BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

OAC Case No. PH 2007-0003 (Board Case No. 2008-568)

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE LICENSE TO PRACTICE PHARMACY IN THE STATE OF COLORADO OF THOMAS W. BADER, RPH, LICENSE NO. 9321,

Respondent.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Thomas W. Bader, RPh, ("Respondent") to resolve all matters pertaining to Case No. 2007-0003 (Board Case Number 2008-568), as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent, his license to practice pharmacy, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmacists and Pharmaceuticals Act at Title 12, Article 22, C.R.S.

2. Respondent was originally licensed to practice as a pharmacist in the State of Colorado on June 23, 1969, and has been so licensed at all times relevant to this disciplinary action.

3. Respondent’s last known address of record with the Board is c/o College Pharmacy, 3505 Austin Bluffs Parkway, Ste. 101, Colorado Springs, Colorado 80918.

4. Respondent is the President of College Pharmacy, Inc. which owns College Pharmacy which is located at and doing business at 3505 Austin Bluffs Parkway, Ste. 101, Colorado Springs, Colorado 80918 ("College Pharmacy").

5. From at least 2004 to October 19, 2007, Respondent was the pharmacist manager of College Pharmacy.

6. On or about October 19, 2007, the Board entered an order, pursuant to §24-4-104(4)(a) C.R.S., summarily suspending Respondent’s license to practice pharmacy in the state of Colorado pending proceedings to determine whether his license should be further disciplined in accordance with §§ 12-22-125 and 125.2, C.R.S., and the Board filed with the Office of Administrative Courts, and Respondent was served with, a Notice to Set, Notice of Hearing, Notice of Duty to Answer, and Notice of Charges (hereafter “NOC,” attached to this Final Agency Order) for violations of §§12-22-101 et seq., ("Pharmaceuticals and Pharmacist Act") and Pharmacy Board Rules at 3 CCR 719-1...
(3/31/06) ("Board Rules") based on the factual allegations set forth in the NOC, under Office of Administrative Courts Case No. PH 2007-0003.

7. Respondent denies the allegations in the NOC, denies committing the violations alleged in the NOC and by entering into this order makes no admissions of any facts alleged in the NOC or that any conduct alleged violated any state or federal law.

8. The parties agree to resolve the NOC on the following terms.

**DISPOSITION**

9. **Permanent Relinquishment of Pharmacy License.** Respondent hereby permanently voluntarily relinquishes his pharmacy license and the right to practice as a pharmacist in the State of Colorado. Such relinquishment shall have full force and effect as a revocation ordered by the Board, except that it shall be permanent and Respondent permanently waives the right to re-apply for a license to practice pharmacy in the State of Colorado as provided under §12-22-116(9). Respondent shall submit all indicia of licensure to the Board simultaneously with his execution of this Final Agency Order.

10. **Transfer of Ownership and Management Functions of College Pharmacy.** Respondent is in the process of transferring all the stock that he and his family owns into an Employee Stock Ownership Plan ("ESOP") which ESOP will then be the record owner of all stock of College Pharmacy, Inc. Neither Respondent nor any members of his family will be beneficial owners of any of the shares of stock of which the ESOP will be the record owner after the transfer by the trustee to the ESOP. During the time of the creation of the ESOP, the transfer of stock to the ESOP and the closing of the sale of the stock to the ESOP ("transfer period"), all stock in College Pharmacy, Inc., owned by Respondent or any member of Respondent’s immediate family shall be placed into trust with an independent trustee who will then transfer the stock to the ESOP. Respondent shall report on the progress of the ESOP transfer every seven (7) days to counsel for the Board. The transfer of the stock in College Pharmacy, Inc. to the ESOP and the closing of such transaction shall take place on or before January 15, 2008. During this transfer period all business operations and management functions of College Pharmacy, and all business operations and management functions of any other business or businesses Respondent owns which require licensure or registration in the State of Colorado under the Pharmaceuticals and Pharmacists Act, have been or will be transferred by Respondent to an individual or individuals other than himself or a family member. During the transfer period, Respondent shall not engage in any activity as a pharmacist, pharmacy technician or pharmacy clerk in the course of performing his responsibilities as owner of College Pharmacy, and as owner of any other business or businesses requiring licensure or registration in the State of Colorado under the Pharmaceuticals and Pharmacists Act, and neither Respondent nor any member of his immediate family shall be employed by or at College Pharmacy. By this paragraph the parties intend that Respondent not engage in any pharmacy related activities in Colorado. Respondent may engage in actions as may be related to matters necessary to the transfer of business operations, ownership and management functions provided for in the paragraph.
However, Respondent has not since October 22, 2007, participated in and will not participate in the future whatsoever in the management or operation of College Pharmacy.

11. Access to records. During the transfer period Respondent is allowed access to his records and those of College Pharmacy so that he may aid in his defense of the criminal charges now pending against him. Respondent’s access to such records and access to College Pharmacy is limited to his office on the second floor of the College Pharmacy location or wherever it may be relocated at the Austin Bluffs Parkway location. However, such records shall not be moved to a location near the operating portion of the pharmacy and if moved only to a location where office functions are preformed.

