



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
PO Box 47879 • Olympia, Washington 98504-7879

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ATTORNEY GENERAL'S OFFICE
AGRICULTURE & HEALTH DIVISION

April 23, 2007

Robert N. Meals
Attorney at Law
PO Box 659
Langley, WA 98260

RE: Biomed Comm Inc.
Docket No. 06-03-A-1021FX

Dear Mr. Meals:

Enclosed please find Declaration of Service by Mail and Findings of Fact, Conclusions of Law and Final Order dated April 19, 2007.

Any questions regarding the terms and conditions of the Order should be directed to Janelle Teachman, Program Manager at (360) 236-4876.

Sincerely,

Michelle Singer, Hearing Scheduler
Adjudicative Service Unit
PO Box 47879
Olympia, WA 98504-7879

cc: Biomed Comm Inc., Respondent
Dorothy Jaffe, AAG
Alice Blado, AAG
Janelle Teachman, Program Manager
Kristi Weeks, Legal Unit
Compliance Officer

Enclosure



**STATE OF WASHINGTON
DEPARTMENT OF HEALTH
ADJUDICATIVE SERVICE UNIT**

In the Matter of the Application to Operate as)
a Drug Manufacturer of:) Docket No. 06-03-A-1021FX
)
BIOMED COMM, INC.) DECLARATION OF SERVICE
Candidate No. CA00058412) BY MAIL
)
Respondent.)

I declare under penalty of perjury, under the laws of the state of Washington, that the following is true and correct:

On April 23, 2007, I served a true and correct copy of the Findings of Fact, Conclusions of Law and Final Order, signed by the Panel Chair on April 20, 2007, by placing same in the U.S. mail by 5:00 p.m., postage prepaid, on the following parties to this case:

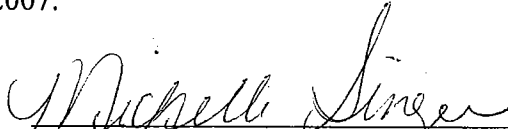
Robert N. Meals
Attorney at Law
PO Box 659
Langley, WA 98260

Biomed Comm. Inc.
4616 25th Ave NE #273
Seattle, WA 98105

Dorothy Jaffe, AAG
Office of the Attorney General
PO Box 40109
Olympia, WA 98504-0109

Alice Blado, AAG
Office of the Attorney General
PO Box 40109
Olympia, WA 98504-0109

DATED: This 23rd day of April, 2007.


Michelle Singer, Adjudicative Service Unit
Hearing Scheduler

cc: Janelle Teachman, Program Manager
Kristi Weeks, Legal Unit
Compliance Officer

DECLARATION OF SERVICE BY MAIL

**STATE OF WASHINGTON
DEPARTMENT OF HEALTH
BOARD OF PHARMACY**

In the Matter of the Application to Operate)	
as a Drug Manufacturer of:)	Docket No. 06-03-A-1021FX
)	
BIOMED COMM, INC.,)	FINDINGS OF FACT,
Candidate No. CA00058412,)	CONCLUSIONS OF LAW
)	AND FINAL ORDER
Respondent.)	
_____)	

APPEARANCES:

Respondent, Biomed Comm, Inc., by
Law Offices of Robert N. Meals, P.L.L.C., per
Robert N. Meals, Attorney at Law

Department of Health Pharmacy Program, by
Office of the Attorney General, per
Dorothy H. Jaffe and Alice M. Blado, Assistant Attorneys General

PANEL MEMBERS: Rebecca Hille, Public Member, Chair
 Assaad Awan, R.Ph.¹
 Don Williams, R.Ph.
 George Roe, R.Ph.
 C. Leon Alzola, R.Ph.

PRESIDING OFFICER: John F. Kuntz, Health Law Judge

The Board of Pharmacy (the Board) convened a hearing on February 6-8, 2007. The Department of Health issued a Statement of Charges with Intent to Deny the Respondent's application, alleging that the Respondent had violated the Uniform Disciplinary Act, chapter 18.130 RCW. The Board finds unprofessional conduct and denies the Respondent's application.

¹ Mr. Awan was the Chair of the Board of Pharmacy at the time of the hearing, but his Board appointment expired prior to the issuance of this Final Order.

ISSUES

A. Whether Biomed Comm, Inc (Biomed), manufactured drug products in the state of Washington?

B. Whether Barbara Brewitt, Ph.D., a corporate officer of Biomed, presented herself as a medical doctor to Ballard Plaza Pharmacy in order to obtain Norditropin, a legend drug used in Biomed's manufacturing process?

C. Whether Biomed's conduct violated subsections (1), (2), (7) (incorporating RCW 18.64.045 and WAC 246-895-020) and (13) of RCW 18.130.180?

SUMMARY OF THE PROCEEDING

The Department presented the testimony of Debra A. Smith; Roberta Richards; Terry Greiling, M.D., Ph.D. (candidate); John B. Syverud; Jeremy Adler; Scott Byhre; Marie Brown; Kelly McLean; Beth McDonald, M.D.; and Stan Jeppersen.

Barbara Brewitt, Ph.D., the sole corporate officer operating Biomed during the relevant time period, testified on behalf of Biomed.

