



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

October 8, 2019

Robert E. Dudley, PhD
President & CEO
Clarus Therapeutics, Inc.
555 Skokie Boulevard, Suite 340
Northbrook, IL 60062

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner establishes clear, written guidance regarding the safety and efficacy standards required for oral testosterone-ester prodrugs as testosterone ("T") replacement therapy for adult men with a deficiency or absence of endogenous T was received by this office on 10/02/2019.

It was assigned docket number FDA-2019-P-4644. 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 Officer
Dockets Management Staff
FDA/Office Operations (OO)