12. Agreement to Cease Work in Any Pharmacy Outlet, Wholesale Outlet or Other Pharmaceutical Business. Respondent agrees that he shall not work in any capacity for any prescription drug outlet, wholesale outlet, other outlet, or any other business requiring licensure or registration in the State of Colorado under the Pharmaceuticals and Pharmacists Act.

12. Other Requirements. Respondent acknowledges and agrees that, as a condition of this Final Agency Order, he shall:

   a. comply fully with this Final Agency Order; and

   b. comply fully with the Pharmacists and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado to the extent they may apply to Respondent.

13. Dismissal of Pending Action. This Final Agency Order fully and finally resolves all pending and potential disciplinary actions against the license of Respondent through October 22, 2007. Upon the transfer of Respondent’s stock in College Pharmacy to the ESOP as described in paragraph 10 hereof, the Board shall move to dismiss Case No. PH 2007-0003 as to Respondent, with prejudice. If such transfer does not occur, at the Board’s sole option this Stipulation shall be null and void and the Board may set the NOC for hearing. Respondent understands and agrees that the Summary Suspension described in paragraph 6 hereof remains in full force and effect during until dismissal of this action. Nothing in this Final Agency Order is intended to, or has the effect of restricting the Board’s right or ability to enforce this Final Agency Order through administrative or Court action or to bring any action in the event that Respondent is engaging in any act or practice over which the Board has jurisdiction, or affects any pending action or Final Agency Order as to College Pharmacy.

14. Advisements and Waivers. Respondent enters into this Final Agency Order freely and voluntarily, after the opportunity to consult with legal counsel of his own choosing. Respondent acknowledges that he has waived the following rights:

   a. to have a formal disciplinary hearing pursuant to Sections 12-22-125 and 12-22-125.2(2)(a), C.R.S.; and
b. to any of the rights set forth in CRS §24-4-105; and

c. to appeal or otherwise challenge this Final Agency Order.

15. Acknowledgments. Respondent has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel, that he understands its legal consequences and agrees that none of its terms or conditions are unconscionable. Respondent is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent further acknowledges that he is not entering into this Final Agency Order under any duress.

16. Violations. Time is of the essence in this Final Agency Order. It is the responsibility of Respondent to take all appropriate steps to comply fully with this Final Agency Order. Respondent acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order. The pendency of any litigation arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent to comply with all terms and conditions of this Final Agency Order.

17. Integration and Severability. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

18. Public Record. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

19. Effective Date. This Final Agency Order shall become effective upon signature by a Board representative.

ACCEPTED AND AGREED:

Respondent

[Signature]

Thomas W. Bader

Subscribed and sworn to before me in the County of El Paso, State of Colorado, this 14th day of December, 2007, by Thomas W. Bader.

[Signature]

Sandy Estledge
Notary Public

MY COMMISSION EXPIRES
05/22/2010
FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an order of the Board.

DONE AND EFFECTIVE this ______ day of __________ 2007.

State Board of Pharmacy

BY:

WENDY ANDERSON
Program Director

APPROVED AS TO FORM

Attorneys for Respondent

Duane Morris, LLC.
Attorneys at Law

By:

HOWARD M. HOFFMANN
FREDERICK R. BALL

227 West Monroe Street, Suite 3400
Chicago, Illinois 60606
Telephone: (312) 499-6700
Fax: (312) 499-6701

Attorneys for State Board of Pharmacy

JOHN W. SUTHERS
Attorney General

JACK M. WESOKY, #50461*
JOANNA LEE KAYE, #20485*
Assistant Attorneys General

1525 Sherman Street, 5th Floor
Denver, Colorado 80203
Telephone: (303) 866-6170
FAX: (303) 866-5690

Attorneys for Respondent

1700 Broadway, Suite 2720
Denver, Colorado 80205
Telephone: (303) 830-8885
FAX: (303) 830-8890

* Counsel of Record
FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an order of the Board.

DONE AND EFFECTIVE this 15th day of December 2007.

State Board of Pharmacy

BY: WENDY ANDERSON
Program Director

APPROVED AS TO FORM

Attorneys for Respondent
Duane Morris, LLC.
Attorneys at Law

By: HOWARD M. HOFFMANN
FREDERICK R. BALL

227 West Monroe Street, Suite 3400
Chicago, Illinois 60606
Telephone: (312) 499-6700
Fax: (312) 499-6701

Attorneys for State Board of Pharmacy
JOHN W. SUTHERS
Attorney General

JACK M. WESOKY, #6001*
JOANNA LEE KAYE, #20486*
Assistant Attorneys General

1525 Sherman Street, 5th Floor
Denver, Colorado 80203
Telephone: (303) 866-6170
FAX: (303) 866-5690

CHARLES H. TORRES, #7986
Attorneys for Respondent

1700 Broadway, Suite 2720
Denver, Colorado 80290
Telephone: (303) 830-8885
FAX: (303) 830-8890

*Counsel of Record
STATE BOARD OF PHARMACY
STATE OF COLORADO
OFFICE OF ADMINISTRATIVE COURTS

633 17th Street, Suite 1300, Denver, Colorado 80202

COLORADO STATE BOARD OF PHARMACY,

Petitioner,

vs.

