



U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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April 22, 2020

Deborah McHugh
Director, Quality Assurance
Fresenius Kabi Compounding, LLC
20 Dan Road
Canton, MA 02021-2809

Dear Deborah McHugh

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Fresenius Kabi Compounding, LLC, located at 20 Dan Road, Canton, MA 02021-2809, from November 7, 2018, to December 4, 2018 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 CDR James Mason, via email at james.mason@fda.hhs.gov or by phone at (570) 262-0519.

Sincerely,

Stephanie T. Durso -S

Digitally signed by Stephanie T. Durso -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=1300194209,
cn=Stephanie T. Durso -S
Date: 2020.04.22 14:40:07 -04'00'

Stephanie Durso
Compliance Branch Director
OPQO Division I
New Jersey District Office

Enclosure: EIR

Cc: MA State Board of Pharmacy (cover letter only)
239 Causeway St., 5th Floor, Suite 500, Boston, MA 02114
Email: pharmacy.admin@massmail.state.ma.us

Office of Pharmaceutical Quality Operations, Division of Pharmaceutical Quality Operations I

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