

June 4, 2020

Via Electronic Mail

Melanie S. Maxwell, Pharmacist-in-Charge Mills Pharmacy at McCalla 4750 Eastern Valley Rd. McCalla, Alabama 35111

Ms. Maxwell:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Mills Pharmacy at McCalla, located at 4750 Eastern Valley Road, McCalla, Alabama 35111, from January 21, 2020 to January 24, 2020, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the Alabama 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 Mark Rivero, Compliance Officer, at (504) 846-6103, or by email at <u>Mark.Rivero@fda.hhs.gov</u>.

Sincerely,

John W. Diehl -S3 0.9.2342.19200300 Date: 2020.06.04 1-

CDR John W. Diehl Director, Compliance Branch Office of Pharmaceutical Quality Operations, Division II

U.S. Food & Drug Administration Office of Pharmaceutical Quality Operations, Division II 4040 N. Central Expressway, Suite 300 Dallas, Texas 75204 www.fda.gov