DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

February 21, 2019

Jin Chon
Takeda Pharmaceuticals U.S.A., Inc.
One Takeda Parkway
Deerfield, IL 60015

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner require that the labeling for any drug product that is either (1) the subject of an abbreviated new drug application (ANDA) for which TRINTELLIX is the reference listed drug (RLD), or (2) a section 505(b)(2) application that relies upon TRINTELLIX, include the information from the TRINTELLIX labeling regarding the association between vortioxetine and sexual dysfunction was received by this office on 02/20/2019.

It was assigned docket number FDA-2019-P-0837. 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 Gorham-bigby -S
Digitally signed by Dynna Gorham-bigby -S
Date: 2019.02.21 11:06:28 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)