

ORDER OF THE STATE BOARD OF PHARMACY
(Docket No. D-000531-062)

In The Matter Of:

STANLEY SHAW SCARBROUGH, R.Ph.
11778 CR 45
Findlay, Ohio 45840
(R.Ph. No. 03-2-12847)

INTRODUCTION

THE MATTER OF STANLEY SHAW SCARBROUGH CAME FOR HEARING ON NOVEMBER 8, 2000, AND DECEMBER 13, 2000, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: SUZANNE L. NEUBER, R.Ph. (presiding); DIANE C. ADELMAN, R.Ph.; SUZANNE R. EASTMAN, R.Ph.; ROBERT P. GIACALONE, R.Ph.; LAWRENCE J. KOST, R.Ph.; AMONTE B. LITTLEJOHN, R.Ph.; AND DOROTHY S. TEATER, PUBLIC MEMBER.

STANLEY SHAW SCARBROUGH WAS REPRESENTED BY JAMES F. FLYNN, AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCE

(A) Testimony

State's Witnesses:

- (1) Mark Keeley, R.Ph., Ohio State Board of Pharmacy

Respondent's Witnesses:

- (1) Stanley Shaw Scarbrough, R.Ph.
- (2) Sue G. Gratz, R.Ph., Respondent
- (3) Alan Spreen, M.D.

(B) Exhibits

State's Exhibits:

- (1) Exhibit 1--Copy of nineteen-page Notice of Opportunity for Hearing letter of Stanley Shaw Scarbrough dated May 31, 2000.
- (2) Exhibit 1A--Copy of fourteen-page Notice of Opportunity for Hearing letter of Sue G. Gratz dated May 31, 2000.
- (3) Exhibit 1B--Copy of eighteen-page Notice of Opportunity for Hearing letter of Scarbroughs Medical Arts Pharmacy dated May 31, 2000.
- (4) Exhibit 1C--Hearing Request letter of Stanley Shaw Scarbrough dated June 28, 2000.
- (5) Exhibit 1D--Hearing Request letter of Sue G. Gratz dated June 28, 2000.

- (6) Exhibit 1E--Hearing Request letter of Scarbroughs Medical Arts Pharmacy dated June 28, 2000.
- (7) Exhibit 1F--Copy of Hearing Schedule letter of Scarbrough's Medical Arts Pharmacy, Stanley Shaw Scarbrough, and Sue G. Gratz dated June 30, 2000.
- (8) Exhibit 1G--Copy of Pharmacist File Front Sheet of Stanley Shaw Scarbrough showing original date of registration as May 4, 1979; and two-page copy of Renewal Application for Pharmacist License, No. 03-2-12847, for a license to practice pharmacy in Ohio from September 15, 2000, through September 15, 2001, signed and dated June 27, 2000.
- (9) Exhibit 1H--Copy of Pharmacist File Front Sheet of Sue G. Gratz showing original date of registration as August 8, 1960; and two-page copy of Renewal Application for Pharmacist License, No. 03-3-07246, for a license to practice pharmacy in Ohio from September 15, 2000, through September 15, 2001, signed and dated July 28, 2000.
- (10) Exhibit 1I--Copy of Renewal Application for DDD License No. 02-0114850 for a Terminal Distributor of Dangerous Drugs license from January 1, 2000, through December 31, 2000, signed by Stan Scarbrough and dated September 9, 1999.
- (11) Exhibit 1J--Copy of two-page letter from James F. Flynn dated October 6, 2000.
- (12) Exhibit 1K--Copy of letter from David L. Rowland to James F. Flynn dated October 6, 2000.
- (13) Exhibit 1L--Two-page Request for Continuance letter from James F. Flynn dated November 2, 2000.
- (14) Exhibit 1M--Copy of Continuance Request Response letter dated November 6, 2000.
- (15) Exhibit 1N--Copy of Hearing Schedule letter dated November 9, 2000.
- (16) Exhibit 1O--Copy of Hearing Schedule letter dated November 15, 2000.
- (17) Exhibit 2--Copy of four-page Dangerous Drug Distributor Inspection Report of Scarbroughs Medical Arts Pharmacy, Terminal Distributor No. 02-0114850, dated March 26, 1997; and copy of response to inspection report violations signed by Stan Scarbrough, received in the Board office on March 31, 1997.
- (18) Exhibit 2A--Copy of eight-page Dangerous Drug Distributor Inspection Report of Scarbroughs Medical Arts Pharmacy, Terminal Distributor No. 02-0114850, dated April 22, 1997; and copy of response to inspection report violations signed by Stan Scarbrough, not dated.
- (19) Exhibit 2B--Copy of five-page Dangerous Drug Distributor Inspection Report of Scarbroughs Medical Arts Pharmacy, Terminal Distributor No. 02-0114850, dated May 4, 1998; and copy of three-page response to inspection report violations signed by Stan Scarbrough, dated May 20, 1998.
- (20) Exhibit 3--Copy of FDA forms FDA 481(E)-CG, FDA 481(A)-CG, and FDA 481(C)-CG completed during limited inspection at Scarbrough Medical Arts Pharmacy on April 22-29, 1997, FDA Central File No. 1528698; and copy of ten-page Summary of Findings (EI: 4/22-29/97 MPS) signed by Michael P. Sheehan, not dated.
- (21) Exhibit 3A--Copy of FDA forms FDA 481(E)-CG, FDA 481(A)-CG, and FDA 481(C)-CG completed during limited inspection at Scarbrough Medical Arts Pharmacy on July 8, 9, 1997, FDA Central File No. 1530500; and copy of seventeen-page Summary of Findings (EI: 7/8-9/97 MPS) signed by Michael P. Sheehan, not dated.
- (22) Exhibit 3B--Copy of two-page Response letter for July 8, 9, 1997 inspection results from Stan Scarbrough dated July 22, 1997.

- (23) Exhibit 3C--Copy of two-page FDA Memorandum (Re: Scarbrough Pharmacy's Response Letter to July, 1997 EI) dated August 5, 1997.
- (24) Exhibit 3D--Copy of Collection Report (Form FDA 464) and C/R Continuation Sheet (Form FDA 464a) for Sample No. 97-740-762, collected July 9, 1997, Central File No. 1530500, with the following attachments: copy of two-page e-mail regarding Non-Traditional Drug Bulletin #21 dated June 27, 1997; copy of two-page Warning Letter Draft, not dated.
- (25) Exhibit 4--Letter from Fred L. Dailey, Director of the Ohio Department of Agriculture, dated June 27, 2000.
- (26) Exhibit 5--Two-page letter from Bruce A. Bouts, M.D. signed and dated May 11, 1998, and re-signed and notarized on May 17, 2000.
- (27) Exhibit 5A--Two-page letter from Gary E. Hirschfield, M.D. signed and dated May 27, 1998, and re-signed and notarized on May 17, 2000.
- (28) Exhibit 5B--Letter from Rick D. Watson, M.D. signed and dated May 21, 1998, and re-signed and notarized on May 17, 2000.
- (29) Exhibit 5C--Letter from William H. Kose, M.D. signed and dated May 6, 1998, and re-signed and notarized on May 17, 2000.
- (30) Exhibit 5D--Letter from Sue Best and Seth Brownlee signed and dated July 10, 1997, and re-signed and notarized March 3, 2000.
- (31) Exhibit 5E--Statement of Heather Zehender signed and notarized April 11, 2000.
- (32) Exhibit 5G--Twenty-five-page transcript of interview with Jill Waldron and Heather Zehender by Compliance Agent Dale Fritz and Compliance Specialist Mark Keeley held on March 6, 2000.
- (33) Exhibit 5I--Seventy-six-page transcript of Tape #4-Interview with Stan Scarbrough by Compliance Specialists Mark Keeley and Joann Predina and Compliance Agent Dale Fritz held on May 4, 1998.
- (34) Exhibit 6--Prescription vial containing 120 capsules of Enalapril 2.5mg.
- (35) Exhibit 7--Copy of Compounding Log for Enalapril 2.5mg capsules, Scarbrough Pharmacy Compound No. 167.
- (36) Exhibit 8--Prescription vial containing 30 capsules of Fenfluramine 20mg.
- (37) Exhibit 9--Copy of Compounding Log for Fenfluramine 20mg capsules, Scarbrough Pharmacy Compound No. 519.
- (38) Exhibit 10--Amber bottle labeled "Stock" containing 170ml of Hydrocortisone Lotion 2.5%.
- (39) Exhibit 11--Copy of Compounding Log for Hydrocortisone Lotion 2.5%, Scarbrough Pharmacy Compound No. 249.
- (40) Exhibit 12--Prescription vial containing 190 capsules of 5-Hydroxytryptophan 50mg.
- (41) Exhibit 13--Copy of Compounding Log for 5-Hydroxytryptophan 50mg, Scarbrough Pharmacy Compound No. 454.
- (42) Exhibit 14--Prescription vial containing 135 capsules of 5-Hydroxytryptophan 100mg.
- (43) Exhibit 15--Copy of Compounding Log for 5-Hydroxytryptophan 100mg, Scarbrough Pharmacy Compound No. 486.
- (44) Exhibit 16--Prescription vial containing 63 capsules of 5-Hydroxytryptophan 200mg.
- (45) Exhibit 17--Copy of Compounding Log for 5-Hydroxytryptophan 200mg, Scarbrough Pharmacy Compound No. 516.
- (46) Exhibit 18--White jar containing Lidocaine 2.5%/Prilocaine 2.5% cream.