The following exhibits were admitted at hearing:

Department Exhibits

Exhibit P-1: Copy of Wholesaler/Manufacturing Application on behalf of the Respondent dated August 29, 2005.

Exhibit P-2: Copy of October 14, 2005 Initial Inspection Report prepared by Kelly McLean.

Exhibit P-3: Copy of October 24, 2005 letter from Dr. Barbara Brewitt to the Board of Pharmacy.

Exhibit P-4: Copy of October 26, 2005 letter from Dr. Barbara Brewitt to the Board of Pharmacy.

FINDINGS OF FACT,
CONCLUSIONS OF LAW
AND FINAL ORDER

Page 2 of 25

Docket No. 06-03-A-1021FX

- Exhibit P-5: Copy of October 26, 2005 letter from the Board of Pharmacy to Dr. Barbara Brewitt.
- Exhibit P-6: Copy of Jeremy Adler's employment agreement with Biomed.
- Exhibit P-7: Copies of e-mail correspondence between various Biomed staff, including Dr. Barbara Brewitt.
- Exhibit P-8: Copies of Certificates of Dilution Preparation dated November 22, 2005.
- Exhibit P-9: Copies of Certificate of Source Content dated November 9, 2005, with attached e-mail correspondence.
- Exhibit P-10: Copies of September 28, 2005 letter from Marie Brown to Jeremy Adler, and September 28, 2005 e-mail correspondence between Marie Brown, Scott Byhre and Jeremy Adler.
- Exhibit P-11: Copies of inventory, repackaging results, and sales summary.
- Exhibit P-12: Copy of December 15, 2005 re-inspection report with attachments, prepared by Kelly McLean.
- Exhibit P-13: Copies of handwritten productions notes.
- Exhibit P-14: Copies of two Work Instructions for Private Label Customers.
- Exhibit P-15: Copies of forty (40) pages of one (1) Log Book containing compounding instructions.
- Exhibit P-16: Copy of Biomed's products for sale on www.walgreen.com.
- Exhibit P-17: Copy of Puget Sound Business Journal Article entitled "Local Firms bite into new chocolate market".
- Exhibit P-18: Copy of Puget Sound Business Journal Article entitled "Brewitt forges ahead with a new kind of medicine".
- Exhibit P-19: Copy of Biomed's reference guide listing which products are effective in treating fifty-six (56) diseases and conditions.
- Exhibit P-20: Copy of "Interview with Barbara Brewitt: the fundamental role of cell signaling in healing and relevance to autism".
- Exhibit P-21: Copies of documents from www.biomedcomm.com.

- Exhibit P-22: Copies of Biomed's advertising material.
- Exhibit P-23: Copies of Biomed's product packaging material.
- Exhibit P-24: Copies of Biomed's literature claiming its effectiveness in treating HIV/AIDS.
- Exhibit P-25: Copies of Biomed's "Basic Protocol Guideline for Autism".
- Exhibit P-26: Copy of Biomed's article entitled "The Scientific Logic of Using Homeopathic Recombinant FGF-2 for Autism Augmented with Homeopathic IFG-1, PDGFbb, and TGRb Growth Factors, A Brief Overview".
- Exhibit P-27: Copies of photographs taken of product shipment from Biomed to Costco.
- Exhibit P-28: Copies of FDA Compliance Policy Guide 7132.5, Section 400.400, "Conditions Under Which Homeopathic Drugs May Be Marketed".
- Exhibit P-29: Copies of photographs of Biomed's Woodinville Site.
- Exhibit P-30: Copies of prescription records from Ballard Plaza Pharmacy.
- Exhibit P-31: Copy of Elizabeth McDonald's curriculum vitae.
- Exhibit P-32: Copies of Dolisos America Production Control Sheet, two (2) pages.
- Exhibit P-33: Physical Evidence-one (1) plastic bag containing five (5) tablets, three (3) imprinted as CSE 20 and two (2) imprinted as HhGH.
- Exhibit P-34: Physical Evidence-one (1) empty bottle of #90 count Naturally hGH.
- Exhibit P-35: Physical Evidence-two (2) 60 ml bottles of CSE 7.
- Exhibit P-36: Physical Evidence-one (1) Cocoa Bliss chocolate bear.
- Exhibit P-37: Physical Evidence-two (2) bottles of EASE chewable tablets and two (2) #90 count bottles of IGF-1 chewable tablets.
- Exhibit P-38: Physical Evidence-original packaging box of Athletic Edge product.
- Exhibit P-39: Physical Evidence-two (2) 60 ml bottles.