COLLEGE PHARMACY,
REGISTRATION No. PDO #240000038,

and

THOMAS W. BADER, R.PH.,
LICENSE No. 9321,

Respondents.

ORDER OF SUMMARY SUSPENSION, NOTICE OF DUTY TO ANSWER, NOTICE TO SET AN INFORMAL PREHEARING CONFERENCE, NOTICE OF HEARING, AND NOTICE OF CHARGES

TO: COLLEGE PHARMACY

ORDER OF SUMMARY SUSPENSION

The State Board of Pharmacy ("Board"), having conducted an investigation as to the matters referenced below, HEREBY FINDS:

1. College Pharmacy ("Respondent Pharmacy") has been located in the State of Colorado at all times relevant herein.

2. The Board has jurisdiction over Respondent Pharmacy and the subject matter herein.

3. Based on the information referenced in the attached Notice of Charges, reasonable grounds exist to believe, and the Board so finds, that Respondent Pharmacy has deliberately and
willfully violated the Pharmaceuticals and Pharmacists Act, Board Rules, and sections of the United States Code.

4. Based on the information referenced in the attached Notice of Charges, reasonable grounds exist to believe, and the Board so finds, that the public health, safety, and welfare imperatively require that emergency action be taken.

THEREFORE, IT IS HEREBY ORDERED that the registration of College Pharmacy as a prescription drug outlet in the State of Colorado be, and hereby is, summarily suspended pursuant to §24-4-104(4)(a), C.R.S. pending proceedings to determine whether Respondent Pharmacy's registration as a prescription drug outlet in the State of Colorado should be further disciplined in accordance with §§12-22-125 and 12-22-125.2, C.R.S.

Pending the outcome of said proceedings, IT IS FURTHER ORDERED that College Pharmacy:

a. immediately cease, desist, and refrain from any further acts for which a registration as a prescription drug outlet is required by the laws of the State of Colorado upon receipt of this Summary Suspension; AND

b. within ninety six (96) hours of receipt of this Summary Suspension, submit its registration card to the Board; AND

c. within ninety six (96) hours of receipt of this Summary Suspension, prepare a complete, detailed inventory of all drugs in Respondent Pharmacy, including the name, strength, and quantity of each drug; AND

d. within ninety six (96) hours of receipt of this Summary Suspension, provide a written copy of said complete, detailed inventory to the Board; AND

e. within ninety six (96) hours of receipt of this Summary Suspension, remove all drugs and records, including all files and dispensing records, to another registered location; AND

f. within ninety six (96) hours of receipt of this Summary Suspension, notify the Board in writing of the name, address, registration number, and DEA registration number of the location to which said drugs and records have been removed.
TO: THOMAS W. BADER, R.PH.

ORDER OF SUMMARY SUSPENSION

Based on its investigation conducted as to the matters referenced below, the Board HEREBY FURTHER FINDS:

1. Thomas W. Bader, R.Ph. ("Respondent Bader") was issued Colorado pharmacy license no. 9321 on June 23, 1969, and has been licensed in the State of Colorado at all times relevant herein.

2. The Board has jurisdiction over Respondent Bader and the subject matter herein.

3. Based on the information referenced in the attached Notice of Charges, reasonable grounds exist to believe, and the Board so finds, that Respondent Bader has deliberately and willfully violated the Pharmaceuticals and Pharmacists Act, Board Rules, and sections of the United States Code pursuant to §24-4-104(4)(a), C.R.S.

4. Based on the information referenced in the attached Notice of Charges, reasonable grounds exist to believe, and the Board so finds, that the public health, safety, and welfare imperatively require that emergency action be taken pursuant to §24-4-104(4)(a), C.R.S.

THEREFORE, IT IS HEREBY FURTHER ORDERED that the license of Thomas W. Bader to practice pharmacy in the State of Colorado be, and hereby is, summarily suspended pursuant to §24-4-104(4)(a), C.R.S. pending proceedings to determine whether his license to practice pharmacy in the State of Colorado should be further disciplined in accordance with C.R.S. §§12-22-125 and 12-22-125.2, C.R.S.

Pending the outcome of said proceedings, IT IS FURTHER ORDERED that Thomas W. Bader immediately:

a. cease, desist, and refrain from any further acts for which a license to practice pharmacy is required by the laws of the State of Colorado, and

b. submit his license card to the Board pending the outcome of this proceeding.

DATED this 17th day of October, 2007.

