目资料的完整性和可追溯性。

项目将建立完善的风险管理机制，及时发现和解决项目中的潜在风险。

项目将建立完善的保密制度，确保企业核心数据的安全。

项目将建立完善的应急响应机制，确保在突发事件发生时能够迅速响应。

项目将建立完善的培训体系，提升员工的信息化应用能力和操作技能。

项目将建立完善的运维体系，确保系统的日常运行和维护工作有序开展。

项目将建立完善的升级机制，确保系统能够适应企业发展的需求。

项目将建立完善的评估机制，定期对项目实施效果进行评估和总结。

项目将建立完善的激励机制，激发员工的积极性和创造性。

项目将建立完善的沟通渠道，确保项目信息的及时传递和反馈。

项目将建立完善的协作机制，提升项目团队的协作效率和执行力。

项目将建立完善的监督机制，确保项目按照既定计划和目标推进。

项目将建立完善的反馈机制，及时收集和处理员工的意见和建议。

项目将建立完善的总结机制，对项目实施过程和成果进行总结和提炼。

项目将建立完善的推广机制，将项目实施经验推广到其他部门和业务领域。

项目将建立完善的持续改进机制，不断优化项目成果和运营效率。

项目将建立完善的合规机制，确保项目实施过程符合相关法律法规的要求。

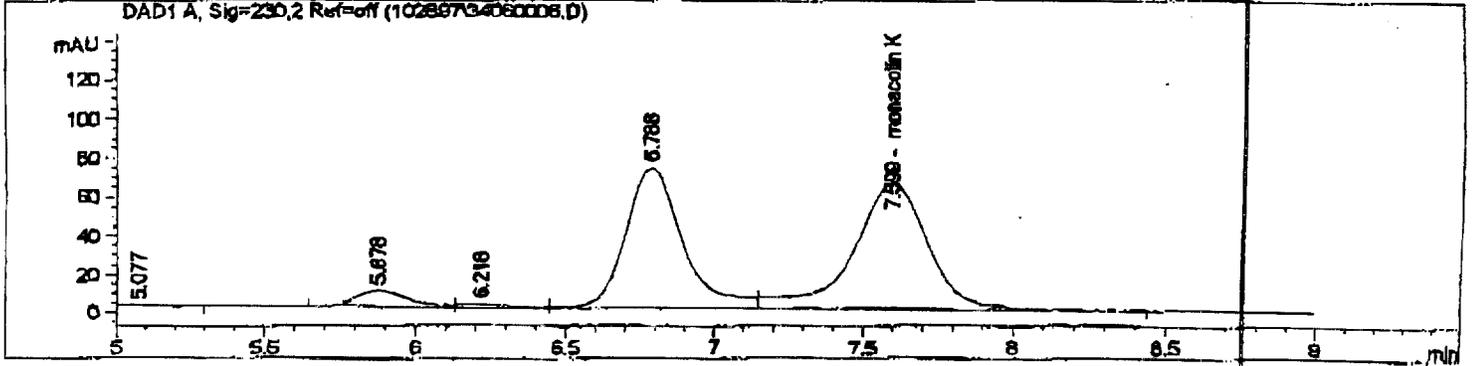
项目将建立完善的审计机制，对项目资金使用和运营情况进行审计和监督。



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Sample Name    : ██████████                    Vial      : 5
Acq. Operator : jrp                            Inj       : 1
                                                    Inj Volume: 8 µl

Sequence File  : C:\HPCHEM\1\SEQUENCE\3406 97.S
Acq. Method   : C:\HPCHEM\1\METHODS\LOVU3406.M
Last changed  : 10/28/97 9:22:34 PM by jrp
Analysis Method : C:\HPCHEM\1\METHODS\LOVU3406.M
Last changed  : 10/29/97 12:24:14 AM by jrp
Modified USP method for Lovistatin (monacolin K) in bulk material (not D.P.)
    
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ESTD Percent Report

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Sorted By          : Signal
Calib. Data Modified : Wednesday, October 29, 1997 12:24:14 AM
Multiplier         : 1.0000
Dilution           : 1.0000
Sample Amount      : 4.22730e4 [ug/g]
Uncalibrated Peaks : not reported
    
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Signal 1: DAD1 A, Sig=230,2 Ref=off
 Results obtained with enhanced integrator!

RetTime [min]	Type	Area [mAU*s]	Amt/Area	Amount %	Grp	Name
7.599	VP	1147.50854	7.82996e-2	0.212546		monacolin K
Totals :				0.212546		

*** End of Report ***