ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Settlement and Release Agreement and Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA"), and Wedgewood Village Pharmacy ("Wedgewood") (each a "Party" and collectively the "Parties").

BACKGROUND

1. Prior to this proceeding, Wedgewood had been registered with DEA since 1980 as a retail pharmacy in good standing. Wedgewood’s DEA Certificate of Registration #AW1289126 ("Registration") specifically authorized Wedgewood to dispense controlled substances in Schedules II-V from its prior location at 279-C Egg Harbor Road, Sewell, New Jersey 08080.

2. Throughout the period relevant to the Parties’ dispute, Wedgewood’s overall business generally, and its compounding of controlled substances specifically, focused primarily on supplying specially formulated medications for use with equine athletes as prescribed and administered by treating veterinarians.


4. On September 3, 2003, DEA issued an Order to Show Cause ("Order") proposing to revoke Wedgewood’s Registration on the basis of alleged compliance questions concerning the precise line separating compounding and dispensing of controlled substances (as authorized by Wedgewood’s Registration as a retail pharmacy) from manufacturing and distribution of controlled substances (as would be in excess of Wedgewood’s Registration) under the Controlled Substances Act, 21 U.S.C. § 801 et seq. ("CSA").

5. On October 16, 2003, Wedgewood via letter from its counsel timely requested a hearing in order to contest DEA’s Order on a variety of factual and legal grounds. Further, on October 21, 2003, Wedgewood submitted a written request for modification of its Registration to reflect an upcoming move to its ensuing premises. Shortly thereafter, Wedgewood relocated to its then-new and still-persisting premises at 405 Heron Drive, Suite 200, Swedesboro, New Jersey 08085-1749. Since Wedgewood’s relocation, DEA has taken the position that no modification of Wedgewood’s Registration to reflect its new facility (and corresponding authorization for Wedgewood to resume handling of controlled substances at its new facility) will be granted until this proceeding is finally resolved.
6. From 2003 through June 2006, Wedgewood disputed the allegations in the Order and sought renewal and modification of its Registration in various proceedings and petitions before DEA. On June 7, 2006, DEA’s Deputy Administrator denied Wedgewood’s request to reconsider an April 3, 2006 order revoking Wedgewood’s Registration and denying Wedgewood’s applications for renewal and modification thereof.


8. On December 11, 2007, the D.C. Circuit issued an opinion unanimously vacating DEA’s final order and remanding for new proceedings in accordance with specific instructions. See Wedgewood v. DEA, 509 F.3d 541 (D.C. Cir. 2007).

9. On February 15, 2008, DEA’s Acting Administrator remanded the case to the presiding Administrative Law Judge (“ALJ”) for proceedings following the remand.

10. On March 6, 2009, following a second administrative hearing held in August 2008, the ALJ issued a second recommended ruling and decision (“Second Recommended Decision”) recommending that the Acting Administrator revoke Wedgewood’s Registration and deny any pending applications for renewal or modification. Shortly thereafter, the Parties each filed exceptions to the Second Recommended Decision and the ALJ certified the completed record for DEA’s Acting Administrator to consider in arriving at DEA’s final order.

11. On March 3, 2010, Wedgewood filed with DEA’s Acting Administrator a motion to ascertain the status of its pending applications for renewal and modification of its Registration and any final order thereon, attaching Wedgewood’s prior, September 10, 2009, submission to like effect, and requesting an immediate ruling.

12. The Parties have concluded that avoiding the acrimony, delays and overall costs associated with continued dispute and litigation is in their mutual interests. Accordingly, the Parties are agreeing to this settlement in good faith and good will, with the understanding that the Agreement will supersede, resolve, and obviate the above-referenced proceedings and any collateral or ensuing proceedings between DEA and Wedgewood otherwise stemming therefrom, except as potentially contemplated by paragraph II.2.b of this Agreement.

STIPULATION AND AGREEMENT

In lieu of continuing to contest proceedings over Wedgewood’s Registration, Wedgewood and DEA hereby agree as follows:
I. General

1. Intention of Parties to Effect Settlement. To avoid the uncertainty, delay, acrimony and expense of litigation, and to further the Parties’ belief that settlement in this administrative matter is in the public interest, the Parties agree to settle and resolve all outstanding administrative claims and/or issues with respect to DEA’s allegations in the 2003 Order and otherwise with respect to Wedgewood’s applications for renewal and modification of its Registration. The Parties further believe – following and consistent with advice from their respective counsel, with whom each Party has consulted – that the terms and conditions of this settlement as set forth below represent a complete, just, and equitable resolution of this administrative matter.

