

July 26, 2024

Tiffany R. Farchione, MD
Director, Division of Psychiatry
Office of Neuroscience
Center for Drug Evaluation and Research
Food and Drug Administration
Attn: Document Control Room
10903 New Hampshire Avenue, Silver Spring,
Building 22, Suite 4200, MD 20993

Re: NDA 207960, Sequence 0610

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 June 13, 2024, notification of non-compliance with PREA for not having submitted a pediatric assessment for post marketing requirement PMR 3009-2. This submission includes a formal written response to the PREA non-compliance letter.

In response to the non-compliance letter, NextWave Pharmaceuticals, Inc., a subsidiary of Tris Pharma Inc., has submitted a deferral extension request to conduct the post marketing requirement studies PMR 3009-2 and 3009-3. The deferral request includes the reason for the delayed pediatric assessment and the dates by which we expect to submit the assessments.

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 TrisRA@trispharma.com or telephone (732) 355-7027.

Sincerely,

Marc Lesnick

Digitally signed by Marc
Lesnick
Date: 2024.07.26 15:09:51
-04'00'

Marc Lesnick, PhD
Chief Development Officer

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	20.0.2211
Virus Definition Date	July 26, 2024
Submission Size	Approximately 3 MB

The Technical point of contact for this submission is:

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