- Exhibit P-40: Physical Evidence-one (1) box of the Respondent's products, including: one (1) Athletic Edge #180-count bottle with seal; one (1) Naturally hGH #90 count bottle in box; one (1) unlabeled bottle; and one (1) Cocoa Bliss chocolate chewable tablets with no lot number.
- Exhibit P-41: Letter dated October 10, 2000, from Dr. Barbara Brewitt to the Homeopathic Pharmacopoeia Convention of the United States regarding the proving of Insulin-like growth factor-1 (IGF- 1) and recombinant human growth hormone (rhGH).
- Exhibit P-42: Letter dated March 24, 2001, from Dr. Barbara Brewitt to Homeopathic Pharmacopoeia Convention of the United States stating monograph previously submitted by Dr. Brewitt was not approved.
- Exhibit P-43: Letter dated April 18, 2001, from Dr. Barbara Brewitt to Homeopathic Pharmacopoeia Convention of the United States regarding her monograph submittal.
- Exhibit P-44: Letter dated June 4, 2001, from Homeopathic Pharmacopoeia Convention of the United States to Dr. Barbara Brewitt requesting clarification of her April 18, 2001 letter.
- Exhibits P-45 through P-50: Spreadsheets prepared from original sales invoices provided by the Respondent in response to the Program's request for production of documents. The copies of the sales invoices were made available at the hearing.
- Exhibit P-45: Spreadsheet entitled "Biomed Yearly Totals Summary" showing the total dollar value of documented sales per year and the number of days a sale occurred each year.
- Exhibit P-46: Spreadsheet entitled "Biomed Daily Totals Summary" showing the dollar value of documented sales per day and identifying each day a sale occurred.
- Exhibit P-47: Spreadsheet entitled "Biomed Daily Sales Total – 2003" showing the details of each documented sales transaction for 2003.
- Exhibit P-48: Spreadsheet entitled "Biomed Daily Sales Total – 2004" showing the details of each documented sales transaction for 2004.
- Exhibit P-49: Spreadsheet entitled "Biomed Daily Sales Total – 2005" showing the details of each documented sales transaction for 2005.

Exhibit P-50: Spreadsheet entitled "Biomed Daily Sales Total – 2006" showing the details of each documented sales transaction for 2006.

Respondent Exhibits

Exhibit R-1: Curriculum vitae-Barbara Brewitt, M.Div., Ph.D.

Exhibit R-2: Business cards – Barbara Brewitt, M.Div., Ph.D., used between 1996 and 2006.

Exhibit R-3: Certificate of Incorporation – Biomed Comm, Inc., dated May 1, 1996.

Exhibit R-4: Initial Annual Report Biomed Comm, Inc., dated June 1, 1996.

Exhibit R-5: License Renewal & Annual Report, Biomed Comm, Inc., dated May 30, 1997.

Exhibit R-6: Biomed Comm, Inc, Master Business Licenses, 1998-2006.

Exhibit R-7: Document entitled "About Biomed-Company Profile".

Exhibit R-8: Amino Acid Sequence, illustrating biological structure of human growth hormone and insulin-like growth factor.

Exhibit R-9: Interview with Dr. Barbara Brewitt: the fundamental role of cell signaling in healing and relevance to autism (2005).

Exhibit R-10: Letter of Correction from Mr. Goldman, Editor-in-Chief, Medical Veritas-July 7, 2006 (typo 2007).

Exhibit R-25: Pharmaceutical Manufacturer Inspection Report dated November 25, 2005.

Exhibit R-26: Final submission and response to inspection issues-February 2006.

Exhibit R-27: Color pictures of Biomed Comm, Inc., Woodinville, Washington facility.

Exhibit R-66: December 17, 1998 Letter from Edward Miracco, DHHS, to Dr. Barbara Brewitt.

Exhibit R-67: Biomed Comm, Inc., Purchase Order No. 219, dated August 17, 2004.

Exhibit R-68: Excerpts from HPRS (1990 through 1996): Cholinum; DNA; Embryo; Fomalinium; Hippozaeinum; Histaminum; Hyupothalmus; Oophorium;

Opium; Orchitinum; Ovi Gallinae Pellcula; Pancreatinum; Proteus;
Psorinum; Pyrogenium; Throidinum; and Torula Cerevsia.

Based on the evidence presented, the Board makes the following findings:

I. FINDINGS OF FACT

1.1 Dr. Barbara Brewitt obtained her Ph.D. in biological structures from the University of Washington School of Medicine in 1989.² While she obtained her Ph.D. degree in biological structures (medical science) from the School of Medicine, Dr. Brewitt's Ph.D. degree does not entitle her to practice medicine and surgery under chapter 18.71 RCW.

1.2 One of Dr. Brewitt's goals as a medical scientist was to understand the disease process. Dr. Brewitt eventually decided to combine this understanding of the disease process with her interest in homeopathy. This goal to combine areas of interest eventually led Dr. Brewitt to enter into business with C. Michael Varner to create homeopathic products to enable people to improve their general health. The business they created was Biomed Comm. Dr. Brewitt and Mr. Varner decided to incorporate the business.

1.3 Biomed obtained a Certificate of Incorporation from the Secretary of State, State of Washington, on May 1, 1996. Biomed described the nature of its business as the development and marketing of biological cell communication products.

² Dr. Brewitt holds a Bachelor of Arts degree and Bachelor of Science in addition to her Ph.D. degree. Dr. Brewitt was awarded a Masters of Divinity degree (Ministry to Special Groups) from the Illiff School of Theology, Denver, Colorado in 1975. See Exhibit R-1.