2. No Admission or Concession. This Agreement is neither an admission by Wedgewood of liability or of the veracity of any allegation made by DEA, nor a concession by DEA that its allegations are not well-founded.

3. Covered Conduct. For purposes of this Agreement, “Covered Conduct” shall mean the conduct that occurred prior to the Effective Date of this Agreement and is alleged by DEA in the Order and in any other aspect of this proceeding, including but not limited to any allegations surrounding Wedgewood’s prior compounding, handling, and transferring of controlled substances or otherwise implicated by Wedgewood’s pending applications for renewal and modification of its Registration.

II. Terms and Conditions

1. The Parties’ Joint Agreements, Acknowledgements, and Undertakings.

   a. The Parties jointly agree and acknowledge that their competing positions in this proceeding have been held respectfully and in good faith. The parties acknowledge one another’s legal positions as set forth below, but neither Party expresses any agreement with the other Party’s stated legal positions.

   i. DEA’s core legal position has been and remains that the transfer of a controlled substance to anyone (including the prescribing practitioner) other than an “ultimate user” as that term is defined in the CSA constitutes a distribution of a controlled substance, and the compounding of controlled substances for distribution is manufacturing.

   ii. Wedgewood’s core legal position agrees with the D.C. Circuit Court of Appeals that the “scope of [statutory] terms [including] ‘distribute’ and ‘dispense’ as used in the CSA remained unsettled,” 509 F. 3d at 543; that “DEA’s view [as to the illegitimacy of “constructive transfer”] is not supported by the statutory definition,” id. at 551; and that DEA’s prohibition against “dispensing” by way of “constructive transfer” had
“failed to address the difference” between the practice of animal medicine by veterinarians as compared to the practice of human medicine by other physicians. *Id.* at 552.

b. Consistent with the Parties’ shared belief that continuing disagreement and discord would be inconsistent with their mutual interests as well as with the public interest, Wedgewood now agrees, as specified below, to comply prospectively with DEA’s position regarding the limits of proper “dispensing” authorized by Wedgewood’s preexisting Registration, just as DEA now agrees, as specified below, on the basis of this understanding to renew Wedgewood’s Registration and to modify it to reflect Wedgewood’s current location.

c. The Parties understand and expect that issues and questions may arise surrounding implementation of this Agreement, particularly (though not exclusively) over how controlled substances may be properly “dispensed” in various circumstances so as to maximize safeguards while minimizing diversion risks. To ensure there are proper channels of communications between the Parties, thereby facilitating compliance and advancing the Parties’ shared goals and understandings, each Party designates its respective point of contact.

As its point of contact, DEA designates as follows:

Barbara J. Boockholdt, Section Chief  
DEA Office of Diversion Control, Regulatory Section  
8701 Morrissette Drive  
Springfield, VA 22152  
Phone: (202) 307-7669  
Barbara.J.Boockholdt@usdoj.gov

As its point of contact, Wedgewood designates as follows:

Dan Bitler, Manager of Quality Analysis and Regulatory Affairs  
Wedgewood Pharmacy  
405 Heron Drive, Suite 200  
Swedesboro, NJ 08085  
Phone: (856) 832-1397  
dbitler@wedgewoodpharmacy.com

In the event that either Party’s designated point of contact should change while this Agreement is in effect, that Party shall promptly so notify the other Party through the respective point of contact.

d. This Agreement reflects the Parties’ understanding that the specified limitations and prohibitions hereinafter governing Wedgewood’s Registration, as to which Wedgewood is pledging itself to comply just as DEA is confirming its intention to enforce, are to be no different (that is, no greater and no lesser) from those to which any similarly-situated
compounding pharmacy will be held in connection with a controlled substances registration.

e. As soon as practicable following the Effective Date of this Agreement, the Parties shall jointly move the Acting Administrator to terminate any and all administrative proceedings and vacate the Second Recommended Decision on the basis of this Agreement and the appropriate resolution it reflects.