- (47) Exhibit 19--Copy of Compounding Log for Lidocaine 2.5%/Prilocaine 2.5%, Scarbrough Pharmacy Compound No. 412.
- (48) Exhibit 20--Prescription vial containing 79 capsules of Extra Strength Met-Fuel
- (49) Exhibit 21--Copy of Compounding Log for Extra Strength Met-Fuel, Scarbrough Pharmacy Compound No. 394.
- (50) Exhibit 22--Prescription vial containing 80 capsules of Methyltestosterone 5mg
- (51) Exhibit 23--Copy of Compounding Log for Methyltestosterone 5mg, Scarbrough Pharmacy Compound No. 472.
- (52) Exhibit 24--Prescription vial containing 39 capsules of Pregnenolone 10mg.
- (53) Exhibit 25--Copy of Compounding Log for Pregnenolone 10mg, Scarbrough Pharmacy Compound No. 378.
- (54) Exhibit 26--Prescription vial containing 25 capsules of Progesterone 100mg with Prescription No. 489790 label.
- (55) Exhibit 27--Copy of Compounding Log for Progesterone 100mg, Scarbrough Pharmacy Compound No. 119.
- (56) Exhibit 28--Prescription vial containing 45 capsules of Progesterone 100mg
- (57) Exhibit 29--Prescription vial containing 60 capsules of Progesterone 20mg with Prescription No. 480637 label.
- (58) Exhibit 30--Copy of Compounding Log for Progesterone 20mg, Scarbrough Pharmacy Compound No. 322.
- (59) Exhibit 31--Prescription vial containing 35 capsules of Progesterone 200mg.
- (60) Exhibit 32--Copy of Compounding Log for Progesterone 200mg, Scarbrough Pharmacy Compound No. 506.
- (61) Exhibit 33--Prescription vial containing 70 capsules of Progesterone 100mg/Estriol 2.5mg.
- (62) Exhibit 34--Copy of Compounding Log for Progesterone 100mg/Estriol 2.5mg, Scarbrough Pharmacy Compound No. 483.
- (63) Exhibit 35--Prescription vial containing 14 capsules of Promethazine 25mg.
- (64) Exhibit 36--Copy of Compounding Log for Promethazine 25mg, Scarbrough Pharmacy Compound No. 417.
- (65) Exhibit 37--Amber bottle containing 30ml of Salicylic Acid 10%/Formalin 40% with Prescription No. 484034 label.
- (66) Exhibit 38--Copy of Compounding Log for Salicylic Acid 10%/Formalin 40%, Scarbrough Pharmacy Compound No. 26.
- (67) Exhibit 39--Prescription vial containing 20 capsules of Sertaline 50mg.
- (68) Exhibit 40--Copy of Compounding Log for Sertaline 50mg capsules, Scarbrough Pharmacy Compound No. 193.
- (69) Exhibit 41--Prescription vial containing 40 capsules of Simvastin 10mg.
- (70) Exhibit 42--Copy of Compounding Log for Simvastin 10mg capsules, Scarbrough Pharmacy Compound No. 517.
- (71) Exhibit 43--Prescription vial containing 40 capsules of Tri-Hormone.
- (72) Exhibit 44--Copy of Compounding Log for Tri-Hormone capsules, Scarbrough Pharmacy Compound No. 521.
- (73) Exhibit 45--Prescription vial containing 40 capsules of Tri-Hormone-2/50/.4 w/Cal Carb Filler.
- (74) Exhibit 46--Copy of Compounding Log for Tri-Hormone-2/50/.4 w/Cal Carb Filler, Scarbrough Pharmacy Compound No. 521.
- (75) Exhibit 47--Prescription vial containing 59 capsules of Tri-Hormone with Prescription No. 490498 label.

- (76) Exhibit 48--Prescription vial containing 50 capsules of Triest Plus Progesterone 200mg.
- (77) Exhibit 49--Copy of Compounding Log for Triest Plus Progesterone 200mg, Scarbrough Pharmacy Compound No. 566.
- (78) Exhibit 50--Prescription vial containing 25 capsules of Triest Plus Pro.
- (79) Exhibit 51--Prescription vial containing 50 capsules of Triest Plus Pro.
- (80) Exhibit 52--Copy of Compounding Log for Triest Plus Pro capsules, Scarbrough Pharmacy Compound No. 499.
- (81) Exhibit 53--White jar containing Urea 40% Ointment.
- (82) Exhibit 54--Copy of Compounding Log for Urea 40% Ointment, PCCA Compound No. 3244.
- (83) Exhibit 55--Sixty-one clear dosette vials containing Albuterol 0.083% Inhalant Solution with Lot No. 971203 label.
- (84) Exhibit 56--Fourteen clear dosette vials containing Albuterol 0.083% Inhalant Solution with Lot No. 970204 label.
- (85) Exhibit 57--Three clear dosette vials containing Albuterol 0.083% Inhalant Solution with Lot No. 961412 label.
- (86) Exhibit 58--Clear dosette vial containing Albuterol 0.083% Inhalant Solution with Lot No. 972402 label.
- (87) Exhibit 59--Copy of two-page Compounding Log for Albuterol 0.083% Inhalant Solution, PCCA Compound No. 0021.
- (88) Exhibit 60--Two copies of label for 4oz. of Colloidal Silver showing Lot No. 970201.
- (89) Exhibit 61--Copy of label for 1oz. of Colloidal Silver showing Lot No. 960409.
- (90) Exhibit 62--Copy of label for 2oz. of Colloidal Silver showing Lot No. 961511.
- (91) Exhibit 63--Label for 4oz. of Colloidal Silver showing Lot No. 972403.
- (92) Exhibit 64--Copy of label for 8oz. of Colloidal Silver showing Lot No. 971504.
- (93) Exhibit 65--Copy of label for 4oz. of Colloidal Silver showing Lot No. 971904.
- (94) Exhibit 66--Copy of Compounding Log for Colloidal Silver, no Compound No. listed.
- (95) Exhibit 67--Copy of label for 120 capsules of Met-Fuel showing Lot No. 962012.
- (96) Exhibit 68--Copy of Compounding Log for Met-Fuel capsule, Scarbrough Pharmacy Compound No. 219.
- (97) Exhibit 69--Prescription vial containing 100 capsules of Extra Strength Met-Fuel with Lot No. 972406 label.
- (98) Exhibit 71--Copy of label for DHEA 5mg Sublingual Tablets showing Lot No. 962407.
- (99) Exhibit 72--Copy of Compounding Log for DHEA 5mg sublingual tablets, Scarbrough Pharmacy Compound No. 253 and PCCA Compound No. 0907.
- (100) Exhibit 73--Copy of label for DHEA 25mg capsules showing Lot No. 970701.
- (101) Exhibit 74--Copy of Compounding Log for DHEA 25mg capsules, Scarbrough Pharmacy Compound No. 127.
- (102) Exhibit 75--Copy of label for DHEA 50mg capsules showing Lot No. 971703.
- (103) Exhibit 76--Copy of Compounding Log for DHEA 50mg capsules, Scarbrough Pharmacy Compound No. 218.
- (104) Exhibit 77--Copy of label for ADD Formula #529 showing Lot No. 972703.
- (105) Exhibit 78--Copy of Compounding Log for ADD Formula #529, Scarbrough Pharmacy Compound No. 529.
- (106) Exhibit 79--Copy of label for ADD Formula #468 showing Lot No. 970201.