1.4 In Biomed's initial Annual Report signed June 1, 1996, Dr. Brewitt was identified as the Chairman of the Board and Treasurer, and C. Michael Varner was identified as the President, Secretary, and Director of the corporation. Exhibit R-4. C. Michael Varner did not participate in the manufacture of drugs at Biomed at any point after 1996. In the Profit Corporation License Renewal & Annual Report form signed May 30, 1997, Dr. Brewitt was identified as the only individual to hold an office or act as a member of the board of directors. Exhibit R-5. Biomed and Dr. Brewitt is the same person.³ During the period 1998 through 2006, Biomed applied for, and was granted, a Master Business License to conduct business in the state of Washington.

1.5 In its company profile, Biomed's stated purpose was to develop and patent a new category of over-the-counter medicines called Cell Signal Enhancers. The purpose of the Cell Signal Enhancer products was to give people control over their health, and to optimize both their physiological and psychological health. Biomed combined advanced molecular biotechnology, homeopathic principles and the bioelectric principles of cellular biology to enhance the physical and mental balance in a human body without the toxic side effects and high costs of pharmacological products. See Exhibit R-7, page 18.⁴

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³ The Administrative Procedure Act, chapter 34.05 RCW, defines "person" to include corporations. See RCW 34.05.010(14).

⁴ The Respondent's exhibit package is paginated sequentially from beginning to end. The pages of each exhibit do not contain an internal numbering system.

Manufacturing of Drug Products – 1996 through 2005.

A. Use of Non-Prescription Grade Human Growth Hormone in the Production of Drug Products.

1.6 Biomed sold drug products that were in both liquid and tablet form. See Exhibit P-21, pages 12 through 18. The liquid and tablet products contained homeopathic growth hormones and insulin-like growth factors to be received by specific cell receptors on the cell's surface. The goal was to enhance nutrient uptake, protein synthesis, regulate cell cycle activities, and RNA/DNA repair. See Exhibit 21, page 7. In addition to the liquid and tablet products, Biomed sold chocolate products. See Exhibit P-21, page 18. Biomed sold its drug product to retail outlets such as Costco and General Nutrition Centers (GNC). Exhibit P-21, pages 5-18. Biomed also sold its products to health care providers and members of the public directly. Biomed took product orders over the internet and over the phone. As a part of its drug manufacturing process, Biomed contracted with an out-of-state business called Dolisos American (Dolisos), a Nevada corporation, from 1995/1996 through 2005. Dolisos manufactured homeopathic products.⁵

1.7 Dolisos had a private label customer relationship with Biomed to manufacture drug products to Biomed's specifications. Biomed and at least one other company (R & D Systems) would supply Dolisos with the raw materials (including human growth hormone) and work instructions for the creation of Biomed's drug

⁵ Homeopathy. School of medicine, founded by Dr. S.S.F. Hahnemann (1755-1843) in 1796 in Philadelphia, based on the theory that large doses of drugs that produced symptoms of a disease in healthy people will cure the same symptoms when administered in small amounts. This is loosely based on the theory that "like cures like". Taber's Cyclopedic Medical Dictionary, Edition 14 (1981), page 667.

product. See Exhibit P-12, pages 7-14 through 7-21. Dolisos would either dilute the human growth hormone received from R & D Systems or receive a diluted form of the human growth hormone already diluted by Biomed, which it would then spray on, or impregnate into, lactose tablets using Biomed's specifications. See Exhibit P-14. Dolisos would then label the finished product and ship it to the Respondent for sale to retail outlets. Dolisos would also ship product directly to retail outlets identified by Biomed (such as Costco and General Nutrition Center or GNC).

1.8 R & D Systems produced the recombinant human growth hormone material which was characterized as research grade. R & D Systems does not produce the research grade human growth hormone using good manufacturing practices. The good manufacturing practices are required for production of prescription grade human growth hormones to ensure patient safety. For this reason R & D Systems did not intend its research grade human growth hormone be used in humans. See Exhibit P-12, page 7-15. This information was clearly set out on the R & D System Certificate of Analysis, a document created to provide information regarding the source, purity and assay method, reconstitution, and other factors regarding the manufacturing of the product. See Exhibit P-12, pages 7-14 and 7-15. Biomed was aware that the human growth hormone it received from R & D Systems was not prescription grade. Despite this knowledge, Biomed diluted the research grade human growth hormone it received from R & D Systems and used it to create Biomed liquid and tablet drug products.

1.9 In July 2004, Biomed requested that R & D Systems make a labeling change, specifically, to remove the "not for human use" language from the Certificate of

Analysis. Biomed indicated this would assist them in their product manufacturing process. R & D Systems declined Biomed's request. R & D Systems made this decision because it knew third party manufacturers such as Dolisos were resistant to using research grade growth hormones in the manufacturing process of products being consumed by humans. R & D also wished to avoid any insurance liability issues which could arise from deleting the "not for human use" language from the Certificate of Analysis.

1.10 Biomed knowingly used research grade human growth hormone obtained from R & D Systems in the creation of the Biomed's drug products. Biomed then requested that Dolisos take the research grade human growth hormone obtained from R & D Systems, dilute it using the instructions provided by Biomed, and manufacture Biomed drug products. Those drug tablet products were then sold to the members of the public for their use and consumption. Dr. Brewitt and Biomed did not have a license to manufacture drugs in the state of Washington during the period 2000 – 2005.

