



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:

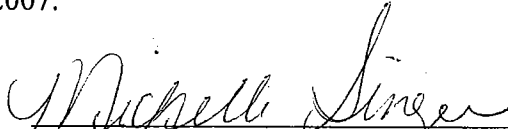
Robert N. Meals  
Attorney at Law  
PO Box 659  
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Biomed Comm. Inc.  
4616 25<sup>th</sup> Ave NE #273  
Seattle, WA 98105

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 23<sup>rd</sup> 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.<sup>1</sup>  
                            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.

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<sup>1</sup> 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](http://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](http://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; Oophorinum;

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.<sup>2</sup> 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.

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<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup>

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

<sup>4</sup> 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.<sup>5</sup>

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

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<sup>5</sup> 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.<sup>6</sup> It is unlawful for any person to sell, deliver, or possess a legend drug except

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<sup>6</sup> "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).

