



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Silver Spring MD 20993

July 17, 2019

John Schultz  
President  
Oxford Pharmaceuticals, LLC  
301 Leaf Lake Parkway  
Birmingham, AL 35211

*Sent via email to:* [jschultz@oxford-rx.com](mailto:jschultz@oxford-rx.com)

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA determine and declare that the drug product, Baclofen Tablets, USP, 15mg, is suitable for submission in a supplemental Abbreviated New Drug Application ("sANDA") was received by this office on 07/16/2019.

It was assigned docket number FDA-2019-P-3423. 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  
Supervisory Administrative Proceedings Specialist  
Division of Dockets Management  
FDA/Office of Operations (OO)