

## ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement (“Agreement”) is entered into by and between the United States Department of Justice, Drug Enforcement Administration (“DEA”) and Cardinal Health, Inc., (“Cardinal”) (each a “Party” and collectively the “Parties”).

### APPLICABILITY

This Agreement shall be applicable to Cardinal and all 28 Cardinal DEA registered distribution facilities.

### BACKGROUND

1. Cardinal is registered with DEA at 28 facilities as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention Act of 1970, 21 U.S.C. § 801 et seq., (“CSA” or “the Act”). See Appendix A.
2. In September 2008, Cardinal entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement (“2008 MOA”). See Appendix B.
3. Cardinal’s Lakeland distribution facility (“Cardinal Lakeland”) is registered with DEA as a distributor of Schedule II-V controlled substances at 2045 Interstate Drive, Lakeland, Florida 33805, with an expiration date of May 31, 2012.
4. On February 2, 2012, the DEA, by its Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to Cardinal Lakeland. See Appendix C.
5. The Order to Show Cause referenced above alleged, among other things, that:
  - a. Despite the 2008 MOA, Cardinal Lakeland failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels as evidenced by sales to certain customers of Cardinal;
  - b. Cardinal Lakeland failed to report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b); and
  - c. Cardinal Lakeland failed to conduct meaningful due diligence of its retail pharmacies, including its retail chain pharmacy customers to ensure that controlled substances were not diverted into other than legitimate channels.



## STIPULATION AND AGREEMENT

The facts alleged in the Order to Show Cause, as well as the facts alleged in the Government's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D, constitute grounds under which DEA could revoke the DEA registration of Cardinal Lakeland. Cardinal admits that its due diligence efforts for some pharmacy customers and its compliance with the 2008 MOA, in certain respects, were inadequate. In lieu of continuing proceedings to revoke the DEA registration of Cardinal Lakeland, Cardinal and DEA agree as follows:

### I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement in this administrative matter is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters involving the conduct described in the Order to Show Cause, as well as DEA's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D. The parties further believe that the terms and conditions of this settlement as set forth below represent a complete resolution of this administrative matter.
2. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following:
  - a. Conduct alleged in the February 2, 2012 Order to Show Cause ("Order to Show Cause"), and in DEA's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D;
  - b. Failure to maintain effective controls against the diversion of controlled substances, including failing to conduct meaningful due diligence to ensure that controlled substances were not diverted into other than legitimate channels, including failing to conduct site visits of its retail pharmacy chain customers on or before May 14, 2012;
  - c. Failure to detect and report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b) on or before May 14, 2012; and
  - d. Failure to adhere to the provisions of the 2008 MOA, on or before May 14, 2012.
3. Effect of 2008 MOA. The obligations contained in the 2008 MOA are superseded by the obligations contained within this Agreement.
4. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination.



## II. Terms and Conditions

### 1. Obligations of Cardinal.

- a. Cardinal agrees to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations. This program shall include procedures to review orders for controlled substances. Orders identified as suspicious will be reported to the DEA as discussed in subsection II.1.f. This compliance program shall apply to all current and future Cardinal distribution centers registered with the DEA in the United States and its territories and possessions. Cardinal acknowledges and agrees that the obligations undertaken in this Agreement do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.
- b. Within 120 days of the Effective Date of this Agreement, for all states, excluding Florida, Cardinal will commence procedures to ensure that any pharmacy, chain or retail, placing orders of controlled substances that are known to be diverted, or should be known to be diverted, at the time of the orders that Cardinal knows or should know are suspicious in nature, given the totality of the circumstances, will receive a site visit or an anonymous site inspection by a Cardinal employee or a qualified third-party inspector to provide an independent assessment of whether that customer's orders are being diverted. For Florida pharmacies, retail and chain, Cardinal, within 20 days of the Effective Date of this Agreement, will commence these site visit procedures. Cardinal will also employ additional field inspectors to perform investigations of Florida pharmacies.