B. Use of Norditropin in the Production of Biomed Drug Products.

1.11 Beginning in August 2000, Dr. Brewitt obtained Norditropin (an injectable form of human growth hormone) from the Ballard Plaza Pharmacy (the Ballard Pharmacy). Norditropin is a legend drug which requires a prescription by a licensed physician.⁶ It is unlawful for any person to sell, deliver, or possess a legend drug except

⁶ "Legend drug" means any drugs which are required by state law or regulation of the state board of pharmacy to be dispensed on prescription only or are restricted to use by practitioners only. RCW 69.41.010(10).

upon the prescription of a physician or other health care license.⁷ The Ballard Pharmacy records identify the prescribing physician for the Norditropin as “Barbara Brewitt M.D.” The patient or client for which the Norditropin was prescribed was also identified as “Barbara Brewitt”. There is no evidence to show that Dr. Brewitt required human growth hormone treatment for any personal medical condition. Dr. Brewitt did not have a license to practice as a physician and surgeon in the state of Washington during the relevant period.

1.12 During the period August 2000-October 2005, the Respondent obtained 23 separate prescriptions for Norditropin from the Ballard Pharmacy. See Exhibit 30, pages 6, 7, and 8. Dr. Brewitt also obtained two prescriptions of insulin from the pharmacy. Dr. Brewitt testified the Norditropin prescription was written by an out-of-state naturopathic physician (Dr. Gary Gordon). The Board finds that Dr. Brewitt’s testimony on this issue is not credible, based on the totality of the evidence presented in this matter. Even if Dr. Gordon had written such a prescription, naturopathic physicians cannot by law prescribe legend drugs in the state of Washington. See RCW 18.36A.040 and WAC 246-836-210.

1.13 None of the 23 Norditropin prescriptions dispensed by the Ballard Pharmacy to Dr. Brewitt are refill prescriptions. In other words, each of the prescriptions Ballard Pharmacy dispensed to Dr. Brewitt constitutes a new and separate prescription. Each of the new and separate Norditropin prescriptions would require a separate prescription order from a licensed physician. See Exhibit P-30, pages 2 and 4.

⁷ See RCW 69.41.030 (which lists the health care professionals who may prescribe or order legend drugs).

Dr. Brewitt personally picked up the prepared Norditropin prescription on four occasions.⁸ Dr. Brewitt instructed Biomed employee Marie Brown to phone in the prescriptions to the Ballard Pharmacy. See Exhibit P-30, pages 1 and 3. The remaining 17 Norditropin prescriptions were either called in by Dr. Brewitt or another employee of the Respondent.

1.14 During the period August 2000 through October 2005, Dr. Brewitt knew on 23 occasions that the Ballard Pharmacy provided her with the legend drug Norditropin under the belief that Dr. Brewitt was authorized to prescribe the medication. Dr. Brewitt knew this fact because the information "Barbara Brewitt, M.D." was clearly printed on the 23 Norditropin prescription bottle labels. Dr. Brewitt failed to inform the Ballard Pharmacy of its error regarding any of the 23 Norditropin prescriptions she received during the period 2000-2005.⁹

1.15 Biomed and Dr. Brewitt used the legend drug Norditropin (which is a human growth hormone) obtained from the Ballard Pharmacy in the manufacturing process for the creation of the homeopathic drug products sold by the Respondent. Dr. Brewitt and other employees of the Respondent then diluted the legend drug Norditropin for use in the drug products sold by the Respondent.

⁸ Respondent Dr. Brewitt also visited the Ballard Pharmacy on a number of occasions to obtain insulin for her personal use. The insulin was available over the counter. Over the counter medications do not require a prescription from a physician.

⁹ Shortly after the technical assistance visit to the Respondent's facility in November 2005, Dr. Brewitt asked Respondent employee Marie Brown to call the Ballard Pharmacy to inform them that Dr. Brewitt was not licensed to practice medicine in Washington. Ms. Brown did not make the call requested by Dr. Brewitt. Dr. Brewitt was unaware that Ms. Brown failed to make the telephone call as instructed until contacted by Ms. Smith.

1.16 Biomed manufactured a component for use in the Biomed tablets and liquid drug products sold to the public. The drug component in question was created by Biomed from the diluted form of the legend drug Norditropin (the prescription form of human growth hormone) prescribed to Dr. Brewitt. The drug component provided by or prepared under instructions from Dr. Brewitt and Biomed were used in the manufacturing of drug products. The drug products were ultimately offered for sale to the public by the Respondent. The Respondent did not have a license to manufacture drugs in the state of Washington during the period 2000–2005.

Drug Manufacturing – 2005 through 2006.

1.17 In June 2005, Brion purchased Dolisos American. Brion decided it would not sell to or manufacture drug products for Biomed following its purchase of Dolisos America. Without any other outside drug manufacturer to assist in the production of Biomed drug products, Biomed decided to manufacture its own products. On or about August 29, 2005, Biomed applied for a license to operate as a drug wholesaler in the state of Washington. On October 26, 2005, Biomed notified the Department of Health to clarify that its application was for a drug manufacturing license, and not a drug wholesaler license. Exhibit P-4.