- (107) Exhibit 80--Copy of Compounding Log for ADD Formula #468, Scarbrough Pharmacy Compound No. 468.
- (108) Exhibit 81--Copy of label for ADD Formula #438 (Modified) showing Lot No. 971501.
- (109) Exhibit 82--Copy of Compounding Log for ADD Formula #438, Scarbrough Pharmacy Compound No. 438.
- (110) Exhibit 83--Copy of label for ADD Formula #441 showing Lot No. 971004.
- (111) Exhibit 84--Copy of Compounding Log for ADD Formula #441, Scarbrough Pharmacy Compound No. 441.
- (112) Exhibit 85--Copy of label for 100cc of Chicken Collagen Solution showing Lot No. 971103.
- (113) Exhibit 86--Label for 500gm of Creatine Monohydrate Powder 99% showing Lot No. 971503; and label for 90 capsules of Herbal Smoke Eliminator showing Lot No. 971503.
- (114) Exhibit 87--Copy of label for 120cc of Creatine Syrup showing Lot No. 960612.
- (115) Exhibit 88--Copy of label for Scarbrough's Diaper Rash Ointment showing Lot No. 970904.
- (116) Exhibit 89--Copy of label for 2oz of Poison Ivy Gel showing Lot No. 960908.
- (117) Exhibit 90--Copy of label for 30 Co-Enzyme Q-10 60mg capsules showing Lot No. 971504.
- (118) Exhibit 91--Copy of Compounding Log for Herbal Smoke Eliminator, no Compound No. listed.
- (119) Exhibit 94--Twenty-page printout of Scarbrough Pharmacy Prescription Log for Albuterol for the period from January 1, 1996, to July 8, 1997.
- (120) Exhibit 95--Prescription No. 463904, dated 10/16/95, for Albuterol.
- (121) Exhibit 96--Prescription No. 464570, dated 12/04/1995, for Proventil.
- (122) Exhibit 97--Prescription No. 473954, dated 4/22/96, for Albuterol.
- (123) Exhibit 98--Prescription No. 476542, dated 6/4/96, for Albuterol.
- (124) Exhibit 101--Prescription No. 485351, dated 11-5-96, for Albuterol.
- (125) Exhibit 108--Two-page printout of Scarbrough Pharmacy Prescription Log for Sertraline for the period from January 1, 1996, to July 8, 1997.
- (126) Exhibit 108a--Two-page printout of Scarbrough Pharmacy Prescription Log for Zoloft for the period from January 1, 1996, to July 8, 1997.
- (127) Exhibit 109--Prescription No. 472590, dated 3-29-96, for Zoloft.
- (128) Exhibit 110--Prescription No. 470127, dated 2/23/96, for Albuterol.
- (129) Exhibit 111--Prescription No. 476809, dated 06/10/1996, for Proventil.
- (130) Exhibit 137--Exempt Narcotics Register from January 27, 1996, to July 5, 1997.
- (131) Exhibit 138--Three-page Section 3719.44 of the Ohio Revised Code (ORC) titled "Authority of board of pharmacy to change schedules".
- (132) Exhibit 139--Rule 4729-11-09 of the Ohio Administrative Code (OAC) titled "Sale of schedule V controlled substance products without a prescription".
- (133) Exhibit 140--Copy of Compounding Log for Morphine Sulfate SR 15mg capsules, Scarbrough Pharmacy Compound No. 406.
- (134) Exhibit 141--Copy of two-page Compounding Log for Phentermine SR 25mg capsules, Scarbrough Pharmacy Compound No. 192.
- (135) Exhibit 142--Copy of Compounding Log for Theophylline 300mg Slow Release capsules, Scarbrough Pharmacy Compound No. 582 and PCCA Compound No. 3183.
- (136) Exhibit 143--Copy of Compounding Log for Phentermine 15mg capsules, no Compound No. listed.

- (137) Exhibit 144--Copy of two-page Compounding Log for Triest 2.5mg, Scarbrough Pharmacy Compound No. 374 and PCCA Compound No. 2813.
- (138) Exhibit 145--Copy of Compounding Log for Morphine Sulfate SR 500mg capsules, Scarbrough Pharmacy Compound No. 203 and PCCA Compound No. 694.
- (139) Exhibit 146--Copy of Compounding Log for Testosterone 1mg/ml in Vanicream, Scarbrough Pharmacy Compound No. 923.
- (140) Exhibit 147--Copy of Compounding Log for Triest Plus Pro Test capsules, Scarbrough Pharmacy Compound No. 498.
- (141) Exhibit 148--Twenty-four-page Table3 product list dated September 24, 1998, and Page 22 of Table3 product list dated August 7, 1998.
- (142) Exhibit 149--Two-page Ohio State Board of Pharmacy Report of Investigation by William F. McMillen dated April 5, 1999.
- (143) Exhibit 150--Two-page printout of VitaminUSA web page titled "Welcome to VitaminUSA".
- (144) Exhibit 151--Two-page printout of VitaminUSA web page titled "Men's Health".
- (145) Exhibit 152--Printout of VitaminUSA web page titled "Testosterone".
- (146) Exhibit 153--Printout of VitaminUSA web page titled "Your Shopping Basket" completed for Testosterone.
- (147) Exhibit 154--Printout of VitaminUSA web page titled "Shipping Form" completed for Testosterone to Bill McMillen.
- (148) Exhibit 155--Two-page printout of VitaminUSA web page titled "Billing Form" to Bill McMillen and printout of VitaminUSA web page titled "Order Confirmation" to Bill McMillen.
- (149) Exhibit 156--VitaminUSA Invoice No. 0174 dated March 31, 1999 to Bill McMillen.
- (150) Exhibit 157--Stock bottle containing 60 tablets of Nuriventon Targeted Dietary Supplement for Testosterone Plus Ester C.
- (151) Exhibit 158--Printout of three VitaminUSA web pages dated May 23, 2000, titled "Testosterone", "Men's Health", and "VitaminUSA.com", and printout of two-page Scarbrough Pharmacy web page dated May 23, 2000.
- (152) Exhibit 160--FDA letter with Summary of Enalapril analysis results from Steven P. Eastham dated August 12, 1997 with copies of twelve pages of selected analysis records attached.
- (153) Exhibit 161--Copy of FDA Memorandum from Charles S. Price dated August 25, 1997 regarding his conversation with Stan Scarbrough.
- (154) Exhibit 162--Copy of FDA Memorandum by Charles J. Ganley, M.D. dated September 16, 1997 regarding Enalapril potential health hazard.
- (155) Exhibit 163--Copy of e-mail from Bob Lamb to Bruce Bouts with analysis results of Colloidal Silver dated September 16, 1998.
- (156) Exhibit 164--Ketoprofen 2% Gel labeled "Sample-Not for Sale".
- (157) Exhibit 165--Two-page letter from Gary E. Hirschfeld, M.D. signed and dated October 29, 1999, and re-signed and notarized on May 17, 2000.
- (158) Exhibit 166--Letter from James R. Robertson, M.D. and Bruce A. Bouts, M.D. signed and dated October 26, 1999 and re-signed by Bruce A. Bouts and notarized on May 17, 2000.
- (159) Exhibit 167--Two-page letter regarding Wilson's Syndrome from Bruce Bouts, M.D., R.Ph. and the following attachments: copy of Scarbrough Pharmacy advertisement regarding Wilson's Syndrome in The Courier, Findlay, Ohio, December 22, 1999, issue; copy of two-page "The Mortar and Pestle" newsletter from Scarbrough Pharmacy dated November 1999; two-page copy of article titled "Naturopath Charged

with Unprofessional Conduct" by Stephen Barrett, M.D. dated December 6, 1999; copy of pages 3 and 4 of web page <http://www.quackwatch.com/01Quackery-RelatedTopics/fad.html> dated December 6, 1999.