2. Obligations of Wedgewood.

a. Wedgewood acknowledges DEA’s statutory interpretation of the terms “dispense” and “constructive transfer” as articulated in this proceeding and shall abide by it insomuch as Wedgewood shall not transfer any controlled substances directly to other practitioners, including physicians or veterinarians, under the auspices of its Registration as a retail pharmacy authorized to dispense controlled substances, except to the extent of any limited transfer specially permitted by DEA’s “five percent,” “central fill” or other such regulations, see, e.g., 21 C.F.R. § 1307.11(a)(iv)&(b); 21 C.F.R. §§ 1300.01(43), 1306.15, 1306.27, or any separate, additional registration Wedgewood may apply for and DEA may grant generally permitting such transfers as “distributions.” Notwithstanding the “Duration of Agreement” provision in Paragraph III.1, below, Wedgewood agrees to abide by the preceding sentence in this paragraph, unless there is a change in the applicable law pursuant to rulemaking, legislative revision, judicial decision, reinterpretation, or otherwise. The Parties contemplate that, as and if questions or issues surrounding implementation of this provision arise, best efforts will be made to address them cooperatively and resolve them in good faith through communications between the Parties’ points of contact, as specified above. Notwithstanding the foregoing, Wedgewood shall not be restricted from transferring controlled substances in any greater or different degree than are comparably-situated registrants authorized to dispense. Thus, to the extent DEA’s interpretation may subsequently change pursuant to rulemaking, legislative revision, judicial decision, reinterpretation, or otherwise, Wedgewood shall be entitled to the benefit of that change and to modify its practices accordingly no less than other practitioners. Nor shall Wedgewood be restricted in any way from pursuing efforts to alter DEA’s interpretation through lawful channels including but not limited to rulemaking proceedings, lobbying, and unrelated court proceedings.

b. Any material breach by Wedgewood of Paragraph II.2.a, above, may be a basis upon which DEA can issue an Order to Show Cause seeking revocation of Wedgewood’s Registration.

c. Wedgewood shall make its specified point of contact reasonably available to field inquiries from and to provide information and input to DEA. In the event the specified point of contact is not timely available for this purpose, Wedgewood shall specify an appropriate alternative designee. In these and other respects, Wedgewood agrees to cooperate with DEA’s efforts to regulate and verify compliance to the extent consistent with all applicable rights and privileges, which Wedgewood respectfully reserves.
d. Wedgewood shall relinquish any claim or recourse it might otherwise have in connection with this proceeding and shall release DEA from any liability it might otherwise have in connection with the same, including but not limited to any claim for attorneys’ fees. Further, Wedgewood fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorneys’ fees, costs, and expenses of every kind and however denominated) which Wedgewood has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to this proceeding and the United States’ investigation and prosecution thereof.

e. Wedgewood shall maintain a typewritten or clearly legible log(s) of all controlled substances it transfers (including all distributions and dispensings) and that log(s) shall include the date, name and address of the patient/transferee and the name, dosage and quantity of the controlled substances transferred. Copies of the controlled substance log, logs, and/or prescriptions shall be submitted to Diversion Group Supervisor Thomas W. Prevoznik at DEA’s Camden Resident Office on a monthly basis for a period of three years from the Effective Date of this Agreement.

f. Wedgewood shall allow DEA personnel to enter its registered location at any time during business hours without prior notice to verify compliance with this Agreement, the Controlled Substances Act and DEA regulations, said entry to be permitted without an Administrative Inspection Warrant or some other means of entry.

3. Obligations of DEA.

a. DEA shall grant, as consistent with the public interest and 21 U.S.C. §823(f), Wedgewood’s pending applications for renewal and modification of its Registration to reflect its new facility as soon as practicable and in all events within five business days following the Effective Date of the Agreement.

b. DEA shall and does hereby withdraw the Order as being no longer necessary, and superseded by this Agreement. DEA further acknowledges that it has considered all other evidence, testimony, and submissions in connection with this proceeding, including but not limited to the investigative file, in determining that this Agreement is an appropriate resolution of the Parties’ dispute.

c. In the event that Wedgewood, which is currently registered with DEA as a pharmacy and compounds controlled substances, subsequently applies for a DEA registration as a manufacturer, which registration DEA would consider as authorization for Wedgewood to distribute controlled substances that it compounded to other practitioners such as physicians and veterinarians, DEA shall promptly consider and process such application with the express understanding that (i) any such registration is necessary in DEA’s opinion to permit Wedgewood to transfer compounded controlled substances to other DEA registrants and (ii) any such registration with DEA would be solely for purposes of
the CSA and its regulations. DEA takes no position on and does not purport to speak to Wedgewood’s status under any other statute or body of law, which is a matter between Wedgewood and the agency or department charged with administering and enforcing such other laws as distinct from the CSA and its regulations. Likewise, DEA shall promptly consider and process any ensuing applications for renewal or modification of Wedgewood’s Registration. In no event will DEA’s consideration of any application, request, or other submission by Wedgewood be prejudiced by the Covered Conduct or by this proceeding (or any aspect thereof), nor will DEA use the Covered Conduct or this proceeding (or any aspect thereof) adversely against Wedgewood for any other purpose.

