

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

March 4, 2020

<u>UPS NEXT DAY</u> SIGNATURE REQUIRED

Gregory M. Killmeier Operations Manager & Pharmacist in Charge Nutrishare Inc. 11020 Plantside Drive Louisville, KY 40299-6105

Dear Mr. Killmeier:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, Nutrishare Inc., located at 11020 Plantside Drive, Louisville, KY 40299-6105, from July 16, 2018, to July 26, 2018, 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 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 Compliance Officer, Brian Garthwaite 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=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300120033 ,cn=Nicholas F. Lyons -S Date: 2020.03.04 13:35:44 -06'00'

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

Enclosure: Redacted 1st party EIR, State Referral Letter

cc: FMD-145 cover letter only

Larry A. Hadley
Executive Director
Kentucky Board of Pharmacy
State Office Building Annex, Suite 300
125 Holmes Street
Frankfort, KY 40601