[Signature]
Wendy Anderson
Program Director
Colorado State Board of Pharmacy
NOTICE OF DUTY TO ANSWER

RESPONDENTS COLLEGE PHARMACY AND THOMAS W. BADER, R.P.H. (hereinafter "Respondents") ARE HEREBY NOTIFIED that, pursuant to §24-4-105(2)(b), C.R.S., Respondents are hereby required to file a written answer to the attached Notice of Charges with the Office of Administrative Courts, 633 Seventeenth Street, Suite 1300, Denver, CO 80202, within thirty (30) days after the service of this Order of Summary Suspension, Notice of Duty to Answer, Notice to Set an Informal Prehearing Conference, Notice of Hearing, and Notice of Charges. Respondents must also mail a copy of such answer to the Board’s attorney who has signed this Notice of Duty to Answer, Notice to Set an Informal Prehearing Conference, Notice of Hearing, and Notice of Charges below.

If Respondent Pharmacy fails to file its written answer within thirty (30) days, an order entering a default decision may be issued against its Colorado registration as a prescription drug outlet for the relief requested in the Notice of Charges, without further notice, or such other penalties which may be provided for by law, without further notice.

If Respondent Bader fails to file his written answer within thirty (30) days, an order entering a default decision may be issued against his license to practice pharmacy in the state of Colorado for the relief requested in the Notice of Charges, without further notice, or such other penalties which may be provided for by law, without further notice.

NOTICE TO SET AN INFORMAL PREHEARING CONFERENCE

RESPONDENTS ARE HEREBY NOTIFIED that the attorney for the State Board of Pharmacy, State of Colorado, will appear at 9:30 a.m. on November 9, 2007, in the Office of Administrative Courts, 633 Seventeenth Street, Denver, CO 80202 in order to set a date and obtain a location for a prehearing conference regarding the following Notice of Charges. At the informal prehearing conference, the parties will obtain a hearing date, arrange an expedited discovery schedule, and obtain motion dates as necessary. Respondents may be present in person by a representative, by counsel, or by telephone by calling the Office of Administrative Courts at (303) 866-2000 at the time and date indicated above.

NOTICE OF HEARING

RESPONDENTS ARE HEREBY NOTIFIED that pursuant to §§12-22-110, 12-22-125, 12-22-125.2, 24-4-104, and 24-4-105, C.R.S., a hearing will be held before an authorized administrative law judge at a time and location to be determined pursuant to the preceding prehearing conference for the purpose of determining whether the registration of Respondent Pharmacy and/or the license of Respondent Bader should be revoked or other lawful discipline imposed for a violation or violations of or pursuant to the relevant portions of the Pharmaceuticals and Pharmacists Act at §§12-22-101 et seq., Pharmacy Board Rules at 3 CCR 719-1 (eff. 7/31/04), and 21 U.S.C. §§301, et seq., which provide as follows:
Colorado Revised Statutes


(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

...(c) Has violated:

(I) Any of the provisions of this part 1, including but not limited to any acts in section 12-22-126;

(II) The lawful rules of the board; or

(III) Any state or federal law pertaining to drugs.

...(h) Has engaged in advertising that is misleading, deceptive, or false;

...(k) Has failed to meet generally accepted standards of pharmacy practice;

...(m) Has violated any lawful board order;

12-22-125.2. Disciplinary actions. (1) The board may deny or discipline an applicant, licensee, or registrant when the board determines that such applicant, licensee, or registrant has engaged in activities that are grounds for discipline.

* * *

12-22-120. Registration of facilities.

(1) All outlets with facilities in this state shall register with the board in one of the following classifications:

(a) Prescription drug outlet;

(b) Wholesale drug outlet;

(c) Manufacturing drug outlet;

(d) Repealed.

(e) Any other outlet, as may be authorized by this article or that meets the definition of outlet as set forth in section 12-22-102(23).
12-22-126. Unlawful acts.

(1) It is unlawful:

...(c) To willfully make a false statement in any order, report, application, or record required by this part 1;

12-22-128. New drugs - when sales permissible.

(1) No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug not authorized to move in interstate commerce under appropriate federal law.


As used in this article:

(3) (a) "Anabolic steroid" means any material, drug, hormonal compound, salt, isomer or salts of isomers of testosterone, or synthetic or natural derivatives of testosterone having pronounced anabolic properties which is used primarily to promote growth of muscle tissue, which includes, but is not limited to, any of the following:

(XI) Human growth hormone...

18-18-205. Schedule III.

(2) Unless specifically excepted by Colorado or federal law, or Colorado or federal regulation, or more specifically included in another schedule, the following controlled substances are listed in schedule III:

...(c) Anabolic steroids.

* * *


The following acts and the causing thereof are prohibited:

...(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 355, or 360bhb-3 of this title.


...(e) Prohibited distribution of human growth hormone
(1) Except as provided in paragraph (2), whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under section 355 of this title and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by Title 18, or both.

...(4) As used in this subsection the term "human growth hormone" means somatrem, somatropin, or an analogue of either of them.


