

December 2, 2020

Tiffany R. Farchione, M.D
Office of Neuroscience
Acting Director, Division of Psychiatry Products
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring,
Building 22, Suite 4200, MD 20993

Re: NDA 207960, Sequence 0360

**QUILLICHEW[®] ER (METHYLPHENIDATE HYDROCHLORIDE) EXTENDED-
RELEASE CHEWABLE TABLETS**

RESPONSE TO PREA NON-COMPLIANCE LETTER

Dear Dr. Farchione

Reference is made to the Approval Letter for New Drug Application (NDA) 207960 for QuilliChew ER (methylphenidate hydrochloride) chewable tablets approved December 04, 2015 and to Investigational New Drug Application IND 111020. Reference is also made to the October 6, 2020 notification of non-compliance with PREA for not having submitted a pediatric assessment for post marketing requirement PMR 3009-2, received October 21, 2020. This submission includes a formal written response to the PREA non-compliance letter.

NextWave Pharmaceuticals, Inc., a subsidiary of Tris Pharma Inc. has requested a waiver to conduct the post marketing requirement studies PMR 3009-2 and 3009-3. A response to the justified waiver request submitted on November 3, 2020 is awaited.

This electronic submission has been scanned for viruses (see the Electronic Submission Specifications below) and is being sent via ESG.

Please forward any written communications and any questions or comments regarding this application to the undersigned at csax@trispharma.com and to TrisRA@trispharma.com or telephone (732) 355-7027.

Sincerely,

**Carol R.
Sax**

Digitally signed by Carol R.
Sax
Reason: I am the author of
this document
Date: 2020.12.02 12:16:01
-05'00'

Carol R. Sax
Director, Regulatory Affairs

Cross-reference IND 111020

Electronic Submission Specifications

This submission is compliant with FDA's Guidelines for Industry and current eCTD Specifications

All files were checked and verified to be free of viruses prior to transmission through the electronic submission gateway.

Anti-Virus Program	Trend Micro Security Standard AntiVirus Software
Program Version	20.0.2087
Virus Definition Date	December 2, 2020
Submission Size	Approximately 3 MB

The Technical point of contact for this submission is:

Name	Myrna Carrillo-Rau
Phone Number	(732) 732-8245
Email Address	mcarrillorau@trispharma.com