



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 17, 2020

Blessy Johns
Aurolife Pharma LLC
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Sent via email to: bjohns@aurobindousa.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to designate the approved "Lidocaine Hydrochloride Jelly 2% (ANDA # 040433) of Akron Inc.", as a new Reference Standard, upon which ANDA applicant can rely for purpose of development and bioequivalence testing required for ANDA filing was received by this office on 09/16/2020.

It was assigned docket number FDA-2020-P-1914. 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 and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

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