1.18 In response to the Biomed application, the Department of Health provided Biomed with technical assistance visits to determine whether the Biomed facility in Woodinville, Washington, was capable of manufacturing drugs in accordance with Washington law and good manufacturing practices. The first technical assistant visit occurred on September 29, 2005. Following this initial visit of the Woodinville facility,

the technical assistant pharmacist (Kelly McLean, R.Ph.) uncovered 15 deficiencies (including, but not limited to, maintaining complete laboratory data related to each batch, testing the stability of the finished product, no provisions for an adequate potable water supply, and no quarantine area for returned goods) that Biomed would need to correct before it could be licensed to manufacture drugs. Exhibit P-2, pages 1-2. When the technical inspection pharmacist asked Dr. Brewitt whether Biomed had manufactured any drug products prior to the inspection, Dr. Brewitt denied that Biomed manufactured any drug products. Exhibit P-2, page 1. This statement was false, given that Biomed had manufactured drug products with Dolisos during the period 1996-2005.

1.19 On September 29, 2005, Biomed employee Jeremy Adler called the Department of Health Pharmacy Program shortly after the technical assistance visit to the Woodinville facility. Mr. Adler informed the Program that Dr. Brewitt had removed components used by Biomed in the manufacturing of Biomed's drug products and placed them in her car to avoid those items being seen during the inspection. Dr. Brewitt returned the components to the facility for use in the manufacture of Biomed's drug products immediately after the technical assistance pharmacist's visit. Dr. Brewitt stated she removed the material merely to perform a general clean up of the Woodinville facility in preparation for the technical assistance visit. The Board finds the testimony of Jeremy Adler to be credible on this issue, based on the totality of the evidence presented in this matter.

1.20 On September 30, 2005, Ms. McLean performed a second technical assistance visit to the Woodinville facility based on the information received in the Jeremy Adler telephone call. Dr. Brewitt was provided with a copy of chapter 246-895 WAC for her information and review. Ms. McLean observed Mr. Adler creating a dilution of a liquid drug product during this second inspection. Ms. McLean observed several bottles of liquids that were not present during the September 29, 2005 inspection. Ms. McLean observed that the bottles of liquid contained insulin, fibrinogen, and growth hormone. Based on these observations, and using her knowledge and experience as a pharmacist, Ms. McLean determined the Respondent was manufacturing drugs. Ms. McLean filed a complaint with the Department of Health Pharmacy Program staff regarding the Respondent's unlicensed manufacturing practices.

1.21 Department of Health Pharmacy Investigator Stan Jeppesen, R.Ph., investigated the complaint filed by technical assistance pharmacist Kelly McLean. On October 14, 2005, Mr. Jeppesen inspected Biomed's Woodinville facility and observed equipment and chemicals which were used for the manufacturing of drug products, labels and bottles for the sale of drug products, a tablet manufacturing machine, and a powder mixing machine. Mr. Jeppesen took photographs of this inspection. See Exhibit P-29. On November 8, 2005, Mr. Jeppesen personally observed Dr. Brewitt and another Biomed employee manufacturing liquid drug products or components of liquid drug products at Biomed's Woodinville facility, including the mixing and transferring of liquids into bottles, and packing the bottles into boxes for shipment.

1.22 On November 28, 2005, Ms. McLean performed another technical assistance visit of the Biomed facility in Woodinville, Washington. During this visit she identified seven additional deficiencies (including, but not limited to, no provisions for documentation of quality, name of supplier, supplier lot number or disposition of rejected items regarding components in the log book presented, no policy or procedures for the documentation of batch failure, and no system in place for which the distribution of each lot of drugs can be readily determined to facilitate its recall if necessary) regarding the Respondent's facility. Exhibit P-12. Ms. McLean discussed these deficiencies with Dr. Brewitt.

1.23 Dr. Brewitt admits Biomed created 145 units or bottles of a liquid drug product, which were intended for sale to the public, during a three day period in September 2005. Dr. Brewitt further admits Biomed created the 145 units or bottles of drug product for sale when the Respondent was not licensed to manufacture drugs. See RCW 18.64.045. According to email information provided from Biomed's records, additional drug sales continued to at least November 28, 2005. Exhibit P-7, pages 1 through 36.

1.24 Marie Brown was employed by Dr. Brewitt and Biomed from April 2005 to July 2006. During her employment, Ms. Brown took orders for the Biomed products over the phone. Ms. Brown observed and heard Dr. Brewitt take orders over the phone and advised customers which product was useful to treat medical conditions. Dr. Brewitt advised customers that the Biomed products could be used to treat the following conditions: Alzheimer's, asthma, AIDS, autism, attention deficit disorder,

diabetes, and hepatitis. Biomed produced literature that specifically claimed that its natural treatment was shown effective in treating HIV/AIDS. See Exhibit P-24. Both Ms. Brown and Dr. Brewitt worked from the list specifically created for that purpose. Exhibit P-19.

1.25 Dr. Brewitt gave Marie Brown the Log Book (Exhibit P-15) containing the dilution information and asked her to destroy the book. Ms. Brown did not destroy the Log Book, but instead took it to her home. Ms. Brown then provided the Log Book to Department investigator Stan Jeppersen. Ms. Brown also sold drug products manufactured by Biomed to Mr. Jeppersen. The drug product packing included “drug facts” for use by the consumer. Exhibit 23, pages 1-4.