- (160) Exhibit 168--"Worst Pills Best Pills News", March 2000 Vol. 6 No. 3, pages 17 through 24.
- (161) Exhibit 169--Copy of Thyroid.org web page dated February 24, 2000, and copy of three-page American Thyroid Association Statement on "Wilson's Syndrome" dated February 24, 2000.
- (162) Exhibit 170--Stock bottle for MGP Promethazine w/Codeine Cough Syrup labeled with NDC 60432-606-16, but containing in part a different syrup with NDC 0472-1627-28.
- (163) Exhibit 172--Copy of Sections 4731.34 (Unauthorized practice of medicine, surgery or podiatry) and 4731.41 (Practice of medicine or surgery without certificate) of the Ohio Revised Code.
- (164) Exhibit 173--Eight-page copy of Section 321 (Definitions; generally) of Title 21, US Code.
- (165) Exhibit 174--Three-page copy of Section 3715.01 (Definitions) of the Ohio Revised Code.
- (166) Exhibit 176--Information Sheet showing "Suggested Formula for Albuterol Inhalant, 1 Liter", and "Suggested Compounding Procedure", dated August 17, 1993.

Respondent's Exhibits:

- (1) Exhibit A--Copy of Dangerous Drug Distributor Inspection Report of Scarbrough's Medical Arts Pharmacy signed and dated July 17, 1996.
- (2) Exhibit B--Copy of Dangerous Drug Distributor Inspection Report of Scarbrough's Medical Arts Pharmacy signed and dated October 25, 2000.
- (3) Exhibit C--Copy of two-page letter to James R. Robertson, M.D. and Bruce A. Bouts, M.D. from Stanley S. Scarbrough dated December 20, 1999.
- (4) Exhibit D--Copy of eight-page Scarbrough Pharmacy Log of Scripts for prescriptions filled between February 1, 2000, and October 30, 2000, dated October 30, 2000.
- (5) Exhibit E--Copy of letter from Sharon A. Carlson dated October 26, 2000.
- (6) Exhibit F--Copy of letter from Mary Basinger dated November 6, 2000.
- (7) Exhibit G--Copy of two-page table sorted by Program and Program Date and two-page table sorted by person, both dated November 2, 2000.
- (8) Exhibit H--Copy of two-page letter from Judy Patton dated November 1, 2000.
- (9) Exhibit I--Copy of pages 2698, 2700, 2701, and 2702 of the First Supplement, USP-NF, not dated.
- (10) Exhibit J--Copy of letter from Susan Alger dated October 31, 2000.
- (11) Exhibit K--Copy of two-page letter from Carol J. Hicks, M.D. dated November 7, 2000.
- (12) Exhibit L--Copy of letter from Carol J. Hicks, M.D. dated December 18, 1998.
- (13) Exhibit M--Copy of pages 344 through 351 of International Journal of Pharmaceutical Compounding, Vol. 3 No. 5, September/October 1999.
- (14) Exhibit N--Copy of pages 180 and 181 of International Journal of Pharmaceutical Compounding, Vol. 4 No. 3, May/June 2000.
- (15) Exhibit O--Copy of letter to Bruce Bouts, M.D. from Stan Scarbrough, not dated.

- (16) Exhibit P--List of Scarbrough's Medical Arts Pharmacy Library Contents dated October, 2000.
- (17) Exhibit Q--Copy of six-page "Good Compounding Practices Applicable to State Licensed Pharmacies" dated November 7, 2000.
- (18) Exhibit R--Copy of letter from Gwynn Jelden, M.D. dated October 25, 2000.
- (19) Exhibit S--Copy of letter from Jeanne L. Ashworth, M.D. dated October 25, 2000.
- (20) Exhibit T--Copy of two PCCA Certificates of Completion for program titled "Primary Compounding Techniques" on June 24 & 25, 1996 issued to Sue Gratz, R.Ph. and Carole Gill, Technician.
- (21) Exhibit U--Copy of nine-page information paper about "Methocel E4M® Premium (Hydroxypropylmethylcellulose (HPMC))".
- (22) Exhibit V--Copy of prescription for 500cc of ADD #441 dated August 14; copy of Logged Formula Worksheet for ADD Formula Liq dated August 17, 2000; copy of prescription for 8oz.of Colloidal Silver 20 PPM; and copy of Logged Formula Worksheet for Colloidal Silver Liquid dated September 6, 2000.
- (23) Exhibit W--Copy of letter from Michael G. Scherer, D.O. dated December 6, 2000.
- (24) Exhibit X--Copy of letter from Lyle T. Calcamuggio, M.D. dated December 11, 2000.
- (25) Exhibit Y--Copy of letter from Jay W. Nielsen, M.D., not dated.
- (26) Exhibit Z--Copy of letter from Robert R. Summers, D.O. and Lorie A. Thomas, D.O. dated December 8, 2000.
- (27) Exhibit AA--Copy of letter from L. Terry Chappell, M.D. dated December 7, 2000.
- (28) Exhibit BB--Copy of two-page letter from James C. Roberts Jr., M.D. dated December 5, 2000.
- (29) Exhibit CC--Copy of letter from Gwynn Jelden, M.D. dated November 29, 2000.
- (30) Exhibit DD--Copy of letter from John C. Biery, D.O. dated December 4, 2000.

FINDINGS OF FACT

After having heard the testimony, observed the demeanor of the witnesses, considered the evidence, and weighed the credibility of each, the State Board of Pharmacy finds the following to be fact:

- (1) Records of the State Board of Pharmacy indicate that Stanley Shaw Scarbrough was originally licensed in the state of Ohio on May 4, 1979, pursuant to examination, and is currently licensed to practice pharmacy in the state of Ohio. Records further reflect that Stanley Shaw Scarbrough is the Responsible Pharmacist at Scarbroughs Medical Arts Pharmacy pursuant to Sections 4729.27 and 4729.55 of the Ohio Revised Code and Rule 4729-5-11 of the Ohio Administrative Code.
- (2) Stanley Shaw Scarbrough did, as the Responsible Pharmacist, on or before April 22, 1997, manufacture, sell, hold for sale, or deliver a drug that was adulterated or misbranded, to wit: Stanley Shaw Scarbrough and/or a pharmacist or technician under his supervision compounded or manufactured the following drugs which lacked required labeling information:
 - (a) Enalapril 2.5mg capsules, #120 capsules: The label has no lot number, no expiration date, no date of manufacture or compounding, and no method to refer to an entry on a compounding log.

- (b) Fenfluramine 20mg capsules, #30 capsules: The label has a date that can be referenced to an entry on a compounding log; however, there is no expiration date on the bottle or on the compounding log. Additionally, no lot numbers are referenced on the compounding log for the bulk medications used to compound or manufacture the drug product.
- (c) Hydrocortisone Lotion 2.5%- Stock, 170ml: The label has no lot number, no expiration date, no date of manufacture or compounding, and no method to refer to an entry on a compounding log. Additionally, no lot numbers are referenced on the compounding log for the bulk medications used to compound or manufacture the drug product.
- (d) 5-Hydroxytryptophan 50mg capsules, #190 capsules: The label has a date that can be referenced to an entry on a compounding log; however, there is no expiration date on the bottle or on the compounding log. Additionally, no lot numbers are referenced on the compounding log for the bulk medications used to compound or manufacture the drug product.
- (e) 5-Hydroxytryptophan 100mg capsules, #135 capsules: The label has no lot number, no expiration date, no date of manufacture or compounding, and no method to refer to an entry on a compounding log.
- (f) 5-Hydroxytryptophan 200mg capsules, #63 capsules: The label has a lot number that can be referenced to an entry on a compounding log; however, there is no expiration date on the bottle or on the compounding log. Additionally, no lot numbers are referenced on the compounding log for the bulk medications used to compound or manufacture the drug product.
- (g) Lidocaine 2.5%/Prilocaine 2.5% in emollient cream base: The label has no lot number, no expiration date, no date of manufacture or compounding, and no method to refer to an entry on a compounding log.
- (h) Extra Strength Met-Fuel capsules, #79 capsules: The label has a date that can be referenced to an entry on a compounding log; however, there is no expiration date on the bottle or on the compounding log. Additionally, no lot numbers are referenced on the compounding log for the bulk medications used to compound or manufacture the drug product.
- (i) Methyltestosterone 5mg capsules, #80 capsules: The label has no lot number, no expiration date, no date of manufacture or compounding, and no method to refer to an entry on a compounding log.
- (j) Pregnenolone 10mg capsules, #39 capsules: The label has no lot number, no expiration date, no date of manufacture or compounding, and no method to refer to an entry on a compounding log.
- (k) Progesterone 100mg capsules, #25 capsules, Rx# 489790: The label has no lot number, no expiration date, no date of manufacture or compounding, and no method to refer to an entry on a compounding log.
- (l) Progesterone 100mg capsules, #45 capsules: The label has no lot number, no expiration date, no date of manufacture or compounding, and no method to refer to an entry on a compounding log.
- (m) Progesterone 20mg capsules, #60 capsules, Rx# 480637: The label has a date that can be referenced to an entry on a compounding log; however, there is no expiration date on the bottle or on the compounding log. Additionally, no lot numbers are referenced on the compounding log for the bulk medications used to compound or manufacture the drug product.