(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

* * *

Pharmacy Rules and Regulations

1.00.11 A pharmacist shall at all times conduct his/her profession in conformity with all federal and state drug laws, rules and regulations; and shall uphold the legal standards of the current official compendia.

1.00.12 A pharmacist shall not be a party or accessory to nor engage in any fraudulent or deceitful practice or transaction in pharmacy, nor knowingly participate in any practice which detrimentally affects the patient, nor discredit his/her profession.

3.00.20 Medical Need. No licensee or registrant shall compound, dispense, deliver or distribute any drug to any person in such quantity or in any situation where the licensee or registrant knows or reasonably should know said drug has no recognized medical utility or application. Violation of this rule shall constitute prima facie proof of violation of CRS 12-22-125.

The pharmacist may not dispense a prescription drug or a controlled substance to a practitioner based on an order that does not list a specific patient. A prescription order for "office use" is not a valid order.
3.01.00 Prepackaging and repackaging

3.01.10

a. In a prescription drug outlet prepackaging and repackaging shall only be done by a pharmacist, or by an intern or an unlicensed assistant under the supervision of a pharmacist. In an other outlet, prepackaging and repackaging may be done by a person not licensed as a pharmacist pursuant to protocols approved by the Board.

b. Such packaged drugs shall only be dispensed or distributed from the premises where prepackaged or repackaged. Such drugs shall only be distributed to a location which is under the same ownership as, or is contractually affiliated with, the premises where prepackaged or repackaged.

3.01.20 Each prepackaged container, whether for use in a unit dose distribution system or a traditional dispensing system, shall be labeled in accordance with this regulation. Any repackaged unit dose, single dose or unit of issue container for which return for restocking and redispensing, pursuant to 3.00.80, is anticipated, shall be labeled in accordance with this regulation. Additionally, any repackaged container from which subsequent dispensing may occur, shall be labeled in accordance with this regulation. Such labeling shall include at least the following:

... (b) A suitable expiration date, which shall be not later than the expiration date on the manufacturer’s container, or one year from the date the drug is prepackaged or repackaged...¹

7.00.30 Compliance of Outlet:

a. The manager of a prescription drug outlet is responsible for the operation of the outlet in compliance with all state and federal laws, rules, and regulations.

* * *

RESPONDENTS ARE FURTHER NOTIFIED that at the hearing in this matter Respondents shall have the right to appear by representative and/or by legal counsel; to present evidence in their own behalf; to cross-examine any witnesses presented by the State Board of Pharmacy; and to rebut any evidence presented by the State Board of Pharmacy. Respondents may also have subpoenas issued on their behalf upon request to the administrative law judge.

¹ Effective March 31, 2007, Board Rule 3.01.20(b) was amended to add the phrase “whichever is less” at the end of the paragraph.
NOTICE OF CHARGES

The State Board of Pharmacy charges and alleges as follows:

General Allegations

1. Respondent Pharmacy was registered as a prescription drug outlet in 1974, was issued PDO # 240000038, and has been registered as a prescription drug outlet and located in the State of Colorado at all relevant times.

2. Respondent Bader was issued Colorado pharmacy license no. 9321 on June 23, 1969, and has been licensed as a pharmacist in the State of Colorado at all relevant times.

3. The Board has jurisdiction over the Respondent Pharmacy, its registration as a prescription drug outlet, Respondent Bader, his license to practice pharmacy, and the subject matter of this proceeding and the Notice of Charges pursuant to the provisions of §§12-22-101, et seq., C.R.S.

4. Respondent Bader was the pharmacist manager at all relevant times.

Specific Allegations

5. On December 21, 2005, Respondent Pharmacy entered into a Stipulation and Final Agency Order ("2005 Stipulation") in which Respondent Pharmacy was charged a fine of $50,000 for violations of state law and Board rules, and was required to submit quarterly reports on casual sales for a period of four years. In paragraph 9(c) of the 2005 Stipulation, Respondent Pharmacy agreed to "comply fully with the Colorado Pharmacy Laws, all Board rules and regulations, and any other State and Federal laws related to pharmacies and the practice of pharmacy."

6. Respondent Bader signed the 2005 Stipulation on behalf of Respondent Pharmacy.

7. At all relevant times, the FDA has considered all human growth hormone ("hGH") products to be "new drugs" within the meaning of federal law.

8. At all relevant times, federal law has required an approval by the FDA of an application for any new drug to be in effect prior to its introduction or delivery for introduction into interstate commerce in the United States.

9. At all relevant times, only FDA-approved human growth hormone ("hGH"); i.e., hGH with an approval of an application by the FDA in effect, can legally be introduced or delivered for introduction into interstate commerce in the United States.
10. At no time has the FDA or the Secretary of Health and Human Services ever approved an application for somatropin produced in China or manufactured in any facility in China.

11. In or around September, 2004, Respondent Bader held meetings at Respondent Pharmacy involving several staff members, during which meetings the purchase of hGH in the form of "somatropin" lyophilized powder manufactured in and/or imported from China ("Chinese somatropin") was discussed.