1.26 Dr. Brewitt denies that she intentionally instructed Ms. Brown to remove and/or destroy her Log Book containing the compounding instructions regarding the manufacturing of Biomed’s drug products in order to prevent detection by the Board of Pharmacy inspector. The Board finds the testimony of Marie Brown to be credible on this issue, based on the totality of the evidence presented in this matter.

1.27 Dr. Brewitt and Biomed manufactured drug products beginning in June 2005 without a license to manufacture drugs in the state of Washington pursuant to RCW 18.64.045. The drug products manufactured by Dr. Brewitt and Biomed were not manufactured in accordance with good manufacturing practices and the regulatory requirements set forth in chapter 246-895 WAC. See WAC 246-895-020. These requirements include, but are not limited to, what constitutes appropriate manufacturing

facilities, production and control procedures, packaging and labeling, laboratory controls and record keeping.

II. CONCLUSIONS OF LAW

2.1 At all times material to the Statement of Charges with Intent to Deny, the Board has jurisdiction to hear this matter. RCW 18.64.163; RCW 18.64.045; and chapter 18.130 RCW (the Uniform Disciplinary Act).

2.2 The Washington Supreme Court held that the constitutional standard of proof in a professional disciplinary hearing is clear and convincing evidence.

Ongom v. Department of Health, 159 Wn.2d 132 (2006).

2.3 The Board reviewed the admitted exhibits and considered the testimony. The Board panel members used their experience, competency, and specialized knowledge to evaluate the evidence presented in this case. RCW 34.05.461(5).

What Constitutes a Drug.

2.4 The threshold question in this case is whether the substance or product Biomed manufactured and sold constitutes a "drug" under Washington law.

RCW 18.64.011 defines "drug" to mean:

- (a) Articles recognized in the official United States pharmacopoeia or the official homeopathic pharmacopoeia of the United States;
- (b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;
- (c) Substances (other than food) intended to affect the structure or any function of the body of man or other animals;

(d) Substances intended for use as a component of any substances specified in (a), (b), or (c) of this subsection, but not including devices or their component parts or accessories.

RCW 18.64.011(3). There are no Washington cases that interpret RCW 18.64.011(3). However, the definition of “drug” in RCW 18.64.011(3) is almost identical to the federal definition in 21 U.S.C sec.321(g)(1). Cases interpreting the term “drug” under the Federal Act are persuasive authority and may be considered in determining what constitutes a “drug” under state law in the absence of Washington state authority. See *Martinez v. City of Tacoma*, 81 Wn. App. 228, 238 (1996) (citing *Blair v. Washington State Univ.*, 108 Wn.2d 558, 570 (1987)).

2.5 Under the Federal Act, determining whether an article is a “drug” is based on a determination that the article is listed in the pharmacopoeia¹⁰ or on the intended use of the article. See *Meserey v. United States*, 447 F. Supp. 548, 553 (D.C. Nev., 1977). Regardless of the actual physical effect of the product, once it is established that its intended use brings it within the drug definition, it will be deemed a drug for purposes of the Act. *Meserey v. United States*, 447 F. Supp. At 553 (internal citation omitted).

2.6 Based on Findings of Fact 1.2, 1.5, 1.6, and 1.24, the Program has proven by clear and convincing evidence that Biomed’s liquid and tablet products are drugs under RCW 18.64.011(3)(b) (substances intended for use in the diagnosis, treatment, or prevention of disease in man).

2.7 Based on Findings of Fact 1.7 through 1.27, the Program has proven by clear and convincing evidence that Biomed’s liquid and tablet products are drugs under

¹⁰ The United States Pharmacopoeia (USP) or the Homeopathic Pharmacopoeia of the United States (HPUS).

RCW 18.64.011(3)(c) (substances intended to affect the structure or any function of the body of man).

2.8 Based on Findings of Fact 1.2, and 1.5 through 1.27, the Program has proven by clear and convincing evidence that Biomed's liquid and tablet products are drugs under RCW 18.64.0110(3)(d) (substances intended for use to affect the structure or any function of the body of man). Therefore, the products produced by Biomed are clearly drugs as defined in RCW 18.64.011(3) (b)(d).

Uniform Disciplinary Act Violations

2.9 The Uniform Disciplinary Act defines what conduct, acts, or conditions constitute unprofessional conduct. RCW 18.130.180. RCW 18.130.180(1) defines unprofessional conduct to include:

The commission of any act involving moral turpitude, *dishonesty*, or corruption relating to the practice of the person's profession, whether the act constitutes a crime or not.

RCW 18.130.180(1) (emphasis added). The Administrative Procedure Act, chapter 34.05 RCW, applies to disciplinary proceedings under the Uniform Disciplinary Act, chapter 18.130 RCW. See RCW 18.130.100. Under the Administrative Procedure Act, chapter 34.05 RCW, a "person" is defined to include a corporation.

RCW 34.05.010(14).

2.10 Based on Findings of Fact 1.6 through 1.27, the Program has proven by clear and convincing evidence that Biomed's conduct violated RCW 18.130.180(1) (dishonesty).

2.11 Under RCW 18.130.180(2), unprofessional conduct is defined as:

Misrepresentation or concealment of a material fact in obtaining a license or in reinstatement thereof.