- (n) Progesterone 200mg capsules, #35 capsules: The label has a date that can be referenced to an entry on a compounding log; however, there is no expiration date on the bottle or on the compounding log. Additionally, no lot numbers are referenced on the compounding log for the bulk medications used to compound or manufacture the drug product.
- (o) Progesterone 100mg/Estriol 2.5mg capsules, #70 capsules: The label has no lot number, no expiration date, no date of manufacture or compounding, and no method to refer to an entry on a compounding log.
- (p) Promethasine (*sic* Promethazine) 25mg capsules, #14 capsules: The label has no lot number, no expiration date, no date of manufacture or compounding, and no method to refer to an entry on a compounding log.
- (q) Salicylic Acid 10%/Formalin 40% in Alcohol, 30ml, Rx# 484034: The label has a date, but it cannot be referenced to an entry on a compounding log; therefore, there is no lot number, no expiration date, no date of manufacture or compounding, and no method to refer to an entry on a compounding log.
- (r) Sertaline 50mg capsules, # 20 capsules: The label has no lot number, no expiration date, no date of manufacture or compounding, and no method to refer to an entry on a compounding log.
- (s) Simvastatin 10mg capsules, #40 capsules: The label has a lot number that can be referenced to an entry on a compounding log; however, there is no expiration date on the bottle or on the compounding log. Additionally, no lot numbers are referenced on the compounding log for the bulk medications used to compound or manufacture the drug product.
- (t) Tri-Hormone capsules, #40 capsules: The label has a date that cannot be referenced to an entry on a compounding log; therefore, there is no lot number, no expiration date, no date of manufacture or compounding, and no method to refer to an entry on a compounding log.
- (u) Tri-Hormone-2/50/.4 w/Cal Carb filler capsules, #40 capsules: The label has a date that cannot be referenced to an entry on a compounding log; therefore, there is no lot number, no expiration date, no date of manufacture or compounding, and no method to refer to an entry on a compounding log.
- (v) Tri-Hormone capsules, #59 capsules, Rx# 490498: The label has a date, but it cannot be referenced to an entry on a compounding log; therefore, there is no lot number, no expiration date, no date of manufacture or compounding, and no method to refer to an entry on a compounding log.
- (w) Triest Plus Progesterone 200mg capsules, #50 capsules: The label has no lot number, no expiration date, no date of manufacture or compounding, and no method to refer to an entry on a compounding log.
- (x) Triest Plus Pro capsules, #25 capsules and #50 capsules: The label has a lot number that can be referenced to an entry on a compounding log; however, there is no expiration date on the bottle or on the compounding log. Additionally, no lot numbers are referenced on the compounding log for the bulk medications used to compound or manufacture the drug product.
- (y) Urea 40% ointment: The label has no lot number, no expiration date, no date of manufacture or compounding, and no method to refer to an entry on a compounding log.

- (z) Albuterol 0.083% Inhalant Solution, #61 vials, lot # 971203, exp. date: 7/97: The label has a lot number and an expiration date but does not indicate the volume per vial. Additionally, the lot number cannot be referenced to an entry on a compounding log; therefore, no lot numbers can be referenced on the compounding log for the bulk medications used to compound or manufacture the drug product.
- (aa) Albuterol 0.083% Inhalant Solution, #14 vials, lot # 970204, exp. date: 7/97: The label has a lot number and an expiration date but does not indicate the volume per vial. Additionally, the lot number cannot be referenced to an entry on a compounding log; therefore, no lot numbers can be referenced on the compounding log for the bulk medications used to compound or manufacture the drug product.
- (bb) Albuterol 0.083% Inhalant Solution, #3 vials, lot # 961412, exp. date: 5/97: The label has a lot number and an expiration date but does not indicate the volume per vial. Additionally, the lot number cannot be referenced to an entry on a compounding log; therefore, no lot numbers can be referenced on the compounding log for the bulk medications used to compound or manufacture the drug product.
- (cc) Albuterol 0.083% Inhalant Solution, #1 vial, lot # 972402, exp. date: 8/97: The label has a lot number and an expiration date but does not indicate volume per vial. Additionally, the lot number cannot be referenced to an entry on a compounding log; therefore, no lot numbers can be referenced on the compounding log for the bulk medications used to compound or manufacture the drug product.

Such conduct is in violation of Section 3715.52(A)(1) of the Ohio Revised Code, Section 331(b) of Title 21 of the United States Code, and Section 201.18 of Title 21 of the Code of Federal Regulations.

- (3) Stanley Shaw Scarbrough did, as the Responsible Pharmacist, on or before April 22, 1997, manufacture, sell, hold for sale, or deliver a drug that was adulterated or misbranded, to wit: Stanley Shaw Scarbrough and/or a pharmacist or technician under his supervision compounded or manufactured the following drugs which were labeled with false and misleading information:
 - (a) Colloidal Silver Solution: The product is labeled without validation as a "Super Antibiotic" and as an "Antiseptic/Antibiotic". The contents of active and inactive ingredients are not listed on the label. The strength was not initially listed on the label, but currently is listed as 3-5ppm. 5ppm, or 15mcgm silver/tsp. without documentation or validation; therefore, there is no basis for suggested use or dose on label. There are no warning instructions on label. Initially no expiration date assigned, then given 1 year expiration date, and finally a 3 month expiration date. The expiration dates were assigned arbitrarily. The manufacturer is not noted on log.
 - (b) Met-Fuel capsules, all combinations: The complete contents of active and inactive ingredients are not listed on the label. The contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. An expiration date of 1 year was arbitrarily assigned. The manufacturer is not noted on log or the log does not

- indicate the ingredients, lot number and valid expiration dates or positive identification of the pharmacist responsible for verification.
- (c) DHEA 5mg sublingual tablets: The complete contents of active and inactive ingredients are not listed on the label. The contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. The label has no warning instructions. An expiration date of 1 year arbitrarily assigned.
 - (d) DHEA 25mg and 50mg capsules: Contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. The label has no warning instructions. Expiration dates are arbitrarily assigned. The manufacturer is not noted on log or the log does not indicate the ingredients, lot number and valid expiration dates or positive identification of the pharmacist responsible for verification.
 - (e) ADD Formula, all combinations: The contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. The label has no warning instructions. An expiration date of 3 to 6 months was arbitrarily assigned. The name of ADD for the product falsely makes one conclude that it is for attention deficit disorder. The manufacturer is not noted on log or the log does not indicate the ingredients, lot number and valid expiration dates or positive identification of the pharmacist responsible for verification.
 - (f) Chicken Collagen Solution: The complete contents of active and inactive ingredients are not listed on the label. Contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. The label has invalid and incomplete warning instructions. An expiration date of 1 year was arbitrarily assigned.
 - (g) Creatine Monohydrate Powder: The contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. The label has no warning instructions. No expiration date was assigned.
 - (h) Creatine Syrup: The complete contents of active and inactive ingredients are not listed on the label. Contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. No warning instructions on label. An expiration date of 23 months was arbitrarily assigned.
 - (i) Scarbrough's Diaper Rash Ointment: The contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. The label has no warning instructions. An expiration date of 22 months arbitrarily assigned.
 - (j) Poison Ivy Gel: The contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. The label has no warning instructions. An expiration date of 2 years was arbitrarily assigned.
 - (k) Co-Enzyme Q-10 60mg capsules: The contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. The label has no warning instructions. An expiration date of 1 year was arbitrarily assigned.

- (l) Herbal Smoke Eliminator capsules: The label was without validation as a "Healthy and Energizing Herbal Synergism to Combat Smoking Habit and Effects". The complete contents of active and inactive ingredients are not listed on the label. The contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. The label has no warning instructions. An expiration date of 1 year was arbitrarily assigned. The manufacturer of the product is not listed on the log.

Such conduct is in violation of Section 3715.52(A)(1) of the Ohio Revised Code; and Section 331(b) of Title 21 of the United States Code.