12. In or around September of 2004, Respondent Pharmacy began purchasing Chinese somatropin from a supplier known as "Hawk Biopharma," for resale, dispensing and/or distribution. Respondent Pharmacy listed Hawk Biopharma as the manufacturer of the somatropin in its records.

13. Purchase of the Chinese somatropin from Hawk Biopharma for resale, dispensing and/or distribution was done under the direction of Respondent Bader.

14. Hawk Biopharma has two addresses: 1400 North Harbor Blvd., Suite 640, Fullerton, California, 92835, and 32 Wallich Street, #03-61 Wallich Building, Singapore, 078880.

15. No company by the name of Hawk Biopharma has ever had an FDA approved new drug application in effect for somatropin.

16. At a date uncertain but no later than September of 2006, Respondent Pharmacy began purchasing Chinese somatropin from a supplier known as "North America GeneScience," for resale, dispensing and/or distribution. Respondent Pharmacy listed "GeneScience" as the manufacturer of the somatropin in its records.

17. Purchase of the Chinese somatropin from North America GeneScience for resale, dispensing and/or distribution was done under the direction of Respondent Bader.

18. North America GeneScience LLC is located at 1270 Crabb River Road, Suite 600 28 in Richmond, Texas.

19. North America GeneScience has never had an FDA approved new drug application in effect for somatropin.

20. The somatropin provided to Respondent Pharmacy by North American GeneScience was manufactured by GeneScience Pharmaceuticals Co. LTD.

21. GeneScience Pharmaceuticals Co. LTD is located at: 1 Tianhe St., Changchun High Tech Dev Zone, 130012, Changchun Jilin, China.

22. GeneScience Pharmaceuticals Co. LTD has never had an FDA approved new drug application in effect for somatropin.
23. From the latter part of 2004 until approximately July of 2007, Respondent Pharmacy sold or otherwise transferred the Chinese somatropin described above in paragraphs 12 through 22 to doctors, individuals and other entities inside and outside the State of Colorado.

24. At all relevant times, FDA-approved hGH can only be legally prescribed in the United States for a limited number of conditions authorized by the Secretary of Health and Human Services, including:

- Hormonal deficiency that causes short stature in children;
- Long-term treatment of growth failure due to lack of exogenous GH secretion;
- Long-term treatment of short stature associated with Turner syndrome;
- Adult short bowel syndrome;
- Adult deficiency due to rare pituitary tumors or their treatment; and
- Muscle-wasting disease associated with HIV/AIDS.

25. The conditions listed above in paragraph 24 are generally uncommon conditions.

26. The most common condition of those listed above in paragraph 24 is hormonal deficiency causing short stature in children.

27. At all relevant times, the distribution or possession with the intent to distribute hGH for anti-aging, bodybuilding, athletic enhancement, or any other use not approved by the FDA was prohibited by federal law.

28. During the relevant times, Respondent Pharmacy distributed marketing documents designed to promote the sale of hGH for “treatment” of the “symptoms” of age, including but not limited to: reduction of body fat, increase of muscle mass, improvement of skin texture and libido, and increased strength and energy. The marketing documents noted that anti-aging clinics throughout the United States “came to” Respondent Pharmacy “for solutions to their age management questions.” The marketing documents bore titles such as “Turn Back the Clock,” “Adios Adipose!,” and “Live Life to the Fullest.”

29. During the relevant times, the majority of Chinese somatropin Respondent Pharmacy sold was ultimately intended for dispensing to adult consumers.

30. Within a seven-day period from approximately November 22 through 29, 2004 Respondent Pharmacy repackaged approximately 230 vials of somatropin acquired from Hawk Biopharma, for resale or other transfer.

31. Respondent Pharmacy provided an expiration date of “7/31/06” in the documentation of the vials repackaged during November 22 through 29, 2004.
32. On or around December 2, 2004, Respondents repackaged at least six vials of Chinese somatropin powder, assigned an expiration date of “2006 12” to each vial, and labeled each vial with the following: Country of Origin: China.”

33. Within a five-day period from approximately September 15 through 19, 2006, Respondent Pharmacy repackaged approximately 500 vials of somatropin acquired from “GeneScience,” for resale or other transfer.

34. Respondent Pharmacy provided an expiration date of “2/28/2008” in the documentation of the vials repackaged during September 15 through 19, 2006.

35. At times between September of 2005 and July of 2007, the Chinese somatropin described above in paragraphs 12 through 22 was one of the top-selling drugs at Respondent Pharmacy.

36. At all relevant times, Respondent Pharmacy’s method of processing the Chinese somatropin was to transfer lyophilized hGH powder from large vials into smaller vials in smaller portions for sale or other transfer under Respondent Pharmacy’s name.

37. When Respondent Pharmacy began selling Chinese somatropin in 2004, Respondent Bader instructed staff members to refer to the method of handling the Chinese somatropin as “repackaged hGH.”