d. DEA acknowledges and agrees that Wedgewood’s status as a registrant authorized to handle controlled substances under the CSA is determined by factors and definitions in the CSA and regulations promulgated by DEA, including DEA requirements that Registrants comply with applicable State law and licensing requirements. The transfer of controlled substances specifically regulated thereby, and the distinction between compounding that is manufacturing and compounding that is not manufacturing, and the distinction between dispensing controlled substances and distributing controlled substances, are likewise determined by the CSA, separate and apart from any other statute or body of law, including but not limited to the Food Drug and Cosmetic Act as administered by the Food and Drug Administration. This acknowledgement and agreement by DEA supersedes any contrary suggestions that may have arisen at earlier points in these proceedings.

e. DEA shall make its specified point of contact reasonably available to field inquiries from and to provide guidance to Wedgewood as issues and questions arise in the course of implementing this Agreement, as set out above. In the event the specified point of contact is not timely available for this purpose, DEA shall specify an appropriate alternative designee.

f. Consistent with the Parties’ acknowledgement and agreement that the limitations and prohibitions Wedgewood will be complying with and DEA will be enforcing are to be no different from those governing any similarly-situated compounding pharmacy, DEA shall promptly advise Wedgewood if and when DEA’s relevant interpretation and/or position changes for other such registrants, whereupon Wedgewood shall be entitled to the corresponding benefit of such change.

g. On the basis of this Agreement and in consideration of Wedgewood’s obligations as assumed hereunder, DEA agrees to release Wedgewood, together with its officers, directors, employees, successors and assigns (collectively, the “Released Parties”) from any administrative claims within DEA’s enforcement authority for the Covered Conduct or for any aspect of Wedgewood’s pending applications for renewal and modification of its Registration, and to refrain from filing any administrative claims against any of the Released Parties within DEA’s enforcement authority under 21 U.S.C. §§ 823, 824 and 842, on the basis of the Covered Conduct. Upon request by Wedgewood, DEA agrees to disclose the terms of this Agreement to any other law enforcement or regulatory agency.
and will represent DEA agrees that Wedgewood’s compliance with this Agreement adequately addresses all Covered Conduct along with any issues and allegations associated with this proceeding. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement and release as to any entity or person (including Wedgewood) are the following: (i) any civil, criminal or administrative liability arising under Title 26 of the U.S. Code (Internal Revenue Code); (ii) any liability to the United States (or its agencies) for any conduct other than the Covered Conduct; or (iii) any liability based upon such obligations as are created by this Agreement.

III. Miscellaneous

1. **Duration of Agreement.** The obligations contained in this Agreement shall remain in full force and effect for a period of six (6) years from the Effective Date of the Agreement, unless and until it is modified or rescinded by both Parties.

2. **Binding on Successors.** This Agreement is binding on Wedgewood, and its respective successors, heirs, transferees, and assigns.

3. **Costs.** Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

4. **No Additional Releases.** This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

5. **Effect of Agreement.** This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the Parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. Wedgewood represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. Wedgewood further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

6. **Execution of Agreement.** This Agreement shall become effective (i.e., “final and binding”) on the date of signing by the last signatory (the “Effective Date”). DEA agrees to notify Wedgewood immediately when the final signatory has executed this Agreement.

7. **Disclosure.** Wedgewood and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction.
8. **Execution in Counterparts.** This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.

9. **Authorizations.** The individuals signing this Agreement on behalf of Wedgewood represent and warrant they are authorized by Wedgewood to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant they are signing in their official capacities and that they are authorized by DEA to execute this Agreement.

10. **Choice of Law and Venue.** This Settlement Agreement shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties over the Parties’ Joint Agreements, Acknowledgements and Undertakings as specified in II.1 or DEA’s Obligations as specified in II.3 generally will be in the United States District Court or, as appropriate, in the Court of Federal Claims. This provision, however, shall not be construed as otherwise waiving or supplanting the jurisdictional provisions of the CSA.
On Behalf of Wedgewood Village Pharmacy

George Malmberg
President & CEO
Wedgewood Village Pharmacy

Dated 5/18/2010

Derek Shaffer
Co-counsel for Wedgewood
Cooper & Kirk

Dated 5/17/2010

Victoria Toensing
Co-counsel for Wedgewood
diGenova & Toensing

Dated 5/17/2010

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

Dated 05/12/2010

D. Linden Barber
Associate Chief Counsel
Diversion and Regulatory Litigation Section

Dated May 12, 2010