DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

December 26, 2019

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

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA require that any abbreviated new drug application (ANDA) referencing APOKYN seek approval of both the drug and device constituent parts of APOKYN and the FDA also 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 seek approval of the device constituent part was received by this office on 12/23/2019.

It was assigned docket number FDA-2019-P-6049. 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: 2019.12.30 12:48:11 -05'00'

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