38. Under Colorado law, repackaging drug products by a pharmacy constitutes manufacturing and requires registration as a manufacturer in the State of Colorado unless they are to be distributed to a location which is under the same ownership as, or is contractually affiliated with, the premises where repackaged or repackaged.

39. Respondent Pharmacy distributed the Chinese somatropin it repackaged to locations not under the same ownership as, or contractually affiliated with, the premises where Respondent Pharmacy repackaged the Chinese somatropin.

40. Repackaging by Respondent Pharmacy and distribution to locations not under the same ownership as, or contractually affiliated with, the premises where Respondent Pharmacy repackaged the Chinese somatropin, required it to be registered as a manufacturing outlet in the State of Colorado.

41. Respondent Pharmacy was not registered as a manufacturing outlet in the State of Colorado during the relevant times.

42. As pharmacist manager, Respondent Bader was responsible for the operation of Respondent Pharmacy in compliance with all state and federal laws, rules, and regulations at all times.

43. Respondent Bader, either personally or through his agents, represented to various staff members and/or employees of Respondent Pharmacy that their processing, sale and/or
distribution of Chinese somatropin did not violate any laws and that they were doing nothing wrong.

Grounds for Discipline

Count I

44. Paragraphs 1 through 43 are incorporated herein by reference.

45. Beginning in September of 2004, and continuing through approximately July of 2007, Respondents College Pharmacy and Thomas W. Bader, R.Ph. purchased Chinese somatropin that was not an FDA-approved drug, and introduced such drug into interstate commerce.

46. Purchasing a non FDA-approved drug, and introducing such drug into interstate commerce, violates 21 U.S.C. §§331 and 355, and §12-22-128(1), C.R.S.

47. Respondents violated 21 U.S.C. §§331 and 355, and §12-22-128(1), C.R.S.

48. The violations described in paragraph 47 above provide grounds for discipline pursuant to §§12-22-125(1)(c)(III) and 12-22-125(1)(k), C.R.S.

Count II

49. Paragraphs 1 through 48 are incorporated herein by reference.

50. Respondents College Pharmacy and Thomas W. Bader, R.Ph. circulated advertisements for somatropin as “treatment” for the “symptoms” of aging, including but not limited to: reduction of body fat, increase of muscle mass, improvement of skin texture and libido, and increased strength and energy, and noting that anti-aging clinics throughout the United States “came to” Respondent Pharmacy “for solutions to their age management questions,” including the availability of HGH.

51. HGH can only legally be prescribed and administered for a limited number of FDA-approved conditions, none of which includes anti-aging or the effects of aging, body-building, athletic enhancement, or any other use not approved by the FDA.

52. Circulation of advertisements such as those described above in paragraph 50 violates §12-22-125(1)(h), C.R.S.

53. Respondents violated §12-22-125(1)(h), C.R.S.

54. The violations described in paragraph 53 above provide grounds for discipline pursuant to §§12-22-125(1)(c)(I) and 12-22-125(1)(k), C.R.S.
Count III

55. Paragraphs 1 through 54 are incorporated herein by reference.

56. Respondents College Pharmacy and Thomas W. Bader knowingly distributed, and/or possessed with intent to distribute, hGH for uses in humans other than the treatment of diseases or other recognized medical conditions other than those recognized by the Secretary of Health and Human Services as approved pursuant to 21 U.S.C. §355.

57. Knowing distribution, or possession with intent to distribute, hGH for any use in humans other than the treatment of a disease or other recognized medical condition authorized by the Secretary of Health and Human Services as evidenced by approval pursuant to 21 U.S.C. §355 violates 21 U.S.C. §333(e).


59. The violations described in paragraph 58 above provide grounds for discipline pursuant to §§12-22-125(1)(c)(I) and 12-22-125(1)(k), C.R.S.

Count IV

60. Paragraphs 1 through 59 are incorporated herein by reference.

61. There is no recognized medical utility or application of somatropin or other forms of hGH for anti-aging or the effects of aging, body-building or athletic enhancement.

62. Respondents College Pharmacy and Thomas W. Bader sold, distributed and/or dispensed Chinese somatropin to persons in quantities and situations where Respondent Pharmacy knew or reasonably should have known the Chinese somatropin had no recognized medical utility or application.

63. Selling, distributing and/or dispensing any drug to any persons in such quantity or in any situation where the registrant knew or reasonably should have known the drug has no recognized medical utility or application violates Board Rule 3.00.20.

64. Respondents violated Board Rule 3.00.20.

65. The violations described in paragraph 64 above provide grounds for discipline pursuant to §§12-22-125(1)(c)(II) and 12-22-125(1)(k), C.R.S.

Count V

66. Paragraphs 1 through 65 are incorporated herein by reference.
67. Respondents College Pharmacy and Thomas W. Bader repackaged the Chinese somatropin and/or caused it to be repackaged by taking the Chinese somatropin from large vials in which it was provided by the supplier and placing it into smaller vials containing smaller amounts.

