DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

October 28, 2019

Areta Kupchyk
Foley Hoag LLP
155 K Street, NW
Washington, DC 20006-5350

Sent via email to: akupchyk@foleyhoag.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the following:

1) Determine that standards for identity are needed for proposed generic versions of VELPHORO® that change the starches used in the sucroferric oxyhydroxide active ingredient.

2) Set standards for identity that require a sponsor of an ANDA for a generic version of VELPHORO® with such changes to show active ingredient sameness by submitting:

    1. Evidence of physicochemical equivalence;
    2. Evidence of equivalence from in vitro assays;
    3. Evidence of equivalence from limited in vivo and genotoxicity studies.

Your submission was received by this office on 10/25/2019, and it was assigned docket number FDA-2019-P-5008. 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,

Karen Malvin Digitally signed by Karen Malvin
Date: 2019.10.29 12:33:49 -04'00'

Karen Malvin
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)