RCW 18.130.180(2). Based on Findings of Fact 1.6 through 1.27, the Program has proven by clear and convincing evidence that Biomed's conduct violated RCW 18.130.180(2).

2.12 Under RCW 18.130.180(7), unprofessional conduct is defined as:

Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or profession conduct or practice.

RCW 18.130.180(7). Based on Findings of Fact 1.1 through 1.27, the Respondent's conduct violated RCW 18.130.180(7) (incorporating RCW 18.64.045 and WAC 246-310-020).

2.13 Under RCW 18.130.180(13), unprofessional conduct is defined as:

Misrepresentation or fraud in any aspect of the conduct of the business or profession.

RCW 18.130.180(13) (emphasis added).

2.14 Based on Findings of Fact 1.1 through 1.27, the Department has proven by clear and convincing evidence that the Respondent's conduct violated RCW 18.130.180(13).

2.15 Upon a finding of unprofessional conduct, the Board has the authority to order appropriate sanctions:

Safeguarding the public's health and safety is the paramount responsibility of every disciplining authority and in determining what action is appropriate, the disciplining

authority must first consider what sanctions are necessary to protect or compensate the public. Only after such provisions have been made may the disciplining authority consider and include in the order requirements designed to rehabilitate the license holder or applicant.

RCW 18.130.160 (emphasis added). The Board concludes that Biomed engaged in unprofessional conduct. The Board further concludes that sanctions are necessary to protect the public's health and safety in this case.

2.16 In determining what constituted the appropriate sanction in this matter, the Board considered the following factors in aggravation:

A. Biomed engaged in the manufacture of drugs from the period 1996-2005 before applying for a license to manufacture pursuant to RCW 18.64.045.

B. In response to a direct question from Kelly McLean R.Ph. (the Department of Health Pharmacy technical assistance pharmacist) whether Biomed was manufacturing or had manufactured drugs, Dr. Barbara Brewitt, Biomed's only corporate officer after 1996, answered that Biomed had not and was not manufacturing drugs. Dr. Brewitt, Biomed's corporate officer, knew that answer was false.

C. Biomed manufactured drug products without following the required good manufacturing practices, including methods used in, or the facilities or controls used for, the manufacture, processing, packing or holding the drug to ensure the safety, identity, strength, quality, and purity characteristics of the drugs being manufactured.

D. Biomed manufactured drug products for sale to the public from 1995 to 2005, using research grade human growth hormone in the manufacture of

those drug products. Biomed's use of research human growth hormone in the manufacturing of drugs created an unreasonable risk that the public might be harmed.

The Board concludes Biomed should not be allowed to manufacture drugs in the state of Washington based on the evidence presented in this case.

III. ORDER

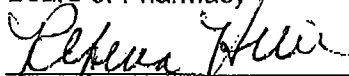
Based on the foregoing Findings of Fact and Conclusions of Law, it is ORDERED:

3.1 Biomed Comm, Inc.'s, application for a license to manufacture drugs in the state of Washington is DENIED.

3.2 Biomed Comm, Inc., is prohibited from applying for a license to manufacture drugs in the state of Washington for a 10 year period from the date of service of this Order.

Dated this 20th day of April, 2007.

Board of Pharmacy



REBECCA HILLE, Public Member
Board Chair

CLERK'S SUMMARY

Charges	Action
RCW 18.130.180(1)	Violated
RCW 18.130.180(2)	Violated
RCW 18.130.180(7)	Violated
RCW 18.130.180(13)	Violated
RCW 18.64.045	Violated
WAC 246-895-020(1)	Violated

FINDINGS OF FACT,
CONCLUSIONS OF LAW
AND FINAL ORDER

Page 24 of 25

Docket No. 06-03-A-1021FX

NOTICE TO PARTIES

This order is subject to the reporting requirements of RCW 18.1300.110, Section 1128E of the Social Security Act, and any other applicable interstate/national reporting requirements. If adverse action is taken, it must be reported to the Healthcare Integrity Protection Data Bank.

Either party may file a **petition for reconsideration**. RCW 34.05.461(3); RCW 34.05.470. The petition must be filed within 10 days of service of this Order with:

Adjudicative Service Unit
P.O. Box 47879
Olympia, WA 98504-7879

and a copy must be sent to:

Board of Pharmacy
P.O. Box 47869
Olympia, WA 98504-7869

The petition must state the specific grounds upon which reconsideration is requested and the relief requested. The petition for reconsideration is considered denied 20 days after the petition is filed if the Adjudicative Service Unit has not responded to the petition or served written notice of the date by which action will be taken on the petition.

A **petition for judicial review** must be filed and served within 30 days after service of this order. RCW 34.05.542. The procedures are identified in chapter 34.05 RCW, Part V, Judicial Review and Civil Enforcement. A petition for reconsideration is not required before seeking judicial review. If a petition for reconsideration is filed, however, the 30-day period will begin to run upon the resolution of that petition. RCW 34.05.470(3).

The order remains in effect even if a petition for reconsideration or petition for judicial review is filed. "Filing" means actual receipt of the document by the Adjudicative Service Unit. RCW 34.05.010(6). This Order was "served" upon you on the day it was deposited in the United States mail. RCW 34.05.010(19).