68. Respondents repackaged and distributed Chinese somatropin to a location or locations not under the same ownership as Respondent Pharmacy nor contractually affiliated with Respondent Pharmacy’s premises where the Chinese somatropin was repackaged.

69. Repackaging for distribution to a location or locations not under the same ownership as a prescription drug outlet where the repackaging occurs, nor contractually affiliated with the premises where the repackaging occurs, is prohibited pursuant to Board Rule 3.01.10.

70. Repackaging for distribution to a location or locations not under the same ownership as a prescription drug outlet where the repackaging occurs, or is contractually affiliated with the pharmacy’s premises, constitutes “manufacturing” pursuant to Board Rule 3.01.10.

71. Respondent Pharmacy was not registered as a manufacturing outlet at any relevant time.

72. Manufacturing a drug in the State of Colorado without a manufacturer’s registration violates §12-22-120, C.R.S.

73. Respondents violated §12-22-120, C.R.S. and Board Rule 3.01.10.

74. The violations described in paragraph 73 above provide grounds for discipline pursuant to §§12-22-125(1)(c)(I) and (II) and 12-22-125(1)(k), C.R.S.

**Count VI**

75. Paragraphs 1 through 74 are incorporated herein by reference.

76. Respondents College Pharmacy and Thomas W. Bader placed, and/or caused to be placed, expiration dates beyond one year from the date the Chinese somatropin was repackaged on repackaged vials of Chinese Somatropin.

77. Placing expiration dates beyond one year from the date a drug was repackaged violates §12-22-126, C.R.S. and Board Rule 3.01.20.

78. Respondents violated §12-22-126, C.R.S. and Board Rule 3.01.20.

79. The violations described in paragraph 78 above provide grounds for discipline pursuant to §§12-22-125(1)(c)(I) and (II), and 12-22-125(1)(k), C.R.S.
Count VII

80. Paragraphs 1 through 79 are incorporated herein by reference.

81. By engaging in the above-described violations of provisions of part 1 of the Pharmaceuticals and Pharmacists Act, the lawful rules of the Board, and other state and federal laws pertaining to drugs, Respondent Pharmacy violated the terms of its 2005 Stipulation.

82. Violations of the 2005 Stipulation constitute violations of a lawful Board order in violation of §12-22-125(1)(m), C.R.S.

83. Respondent violated §12-22-125(1)(m), C.R.S.

84. The violations described in paragraph 83 above provide grounds for discipline pursuant to §§12-22-125(1)(c)(I) and 12-22-125(1)(k), C.R.S.

Count VIII

85. Paragraphs 1 through 84 are incorporated herein by reference.

86. Respondent Bader, as pharmacist manager, was responsible for the operation of Respondent Pharmacy in compliance with all state and federal laws, rules, and regulations.

87. Respondent Bader failed to operate Respondent Pharmacy in compliance with all state and federal laws, rules and regulations in each instance of each violation set forth above in paragraphs 44 through 84.

88. Failure, as pharmacist manager, to be responsible for the operation of the outlet in compliance with all state and federal laws, rules and regulations violates Board Rule 7.00.30(a).

89. The violations described above in paragraph 88 provide grounds for discipline pursuant to §§12-22-125(1)(c)(I) through (III) and 12-22-125(1)(k), C.R.S.

Count IX

90. Paragraphs 1 through 89 are incorporated herein by reference.

91. By violating any statute or Board Rule, or committing any of unlawful acts set forth above in Counts I through VIII, a pharmacist violates Board Rule 1.00.11.

92. Respondent Bader violated Board Rule 1.00.11 in the instance of each of the violations set forth above in Counts I through VIII, and is subject to discipline under §§12-22-125(1)(c)(I) through (III) and 12-22-125(1)(k), C.R.S.
Count X

93. Paragraphs 1 through 92 are incorporated herein by reference.

94. By being a party or accessory to, or engaging in a fraudulent or deceitful practice or transaction in pharmacy, or knowingly participating in any practice which detrimentally affects the patient, or discredits the profession, a pharmacist violates Board Rule 1.00.12.

95. Respondent Bader violated Board Rule 1.00.12, and is subject to discipline under §§12-22-125(1)(c)(I) through (III) and 12-22-125(1)(k), C.R.S.

WHEREFORE, the Board prays for an Order revoking, suspending, or otherwise appropriately disciplining College Pharmacy’s Colorado registration as a prescription drug outlet, and Thomas W. Bader’s license to practice as a pharmacist in the state of Colorado, and for such other relief as deemed proper and just.

DATED this 14th day of October, 2007.

JOHN SUTHERS
Attorney General

[Signature]

JOANNA LEE KAYE, #20486*
JACK WESOKY, #6001*
Assistant Attorneys General
Business and Licensing Section

Attorneys for State Board of Pharmacy

1525 Sherman Street, 5th Floor
Denver, Colorado 80203
Telephone: (303) 866-6170
FAX: (303) 866-5395
*Counsel of Record