Cardinal will review and enhance its Quality and Regulatory Affairs ("QRA") processes and practices for establishing and increasing thresholds, including thresholds for Florida retail and chain pharmacies. Under the new processes and practices, two-person concurrence will be required before increasing thresholds for higher volume customers for specific drug classes. Cardinal understands that DEA does not endorse or otherwise approve threshold procedures, and that thresholds do not necessarily determine whether an order is suspicious.

- c. Cardinal will create a Large Volume-Tactical and Analytical Committee to review and make decisions regarding higher-volume retail and chain pharmacy customers, including higher-volume pharmacies in Florida. The committee will include the SVP of QRA (chair), VP Supply Chain Integrity, Regulatory Counsel, and the Director of QRA Analytics or designated equivalent officers.



- d. Cardinal will enhance existing processes and practices for conducting due diligence reviews of pharmacies, chain and retail, including those located in Florida.
- e. On a monthly basis, Cardinal shall provide DEA Headquarters with a report of all sales transactions of controlled substances, as well as tramadol, through Electronic Data Interchange in a format mutually and reasonably agreed upon by the Parties. The data shall be due by the 15<sup>th</sup> of each month for the previous month's report. This information will be reconciled in the manner that Automation of Reports and Consolidated Orders System (ARCOS) data is reconciled. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for Cardinal's compliance with recordkeeping and reporting requirements under the CSA or applicable DEA regulations. The Parties agree that such report is not required under the CSA or DEA regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5).
- f. Cardinal shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties, except that contrary to DEA regulations, Cardinal shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters. DEA has previously notified all of the DEA Field Offices that Cardinal is not required to provide suspicious order reports or any other type of report regarding suspicious purchases of controlled substances to the DEA Field Offices. Execution of this Agreement by DEA shall waive the DEA regulatory requirements to report suspicious orders to DEA Field Offices for the duration of the Agreement.
- g. Cardinal agrees to the continued suspension of its authority to handle controlled substances at Cardinal Lakeland until May 15, 2014, so long as the provisions of II.2.c are met.
- h. Cardinal agrees that any express or implied approval by DEA of any previously implemented system to detect and report suspicious orders, is hereby rescinded and is of no legal effect with respect to Cardinal's obligations to detect and report suspicious orders in accordance with 21 C.F.R. § 1301.74(b).
- i. Cardinal's policy and procedure is to cooperate with the government in any investigation. Cardinal agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting Cardinal's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of Cardinal in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by the DEA or other law enforcement



authorities. However, nothing in this paragraph shall be construed as a waiver by Cardinal or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

- j. Any material breach by any Cardinal facility of subsections II.1.a-f of this Agreement by Cardinal after the Effective Date of this Agreement may be a basis upon which DEA can issue an Order to Show Cause seeking the revocation of Cardinal's DEA certificate of registration for that facility.
- k. Cardinal agrees that it will dismiss, with prejudice, the pending appeal by Cardinal in Case No. 12-5061 as well as the pending petition for review by Cardinal in Case No. 12-1126 in the United States Court of Appeals for the District of Columbia Circuit. Cardinal agrees that it will also dismiss, with prejudice, Case No. 12-cv-185 in the United States District Court of the District of Columbia.

2. Obligations of DEA.

- a. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as required under 21 C.F.R. § 1301.74(b) and as described in subsection II.1.g. of this Agreement. DEA agrees to waive the regulatory requirement to report suspicious orders of controlled substances to the DEA Field Offices.
- b. In the event that DEA discovers information that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider Cardinal's entry into this Agreement; all actions taken by Cardinal pursuant to this Agreement; any remedial actions taken by Cardinal to address the alleged or perceived violative conduct; and the compliance history of Cardinal at the particular facility, and at other Cardinal facilities.
- c. If Cardinal is in compliance with the terms of this Agreement, DEA agrees that it will take appropriate steps to lift the suspension of Cardinal Lakeland's DEA registration and, if needed, to grant any requisite registration renewal on May 14, 2014.

