

October 22, 2019

VIA ELECTRONIC SUBMISSION

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5360 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Withdrawal of Petition; Docket No. FDA-2019-P-4507

Dear Sir or Madam:

Petitioner requests withdrawal of the above-referenced citizen petition requesting to designate an additional Reference Standard (RS) status for Oxybutynin Chloride Extended Release Tablets 15 mg, specifically the ANDA held by Accord Healthcare Inc. (ANDA No. 207138). FDA has already designated this product as the RS for the above mentioned product. Consequently, a formal response to Docket No. FDA-2019-P-4507 is no longer necessary.

Sincerely yours,



David L. Rosen, B.S. Pharm., JD