- (4) Stanley Shaw Scarbrough did, as the Responsible Pharmacist, on or before April 22, 1997, sell, deliver, offer for sale, and/or hold for sale a new drug when not in accordance with Section 3715.65 of the Ohio Revised Code, to wit: the following drugs were not tested and found to be safe under the conditions recommended or suggested in its labeling, and prior to selling the drug or offering it for sale, Stanley Shaw Scarbrough failed to file an application for new drugs with the director of agriculture:
 - (a) Colloidal Silver Solution: The product is labeled without validation as a "Super Antibiotic" and as an "Antiseptic/Antibiotic". The contents of active and inactive ingredients are not listed on the label. The strength was not initially listed on the label, but currently is listed as 3-5ppm. 5ppm, or 15mcgm silver/tsp. without documentation or validation; therefore, there is no basis for suggested use or dose on label. There are no warning instructions on label. Initially no expiration date assigned, then given 1 year expiration date, and finally a 3 month expiration date. The expiration dates were assigned arbitrarily. The manufacturer is not noted on log.
 - (b) Met-Fuel capsules, all combinations: The complete contents of active and inactive ingredients are not listed on the label. The contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. An expiration date of 1 year was arbitrarily assigned. The manufacturer is not noted on log or the log does not indicate the ingredients, lot number and valid expiration dates or positive identification of the pharmacist responsible for verification.
 - (c) DHEA 5mg sublingual tablets: The complete contents of active and inactive ingredients are not listed on the label. The contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. The label has no warning instructions. An expiration date of 1 year arbitrarily assigned.
 - (d) DHEA 25mg and 50mg capsules: Contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. The label has no warning instructions. Expiration dates are arbitrarily assigned. The manufacturer is not noted on log or the log does not indicate the ingredients, lot number and valid expiration dates or positive identification of the pharmacist responsible for verification.

- (e) ADD Formula, all combinations: The contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. The label has no warning instructions. An expiration date of 3 to 6 months was arbitrarily assigned. The name of ADD for the product falsely makes one conclude that it is for attention deficit disorder. The manufacturer is not noted on log or the log does not indicate the ingredients, lot number and valid expiration dates or positive identification of the pharmacist responsible for verification.
- (f) Chicken Collagen Solution: The complete contents of active and inactive ingredients are not listed on the label. Contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. The label has invalid and incomplete warning instructions. An expiration date of 1 year was arbitrarily assigned.
- (g) Creatine Monohydrate Powder: The contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. The label has no warning instructions. No expiration date was assigned.
- (h) Creatine Syrup: The complete contents of active and inactive ingredients are not listed on the label. Contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. No warning instructions on label. An expiration date of 23 months was arbitrarily assigned.
- (i) Scarbrough's Diaper Rash Ointment: The contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. The label has no warning instructions. An expiration date of 22 months arbitrarily assigned.
- (j) Poison Ivy Gel: The contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. The label has no warning instructions. An expiration date of 2 years was arbitrarily assigned.
- (k) Co-Enzyme Q-10 60mg capsules: The contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. The label has no warning instructions. An expiration date of 1 year was arbitrarily assigned.
- (l) Herbal Smoke Eliminator capsules: The label was without validation as a "Healthy and Energizing Herbal Synergism to Combat Smoking Habit and Effects". The complete contents of active and inactive ingredients are not listed on the label. The contents listed are invalid due to lack of end product testing; therefore, there is no basis for suggested use or dose on label. The label has no warning instructions. An expiration date of 1 year was arbitrarily assigned. The manufacturer of the product is not listed on the log.

Such conduct is in violation of Section 3715.65(A)(2) of the Ohio Revised Code.

- (5) Stanley Shaw Scarbrough did, as the Responsible Pharmacist, on and prior to May 4, 1998, fail to meet the minimum standards for compounding parenteral or sterile product prescriptions, to wit: the pharmacy's clean room and/or laminar flow hood had never been certified; thus, all drugs compounded or manufactured in the

pharmacy's laminar flow hood were adulterated. Such conduct is in violation of Rule 4729-19-04 of the Ohio Administrative Code and Section 3715.63 of the Ohio Revised Code.

- (6) Stanley Shaw Scarbrough did, as the responsible pharmacist, on or about the following dates, fail to assign a new serial number to prescriptions that were not refillable, to wit: Stanley Shaw Scarbrough or someone under his supervision filled the following prescriptions and, upon refilling the prescriptions with newly compounded drugs which were not generically equivalent, failed to assign a new serial number to the compounded drug and vice versa:

- (a) The following prescriptions were changed by Stanley Shaw Scarbrough:

<u>Date of Change</u>	<u>Rx No.</u>	<u>Drug Initially Dispensed</u>	<u>Second Drug Dispensed</u>	<u>Qty.</u>
07/02/96	472590	Zoloft 50mg	Compounded Sertaline 50mg	30
07/05/96	473954	Albuterol UD	Compounded Albuterol Inhaler	360
07/08/96	464570	Proventil UD	Compounded Albuterol Inhaler	360
07/26/97	476542	Albuterol	Compounded Albuterol Inhaler	360

- (b) The following prescriptions were changed by Sue G. Gratz:

<u>Date of Change</u>	<u>Rx No.</u>	<u>Drug Initially Dispensed</u>	<u>Second Drug Dispensed</u>	<u>Qty.</u>
07/02/96	463904	Albuterol UD	Compounded Albuterol Inhaler	360
09/25/96	470127	Albuterol UD	Compounded Albuterol Inhaler	360
10/21/96	476809	Proventil UD	Compounded Albuterol Inhaler	360
06/27/97	485351	Compounded Albuterol Inhaler	Albuterol UD	180

Such conduct is in violation of Rules 4729-5-19, 4729-5-27, and 4729-5-30 of the Ohio Administrative Code, and Section 4729.38 of the Ohio Revised Code.

- (7) Stanley Shaw Scarbrough did, as the Responsible Pharmacist, from on or about June 21, 1996, through June 5, 1997, sell, deliver, offer for sale, and/or hold for sale a new drug when not in accordance with Section 3715.65 of the Ohio Revised Code, to wit: on 213 separate occasions, Stanley Shaw Scarbrough or a pharmacist under his supervision sold one of the following new drugs which were not tested and found to be safe under the conditions recommended or suggested in its labeling, and prior to selling the drug or offering it for sale, Stanley Shaw Scarbrough and/or a pharmacist under his supervision failed to file an application for new drugs with the director of agriculture:

- (a) Met-Fuel-Caffeine Free: Contents, in part--Ephedrine 1.0gm, L-Carnitine 5.0gm, Chromium Picolinate 0.010gm, and Ginger Root 1.0gm per 100 capsules.
- (b) Met-Fuel: Contents, in part--Ephedrine 1.0gm, Caffeine 10gm, L-Carnitine 5.0gm, Chromium Picolinate 0.010gms, and Ginger Root 1.0gm per 100 capsules.
- (c) Extra Strength Met-Fuel: Contents, in part--Ephedrine 1.0gm, Caffeine 10gm, L-Carnitine 5.0gm, Chromium Picolinate 0.010gm, Ginger Root 1.0gm, and Aspirin 4.05gm per 100 capsules.

Such conduct is in violation of Section 3715.65(A)(2) of the Ohio Revised Code.