3. Joint Obligations of the Parties.

- a. Cardinal and DEA agree that upon the execution of this Agreement, DEA and Cardinal shall file a joint motion with the DEA Administrative Law Judge to terminate all pending administrative proceedings against Cardinal Lakeland in *The Matter of Cardinal Health*, DEA Docket No. 12-32.

4. Release by DEA. (i) In consideration of the fulfillment of the obligations of Cardinal under this Agreement, DEA agrees to:



- a. Release Cardinal, together with its subsidiary entities, distribution facilities, and registrants that are listed in Appendix A, along with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 for the conduct alleged in the Order to Show Cause, DEA's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D, and for the conduct alleged in this Agreement; and
- b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct, only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of May 14, 2012, and the review of the reports and records Cardinal submitted to DEA prior to May 14, 2012. This release applies only to administrative actions brought before or by the Agency.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-covered conduct. Further, nothing in this Paragraph shall prohibit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct and DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action, or proceeding involving the Covered Conduct. DEA expressly reserves the right to pursue civil action, through the United States Attorney's Office, against Cardinal for the "Covered Conduct" as described in this Agreement. At Cardinal's request, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming Cardinal is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

5. Release by Cardinal. Cardinal fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Cardinal 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 the Covered Conduct and the United States' investigation and prosecution thereof.

6. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Cardinal) are the following:



- a. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any liability other than administrative claims released in Paragraph II.4.a. and b.;  
or
- c. Any liability based upon such obligations as are created by this Agreement.

### III. Miscellaneous

1. Binding on Successors. This Agreement is binding on Cardinal, and its respective successors, heirs, transferees, and assigns.
2. 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.
3. 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.
4. 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. Cardinal represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. Cardinal further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.
5. 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"). The government agrees to notify Cardinal immediately when the final signatory has executed this Agreement.
6. Notices. All communications and notices to Cardinal pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by Cardinal providing written notification to DEA:
  - a. Gilberto Quintero, Senior Vice President, Supply Chain Integrity and Regulatory Operations, 7000 Cardinal Place, Dublin, Ohio 43017; fax: 614-757-6597; email: gilberto.quintero@cardinalhealth.com;
  - b. With copy to: Steve Falk, Executive Vice-President and General Counsel, 7000 Cardinal Place, Dublin, Ohio 43017, fax: 614-652-7325; email: steve.falk@cardinalhealth.com.



7. Disclosure. Cardinal 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 Cardinal represent and warrant that they are authorized by Cardinal to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.
10. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement 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 this Agreement will be the United States District Court or, as appropriate, in the Court of Federal Claims, in which the Cardinal distribution facility at issue is located. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the Controlled Substances Act.

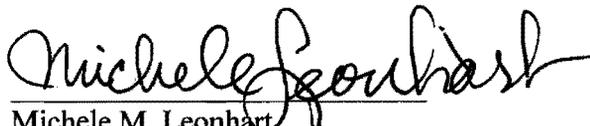
IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement.

**On Behalf of Cardinal Health:**

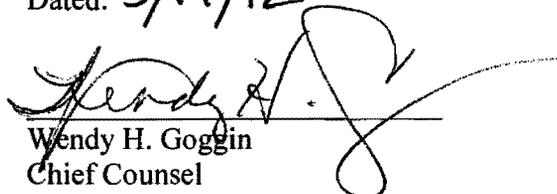
\_\_\_\_\_  
Craig S. Morford  
Chief Legal and Compliance Officer

Dated:

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

  
\_\_\_\_\_  
Michele M. Leonhart  
Administrator

Dated: 5/14/12

  
\_\_\_\_\_  
Wendy H. Goggin  
Chief Counsel

Dated: 5/14/12

