



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

October 29, 2019

UPS NEXT DAY
SIGNATURE REQUIRED

Michael C. Fieri
Chief Executive Officer
Orsini Pharmaceutical Services, Inc. dba Orsini Healthcare
1111 Nicholas Blvd.
Elk Grove Village, IL 60007-2516

Dear Mr. Fieri:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Orsini Pharmaceutical Services, Inc. dba Orsini Healthcare, located at 1107 Nicholas Blvd., Elk Grove Village, IL 60007-2516, from July 17, 2018, to July 25, 2018, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation, Illinois Board of Pharmacy for follow up.

When the Agency concludes that an inspection is “closed” under 21 CFR 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 CFR 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 Nicholas Lyons at (312) 596-4220 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=U.S. Government,
ou=HHS, ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=130012003
3, cn=Nicholas F. Lyons -S
Date: 2019.10.29 13:51:17 -05'00'

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