November 11, 2020

To,
Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION – WITHDRAWAL REQUEST
(Ref. FDA docket no. FDA-2020-P-1914)

Dear Sir/Madam,

The undersigned ('petitioner') wish to inform the agency that Aurobindo Pharma Limited had submitted a Citizen Petition (vide docket no. FDA-2020-P-1914, dated Sept. 16, 2020) electronically under Section 505(j) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 10.25(a), 10.30 and 314.93, to request the Food and Drug Administration to **designate** approved generic product, "Lidocaine Hydrochloride Jelly 2% (**ANDA # 040433) of Akron Inc.**" **as a new Reference Standard (RS**), upon which ANDA applicant can rely for the purpose of development and bioequivalence testing to support ANDA filing for Lidocaine Hydrochloride Jelly 2%.

Reference is made to the recently published FDA Final guidance, "***Referencing Approved Drug Products in ANDA Submissions (October 2020)",*** where there is a change in the procedure "for requesting designation of a suitable alternate reference standards". As per current FDA guidance, an applicant can submit a controlled correspondence to the agency to request for designation of a suitable alternate reference standards instead of filing a Citizen Petition to the agency. In ***section III.* C.3** of this guidance following information is provided:

> *"There are circumstances in which a potential ANDA applicant may ask FDA to select a reference standard. These circumstances include, for example, if FDA has not selected a reference standard, if a reference standard is moved to the Discontinued Section and FDA has not selected a new reference standard for the same drug product, if a potential ANDA applicant believes a reference standard other than the one selected by FDA is appropriate, or if the quantity of the reference standard in distribution is so limited that a potential ANDA applicant is not able to obtain a sufficient quantity for in vivo*

bioequivalence testing. ***A potential applicant may submit controlled correspondence to FDA to ask FDA to select a reference standard for a drug product.*** *If the Agency selects a new reference standard, that product generally will remain the reference standard even if the original reference standard resumes marketing".*

In lieu of the above, Aurobindo Pharma Limited is **withdrawing the Citizen Petition, docket no. FDA-2020-P-1914** submitted on Sept. 16, 2020 and request the agency to provide an acknowledgement letter for the same.

Sincerely yours,

Blessy Johns

Digitally signed by Blessy Johns
DN: c=US, st=New Jersey, l=Dayton, o=Aurobindo Pharma USA, Inc., cn=Blessy Johns, email=bjohns@aurobindousa.com
Date: 2020.11.11 16:01:12 -05'00'

Blessy Johns
US Agent for Aurobindo Pharma Limited

Contact details of US agent:
Aurobindo Pharma USA, Inc.,
279 Princeton-Hightstown Road,
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Encl.: FDA acknowledgement letter for Citizen Petition [FDA-2020-P-1914]

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)