DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

July 2, 2019

Kristen Gullo
VP, Development & Regulatory Affairs
US WorldMeds
4441 Springdale Rd.
Louisville, KY 40241

Dear Petitioner:

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

1. that the Commissioner require that any ANDA referencing APOKYN seek approval of both the drug and device constituent parts of APOKYN.

2. you also requested, that the Commissioner establish a policy framework clarifying the circumstances, if any, under which the drug constituent part of a generic drug device combination product can be approved in an ANDA that does not also seek approval of the device constituent part.

The citizen petition was received by this office on 07/01/2019, and was assigned docket number FDA-2019-P-3192. Please refer to this docket number in future correspondenceon 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: 2019.07.03 10:16:50 -04'00'

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