- (8) Stanley Shaw Scarbrough did, as the Responsible Pharmacist, on or about July 11, 1997, fail to perform prospective drug utilization review and patient counseling, to wit: Stanley Shaw Scarbrough and/or a pharmacist under his supervision, when dispensing Extra Strength Met-Fuel to a patient, failed to review the log book for over-utilization, incorrect drug dosage and duration of drug treatment, and misuse; and Stanley Shaw Scarbrough and/or someone under his supervision failed to offer, and maintain records of, patient counseling. Such conduct is in violation of Rules 4729-5-20 and 4729-5-22 of the Ohio Administrative Code.
- (9) Stanley Shaw Scarbrough did, as the Responsible Pharmacist, on or about July 11, 1997, sell a schedule V controlled substance product without a prescription, failing to require patient identification and failing to maintain a record of transaction for the sale, to wit: Stanley Shaw Scarbrough and/or a pharmacist under his supervision, sold Extra Strength Met-Fuel to a patient and failed to require identification to check for the patient's age, name, address and signature, and failed to maintain a record of the transaction. Such conduct is in violation of Rules 4729-11-09 of the Ohio Administrative Code.
- (10) Stanley Shaw Scarbrough did, as the Responsible Pharmacist, from on or about June 21, 1996, through July 5, 1997, sell a schedule V controlled substance without a prescription in an amount exceeding one hundred times the bulk amount when the conduct was not in accordance with Chapters 3719., 4729., and 4731. of the Ohio Revised Code, to wit: throughout this time period Stanley Shaw Scarbrough and/or a pharmacist under his supervision made 161 individual sales of Met Fuel for a total of 19,500 unit doses; and, on each occasion, Stanley Shaw Scarbrough and/or a pharmacist under his supervision dispensed to each patient over 100 unit doses in a 30-day time period without a legitimate medical purpose. Such conduct is not in accordance with Rule 4729-11-09 of the Ohio Administrative Code and, therefore, is in violation of Section 2925.03(A) of the Ohio Revised Code.
- (11) Stanley Shaw Scarbrough did, as the Responsible Pharmacist, from on or about October 26, 1996, through June 25, 1997, sell a schedule V controlled substance without a prescription in an amount exceeding five times the bulk amount, but in an amount less than fifty times that amount when the conduct was not in accordance with Chapters 3719., 4729., and 4731. of the Ohio Revised Code, to wit: throughout this time period Stanley Shaw Scarbrough and/or someone under his supervision made 40 individual sales of Extra Strength Met Fuel for a total of 4,800 unit doses; and, on each occasion, Stanley Shaw Scarbrough or someone under his control dispensed to each patient over 100 unit doses in a 30-day time period without a legitimate medical purpose. Such conduct is not in accordance with Rule 4729-11-09 of the Ohio Administrative Code and, therefore, is in violation of Section 2925.03(A) of the Ohio Revised Code.
- (12) Stanley Shaw Scarbrough did, as the Responsible Pharmacist, on or about April 11, 1997, sell a schedule V controlled substance without a prescription in an amount exceeding the bulk amount, but in an amount less than five times that amount when the conduct was not in accordance with Chapters 3719., 4729., and 4731. of

the Ohio Revised Code, to wit: Stanley Shaw Scarbrough and/or someone under his supervision sold 120 unit doses of Met Fuel w/ASA, which allowed the patient to obtain over 100 unit doses in a 30-day time period and not for a legitimate medical purpose. Such conduct is not in accordance with Rule 4729-11-09 of the Ohio Administrative Code and, therefore, is in violation of Section 2925.03(A) of the Ohio Revised Code.

- (13) Stanley Shaw Scarbrough did, as the Responsible Pharmacist, prior to May 4, 1998, permit technicians to compound prescriptions, to wit: Stanley Shaw Scarbrough and/or a pharmacist under his supervision allowed technicians to compound drugs without the supervision of a pharmacist, placing them in a position that requires professional judgment. The products were never checked for error, weight and content uniformity, drug absorption and/or sterility. Further, pharmacists failed to perform the final check of the finished product. The following list is an example of the drugs compounded in such a manner:
- (a) Albuterol Inhalant 0.83mg/ml: PCCA Compound Number 0021, with violation dates of 6-5-96, 6-13-96, 7-8-96, 7-26-96, 8-9-96, 8-12-96, 8-30-96, 10-24-96, 11-12-96, 12-6-96, 12-15-96, 12-26-96, 1-20-97, 2-13-97, 4-2-97, 4-11-97, 5-13-97, and 6-26-97 (two pages): The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials.
 - (b) Morphine Sulfate SR 15mg Caps: Scarbrough Pharmacy Compound Number 406, with violation date of 2-19-98: The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials.
 - (c) Phentermine SR 25mg Caps: Scarbrough Pharmacy Compound Number 192, with violation date of 7-2-97: The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials.
 - (d) Phentermine 25mg SR Capsules: Scarbrough Pharmacy Compound Number 192, with violation dates of 7-24-96, 8-7-96, 8-20-96, 9-24-96, 10-22-96: The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials. Additional violation dates of 4-7-97, 5-7-97, and 5-28-97: The technician signed the pharmacist's initials.
 - (e) Theophylline Slow Release Caps 300mg with CaCO₃ as Filler: Scarbrough Pharmacy Compound Number 582, PCCA Compound Number 3183, with violation date of 4-28-97: The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials.
 - (f) Phentermine 15mg Caps: no Compound Number reference, with violation dates of 2-20-97 and 3-24-97: The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials.
 - (g) Estriol/Estrone/Estradiol (Triest 2.5mg): Scarbrough Pharmacy Compound Number 374, PCCA Compound Number 2813, with violation dates of 9-20-96, 10-11-96, 11-25-96, 12-20-96, 1-14-97, 3-7-97, 3-31-97, 4-16-97, 5-29-97, 7-1-97, 7-25-97, 8-11-97, 8-22-97, 10-2-97, 10-21-97, 3-16-98, 4-6-98, and 4-29-98 (two pages): The log does not indicate the drug lot numbers of

- the ingredients used, and the technician signed the pharmacist's initials. Additional violation dates of 12-5-97, 12-16-97, 1-12-98, 1-23-98, and 2-13-98: The technician signed the pharmacist's initials.
- (h) Morphine Sulfate Sustained Release Caps 500mg: Scarbrough Pharmacy Compound Number 203, PCCA Compound Number 694, with violation dates of 6-7-96, 7-10-96, and 7-16-96: The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials.
- (i) Testosterone 1mg/ml in Vanicream: Compound Number 923, with violation dates of 2-24-98, 2-27-98, 3-2-98, 3-2-98, 3-2-98, 3-3-98, 3-3-98, 3-6-98, 3-26-98, 3-27-98, 3-30-98, 3-31-98, 4-2-98, 4-23-98, 4-27-98, 4-28-98, and 5-4-98 (two pages): The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials. Additional violation dates of 1-19-98, 2-6-98, and 2-24-98: The technician signed the pharmacist's initials.
- (j) Fenfluramine 20mg Capsules: Scarbrough Pharmacy Compound Number 519, with violation dates of 2-19-97 and 4-1-97: The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials.
- (k) Ripped Fuel (Met Fuel) (Manufactured): Scarbrough Pharmacy Compound Number 219, with violation dates of 6-17-96, 6-17-96, 7-1-96, 7-2-96, 7-15-96, 7-16-96, 7-18-96, 7-24-96, 7-25-96, 8-6-96, 8-19-96, 9-6-96, 9-25-96, 10-4-96, 10-9-96, 10-24-96, 11-11-96, and 11-13-96 (two pages): The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials.
- (l) Ex Strength Met-Fuel (Manufactured): Scarbrough Pharmacy Compound Number 394, with violation dates of 10-11-96, 11-13-96, and 12-20-96: The log does not indicate the drug lot numbers of the ingredients used, and there is no positive identification of the pharmacists.
- (m) Ex Strength Met-Fuel (Manufactured): Scarbrough Pharmacy Compound Number 394, with violation dates of 1-22-97, 2-7-97, 2-18-97, 2-24-97, 3-20-97, 4-2-97, 4-15-97, 5-7-97, 5-24-97, 6-4-97, 6-20-97, and 6-24-97: The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials.
- (n) Lidocaine 2.5%/Prilocaine 2.5% in Emollient Cream Base: Scarbrough Pharmacy Compound Number 412, with violation date of 11-1-96: The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials.
- (o) Pregnenolone 10mg Capsules: Scarbrough Pharmacy Compound Number SP378, with violation dates of 9-26-96 and 9-27-96: The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials..
- (p) Progesterone 100mg Caps: Scarbrough Pharmacy Compound Number 119, with violation date of 7-17-97: The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials.

