

U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
300 River Place, Suite 5900
Detroit, MI 48207

Telephone: (313) 393-8100 Fax: (313) 393-8139 www.fda.gov

February 19, 2019

UPS NEXT DAY SIGNATURE REQUIRED

Curtis D. Rising, PharmD.

Owner

CSRX Inc., dba Rushmore Compounding Pharmacy
1308 Mount Rushmore Road

Rapid City, SD 57701-3667

Dear Dr. Rising:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, CSRX Inc., dba Rushmore Compounding Pharmacy, located at 1308 Mount Rushmore Road, Rapid City, South Dakota 57701-3667, from July 12, 2016, to July 15, 2016, by the U.S. Food and Drug Administration (FDA).

When the Agency concludes that an inspection is "closed" under 21 C.F.R. 20.64(d)(3), it will release a copy of the EIR to the inspected establishment.

The Agency continually works to make its regulatory process and activities more transparent for regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 C.F.R. Part 20. This, however, does not preclude you from requesting and possibly obtaining any additional information under FOIA.

If there is any question about the released information, please contact Brian D. Garthwaite, Ph.D., Compliance Officer, at (612) 758-7132 or by email at: ORAPHARM3_RESPONSES@fda.hhs.gov.

Sincerely,

Nicholas F. Lyons -S Digitally signed by Nicholas F. Lyons -S DN: c=US, o=US. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300120033, cn=Nicholas F. Lyons -S Date: 2019.02.19 11:01:06 -06'00'

Nicholas F. Lyons Compliance Director Division of Pharmaceutical Quality Operations III

Enclosures: EIR, Microsoft Advisory Notice