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DEA Suspends for Two Years Pharmaceutical Wholesale Distributor's Ability to Sell Controlled Substances from Lakeland, Florida Facility

May 15 (Arlington, VA) – The Drug Enforcement Administration (DEA) announced today a settlement agreement with Cardinal Health, a pharmaceutical wholesale distributor headquartered in Dublin, Ohio, that suspends for two years its ability to sell controlled-substance (CS) medications from its Lakeland, Florida, distribution facility. The settlement also includes a signed Administrative Memorandum of Agreement (MOA), the terms of which will apply to all of Cardinal’s 28 registered distribution facilities.

In the agreement, Cardinal admits that it’s due diligence efforts for some pharmacy customers and its compliance with an earlier MOA signed in 2008 for similar violations at the same facility were, in certain respects, inadequate. The terms of the agreement of this settlement represent a complete resolution of this administrative matter; however, the MOA expressly reserves the right for DEA to pursue civil penalties. The obligations in this MOA remain in full force and effect for a period of five years unless DEA agrees in writing to an earlier termination.

“The Drug Enforcement Administration is committed to battling the prescription drug abuse epidemic in this country at all levels, from corporate America to pill mills. Regardless of the size of a company or its profitability, organizations that fail to prevent the diversion of powerful controlled substances will be held accountable,” said Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control. “Cardinal Health is not above the law, and with this agreement it admits that it neglected its vital responsibility to prevent the diversion of controlled substance medications.”

On February 3 of this year, DEA’s Miami Field Division served an Immediate Suspension Order (ISO) against Cardinal Health’s distribution center at 2045 Interstate Drive in Lakeland, Florida, alleging that this distribution center failed to maintain effective controls against the diversion of controlled substances, specifically oxycodone. In just three years, Cardinal’s Lakeland center supplied more than 12 million dosage units of oxycodone, a highly addictive, powerful painkiller, to four area pharmacies. Over the past several years, Florida has been at the epicenter of the nationwide prescription drug abuse epidemic. Various illicit schemes operating in Florida, and those who supply them, have been responsible for the diversion of millions of dosage units of prescription drugs containing oxycodone or hydrocodone that are in turn redistributed along the entire eastern seaboard and parts of the Midwest.

The February 3 ISO was not DEA’s first action against Cardinal’s Lakeland facility. In December 2007, DEA issued an ISO at the location as a result of its distribution of hydrocodone to ‘rogue’ internet pharmacies. That action, and similar actions at other Cardinal Health facilities across the United States, resulted in a $34 million fine. Since October 2008, Cardinal Health has been operating under an Administrative Memorandum of Agreement (MOA) with the DEA that requires Cardinal Health to “maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the Controlled Substances Act and applicable DEA regulations.” The February 3 action was based, in part, on Cardinal’s failure to live up to the terms of the 2008 MOA. More details regarding the previous cases against Cardinal Health can be found at www.DEA.gov.

The covered conduct in the agreement includes:

- 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;
- Failure to detect and report suspicious orders of controlled substances as required by the CSA, on or before May 14, 2012; and
- Failure to adhere to the provisions of the 2008 MOA, on or before May 14, 2012.

http://www.justice.gov/dea/pubs/pressrel/pr051512.html
DEA agrees to release Cardinal and its subsidiaries, distribution facilities and registrants listed in the agreement from any administrative claims within DEA's enforcement authority for the Covered Conduct in this agreement prior to the effective date of this agreement. However, conduct other than that covered in the agreement, or any conduct afterward, is subject to administrative claims within DEA's enforcement authority. Again, this agreement does not preclude DEA from pursuing civil penalties.

Actions and agreements such as the February 3 ISO and the May 14 MOA are part of the continuing efforts by the DEA's Office of Diversion Control and the agency's field divisions to combat the prescription drug abuse epidemic in the U.S.

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