

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

June 4, 2020

## UPS NEXT DAY SIGNATURE REQUIRED

Anne Marie Megibben Catherine B. Hance Co-Owners Compound Care Pharmacy LLC 12121 Shelbyville Road Suite 107 Louisville, KY 40243-1094

## Dear Ms. Megibben and Ms. Hance:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Compounding Care Pharmacy LLC, located at 12121 Shelbyville Rd., Suite 107, Louisville, KY 40243-1094, from May 13, 2019, to May 16, 2019, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the Kentucky State Board of Pharmacy for follow up.

When the Agency considers an inspection to be "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 Russell Riley, Compliance Officer, at 630-323-2763 x. 101.

Sincerely,

## Nicholas F. Lyons -S

Digitally signed by Nicholas F. Lyons -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300120033, cn=Nicholas F. Lyons -S Date: 2020.06.04 09:05:43 -05'00'

Nicholas F. Lyons Director, Compliance Branch Division of Pharmaceutical Quality Operations III Office of Regulatory Affairs U.S. Food and Drug Administration

Enclosure: Redacted first party EIR, SRL

Cc: Kentucky State Board of Pharmacy (cover letter only)

Attn: Larry Hadley, Executive Director State Office Building Annex, Suite 300

125 Holmes St. Frankfort, KY 40601