- (q) Progesterone Caps 20mg: Scarbrough Pharmacy Compound Number 322, with violation date of 8-15-96: The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials.
- (r) Progesterone 200mg Caps: Scarbrough Pharmacy Compound Number 506, with violation dates of 2-21-97 and 4-1-97: The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials.
- (s) Promethazine 25mg Capsule: Scarbrough Pharmacy Compound Number 417, with violation date of 11-8-96: The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials.
- (t) Salicylic Acid 10%/Formalin 40%/in Alcohol: Scarbrough Pharmacy Compound Number 26, with violation dates of 6-26-96 and 3-31-97: The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials.
- (u) Simvastin 10mg Capsules: Scarbrough Pharmacy Compound Number SP517, with violation date of 3-4-97: The log does not indicate the drug lot numbers of the ingredients used.
- (v) Triest Plus Pro Caps: Scarbrough Pharmacy Compound Number 499, PCCA Compound Number 2813, with violation date of 2-14-97. The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials.
- (w) Triest Plus Pro Test Caps: Scarbrough Pharmacy Compound Number 498, with violation dates of 2-14-97, 3-17-97, and 4-1-97: The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials.
- (x) ADD Formula (Manufactured): Scarbrough Pharmacy Compound Number 438, with violation dates of 11-29-96, 12-3-96, and 1-15-97: The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials.
- (y) Colloidal Silver (Manufactured): no Compound Number reference, with violation dates of 10-7-96, 11-16-96, 12-23-96, 12-24-96, 12-26-96, and 12-31-96: The log does not indicate the drug lot numbers of the ingredients used, and the technician signed the pharmacist's initials.
- (z) Colloidal Silver (Manufactured): no Compound Number reference, with violation dates of 2-5-97 and 3-24-97: The log does not indicate the drug lot numbers of the ingredients used, Scarbrough Pharmacy's internal lot number, and there is no positive identification of the pharmacists or technicians. Additional violation date of 1-13-97: The log does not indicate the drug lot numbers of the ingredients used, Scarbrough Pharmacy's internal lot number, and there is no positive identification of the pharmacist.

Such conduct is in violation of Rules 4729-5-25 and 4729-9-21(C) of the Ohio Administrative Code and Section 4729.28 of the Ohio Revised Code.

- (14) Stanley Shaw Scarbrough did, as the Responsible Pharmacist, on or about April 22, 1997, and again on or about May 4, 1998, fail to maintain minimum standards for a pharmacy, to wit: the pharmacy was not equipped with a library containing current literature and references for compounding drugs. Such conduct violates Rule 4729-9-02 of the Ohio Administrative Code.
- (15) Stanley Shaw Scarbrough did, on or about March 30, 1999, and again on May 23, 2000, directly or indirectly represent a counterfeit controlled substance as a controlled substance by describing its effects as the physical or psychological effects associated with use of a controlled substance, to wit: Stanley Shaw Scarbrough advertised the sale of testosterone using false and misleading information through an Internet site, VitaminUSA.com. Such conduct is in violation of Section 2925.37(E) of the Ohio Revised Code.
- (16) Stanley Shaw Scarbrough did, from on or about December 26, 1996, through April 22, 1997, sell a misbranded drug, to wit: Stanley Shaw Scarbrough compounded drugs which failed content uniformity, which contained incorrect amounts of ingredients as suggested in the labeling, and/or which contained fillers that had not been approved by the Food and Drug Administration, to wit: Stanley Shaw Scarbrough compounded Enalapril 5mg capsules dated December 26, 1996, which failed content uniformity. Such conduct is in violation of Section 3715.52 of the Ohio Revised Code.
- (17) Stanley Shaw Scarbrough did, on or before September 16, 1998, hold for sale a misbranded drug, to wit: Stanley Shaw Scarbrough manufactured drugs which failed content uniformity, which contained incorrect amounts of ingredients as suggested in the labeling, and/or which contained fillers that had not been approved by the Food and Drug Administration, to wit: Stanley Shaw Scarbrough manufactured Colloidal Silver Solution 3 to 5 ppm which failed content uniformity. Such conduct is in violation of Section 3715.52 of the Ohio Revised Code.
- (18) Stanley Shaw Scarbrough did, on or before May 4, 1998, hold for distribution manufactured sample drugs and furnished manufactured sample drugs to physicians as a marketing tool, to wit: Stanley Shaw Scarbrough manufactured and distributed Ketoprofen 2% Gel labeled "Sample-Not For Sale". Such conduct is in violation of Section 3719.81 of the Ohio Revised Code.
- (19) Stanley Shaw Scarbrough did, as the Responsible Pharmacist, on or before May 4, 1998, fail to keep complete and accurate records in Scarbroughs Medical Arts Pharmacy's automated data system, to wit: the pharmacy's computer system, NDC Data Stat, does not allow a log to be created that documents necessary changes made to a prescription. Such conduct is in violation of Rule 4729-5-27 of the Ohio Administrative Code and Section 4729.38 of the Ohio Revised Code.
- (20) Stanley Shaw Scarbrough did, as the Responsible Pharmacist, on or about April 22, 1997, manufacture, sell, hold for sale, or deliver a drug that was adulterated or misbranded, to wit: an agent of the Board witnessed a technician, refill a one pint bottle of Promethazine with Codeine Cough Syrup having NDC 60432606-16 with another brand of a one gallon bottle of Promethazine with Codeine Cough Syrup

having NDC 0472-1627-28. The adulterated or misbranded Promethazine with Codeine Cough Syrup was then dispensed by Stanley Shaw Scarbrough or a pharmacist under his supervision with a label bearing a completely different NDC of 00182-1712-4. Such conduct is in violation of Section 3715.52(A)(1) of the Ohio Revised Code; Section 331(b) of Title 21 of the United States Code, and Section 201.18 of Title 21 of the Code of Federal Regulations.

CONCLUSIONS OF LAW

- (1) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (2) through (18) and (20) of the Findings of Fact constitute being guilty of dishonesty and unprofessional conduct in the practice of pharmacy as provided in Division (A)(2) of Section 4729.16 of the Ohio Revised Code.
- (2) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (2) through (7), (10) through (13), and (15) through (20) of the Findings of Fact constitute being guilty of willfully violating, conspiring to violate, attempting to violate, or aiding and abetting the violation of provisions of Sections 3715.52 to 3715.72 or Chapter 2925., 3719., or 4729. of the Revised Code as provided in Division (A)(5) of Section 4729.16 of the Ohio Revised Code.
- (3) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraph (13) of the Findings of Fact constitutes being guilty of permitting anyone other than a pharmacist or pharmacy intern to practice pharmacy as provided in Division (A)(6) of Section 4729.16 of the Ohio Revised Code.

ACTION OF THE BOARD

Pursuant to Section 4729.16 of the Ohio Revised Code, the State Board of Pharmacy takes the following actions in the matter of Stanley Shaw Scarbrough:

- (A) On the basis of the Findings of Fact and paragraphs (1) and (3) of the Conclusions of Law set forth above, the State Board of Pharmacy hereby suspends for five years the pharmacist identification card, No. 03-2-12847, held by Stanley Shaw Scarbrough effective as of the date of the mailing of this Order.
- (B) On the basis of the Findings of Fact and paragraph (2) of the Conclusions of Law set forth above, the State Board of Pharmacy hereby imposes a monetary penalty of five thousand dollars (\$5,000.00) on Stanley Shaw Scarbrough effective as of the date of the mailing of this Order. The monetary penalty is due and owing within thirty days of the mailing of this Order. The remittance should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed form to the State Board of Pharmacy, 77 South High Street, Room 1702, Columbus, Ohio 43215-6126.
- (C) Further, the Board will suspend the suspension imposed in paragraph (A) above and place Stanley Shaw Scarbrough on probation for five years provided that he successfully completes six hours of continuing pharmacy education in Board-approved Jurisprudence and submits the original certificates of completion to the Board

within six months from the effective date of this Order. The terms of probation are as follows:

- (1) The State Board of Pharmacy hereby declares that Stanley Shaw Scarbrough's pharmacist identification card is not in good standing and thereby denies the privilege of being a preceptor and training pharmacy interns pursuant to paragraph (D)(1) of Rule 4729-3-01 of the Ohio Administrative Code.
- (2) Stanley Shaw Scarbrough must not violate the drug laws of the state of Ohio, any other state, or the federal government.
- (3) Stanley Shaw Scarbrough must abide by the rules of the State Board of Pharmacy.
- (4) Stanley Shaw Scarbrough must comply with the terms of this Order.

Stanley Shaw Scarbrough is hereby advised that the Board may at any time revoke probation for cause, modify the conditions of probation, and reduce or extend the period of probation. At any time during this period of probation, the Board may revoke probation for a violation occurring during the probation period.

THIS ORDER WAS APPROVED BY A VOTE OF THE STATE BOARD OF PHARMACY (Aye-4/Nay-2).

MOTION CARRIED.

SO ORDERED.

ORDER EFFECTIVE JANUARY 12, 2001