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STATE OF NEW JERSEY DEPARTMENT OF LAW AND PUBLIC SAFETY DIVISION OF CONSUMER AFFAIRS

IN THE MATTER OF

CVS-CHATHAM NJ CDS REG. NO. DO5649500 PERMIT NO. 28RS00464700 Administrative Action

ORDER

This matter was opened to Thomas R. Calcagni, Director of the New Jersey Division of Consumer Affairs (the "Director"), upon receipt of information that a CVS pharmacy located at 471 Main Street in Chatham, New Jersey ("CVS-Chatham"), has publicly acknowledged that it improperly dispensed the breast cancer fighting drug Tamoxifen instead of chewable 0.5 mg fluoride tablets to children in as many as 50 families. This improper dispensing allegedly occurred between December 1, 2011, and February 20, 2012.

WHEREAS, the Director has received and reviewed information, including statements made by CVS in a press release, admitting that medications were dispensed which were not prescribed and that CVS was in the process of contacting every family whose child was dispensed a 0.5 mg fluoride prescription from the CVS-Chatham location within the past sixty days; and

WHEREAS, the Director finds it to be in the public interest to inquire further into any violation of the New Jersey Statutes and Regulations regarding the handling of all pharmaceutical agents in accordance with <u>N.J.S.A.</u> 45:1-18; and

WHEREAS, the Director finds that CVS-Chatham's admitted improper dispensing of medications to children over an extended period of time reflects adversely on CVS' reliability and integrity with respect to the maintenance and control of Controlled Dangerous Substances pursuant to <u>N.J.S.A.</u> 24:21-12; and for good cause shown:

IT IS ON THIS 2nd DAY OF MARCH 2012 ORDERED:

1. The holder or holders of the Controlled Dangerous Substances ("CDS") registration assigned to the CVS pharmacy located at 471 Main Street in Chatham, N.J. ("CVS-Chatham"), shall cease and desist from any and all violations of the New Jersey statutes and regulations governing the handling of all medications, both CDS and PLD, in the State of New Jersey. They shall also take all reasonable steps necessary to ensure that no future violations occur.

2. The corporate holder or holders of the New Jersey CDS registration assigned to the CVS-Chatham pharmacy and all other persons with direct, relevant knowledge of the improper dispensing and investigation thereof shall appear and submit to an inquiry under oath by the Director or his designee on March 9, 2012 at 10:00 a.m.

3. Prior to this inquiry under oath, and no later than 5:00 p.m. on March 7, 2012, the individuals directed to appear pursuant to paragraph 2 shall produce certified true copies of the following:

-All communications, complaints, emails, telephone calls, and information received by or on behalf of CVS from individuals who believe they received Tamoxifen instead of 0.5 mg Fluoride in prescriptions filled by CVS-Chatham.

-All documentation pertaining to the reported improper dispensing of Tamoxifen and 0.5 mg Fluoride at CVS-Chatham, including notices sent to customers and prescribers,

communications between the pharmacy and corporate headquarters, telephone scripts for any such communications, internal quality control assurance, audit trails, and investigative documents.

-Any and all manuals containing policies and procedures which address the security and quality control procedures, including inventory controls, in place and pertaining to the handling and/or dispensing of Prescription Legend Drugs (PLD) and Controlled Dangerous Substances (CDS) at CVS-Chatham.

-All inventory receipts for both Tamoxifen and 0.5 mg Fluoride delivered to CVS-Chatham from December 1, 2011, through March 1, 2012 as documented in an audit trail.

-All documents and other items pertaining to the investigation of CVS-Chatham's handling of both PLD and CDS and the reported commingling of Tamoxifen and Fluoride from that location.

-All documents pertaining to the corrective actions taken by CVS after the reported commingling of Tamoxifen and Fluoride from the CVS-Chatham location.

-The names, license or registration number and contact information for all employees of the CVS-Chatham from December 1, 2011, through March 1, 2012.

-All original prescriptions reflecting prescriber directions to dispense either Tamoxifen or 0.5 mg Fluoride from CVS-Chatham from December 1, 2011, through March 1, 2012.

-The name and contact information for all persons who submitted prescription for either Tamoxifen or 0.5 mg Fluoride from CVS-Chatham from December 1, 2011, through March 1, 2012 whether or not dispensed to the customer.

-Any and all directives issued by CVS to other pharmacies in New Jersey regarding the reported commingling of Tamoxifen and Fluoride from CVS-Chatham. -All reported instances of the commingling of prescription medications in CVS stores in the State of New Jersey for the last twelve months.

-Any and all additional documents that the Director may later deem necessary for a full and complete investigation into the legality and propriety of the conduct on the registered premises and of all individuals involved.

4. A copy of this Order shall be immediately served upon the corporate holder or holders of CVS-Chatham pharmacy permit via service at the address of record with the State Board of Pharmacy and/or electronic delivery sufficient to ensure receipt of same; and

5. The entry of this Order is without prejudice to further action or investigation by the Drug Control Unit of the Division, the New Jersey State Board of Pharmacy, the Attorney General, or any other law enforcement entity.

NEW JERSEY DIVISION OF CONSUMER AFFAIRS By: Thomas R. Calcagni, Director