DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

January 3, 2020

Ramin (Ron) Najafi, Ph.D.
President and CEO
Emery Pharma
1000 Atlantic Ave, Ste 110
Alameda, CA 94501

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA take the following two actions described below:

1) Request a recall and suspend sale of all lots of all products containing ranitidine. Given ranitidine's propensity to deteriorate at elevated temperatures to the probable carcinogen NDMA, the drug is misbranded under Section 502 of the FDCA (21 U.S.C. § 352(h));
2) Conduct examinations and investigations under Section 702 (a) of the FDCA (21 U.S.C. § 372(a)) regarding ranitidine products, specifically stability assessment and the manufacturer submissions made for FDA approval under 704(a) of the FDCA (21 U.S.C. § 374(a));
3) Provide information to the public regarding the high temperature instability of ranitidine products under Section 705(b) of the FDCA (21 U.S.C. § 375(b));
4) In addition to the instructions for disposal and/or return in the recall notices, issue additional guidance to the public for the safe disposal of ranitidine, given the recognized potential that the drug may degrade to form the probable carcinogen NDMA in municipal wastewater treatment plants and impact the public water supply as was cited in the September 9 Citizen Petition
5) Issue a directive to the manufacturers of ranitidine products to conduct a thorough stability assessment of the compound towards formation of NDMA, both in drug substance and drug product forms
6) Issue a directive to the manufacturers and distributors to ship ranitidine products in temperature-controlled vehicles;
7) Issue a directive to the manufacturers to clearly label ranitidine products with a warning, such as: "by-products that are probable carcinogens can be generated if exposed to heat;" and
8) In the interest of public safety, require that ranitidine-containing products be moved behind the counter and dispensed by "prescription only" and ideally tested for NDMA or otherwise assessed for heat exposure (as with a temperature-indicator label) at the dispensing pharmacy and not just at the manufacturing site.

This petition was received by this office on 01/02/2020 and it was assigned docket number FDA-2020-P-0042. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby

Digitally signed by Dynna Bigby
Date: 2020.01.03 11:25:35 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of Operations (OO)