



Stephen Joel Coons, PhD
Executive Director, PRO Consortium
Critical Path Institute
1730 E. River Road
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Email: SJCoons@c-path.org

November 27, 2017

Dear Dr. Coons,

On behalf on the qualification review team, in reference to your qualification review package submitted March 28, 2017 for Symptoms for Major Depressive Disorder Scale (SMDDS), we have qualified the SMDDS for exploratory use. Attached you will find the qualification statement for the SMDDS, which describes the SMDDS and its qualified context of use.

If you have any questions, please contact the COA Staff via email at coaddtqualification@fda.hhs.gov. Please reference DDT #000008.

Sincerely,

Elektra J.
Papadopoulos -S
Elektra Papadopoulos, MD, MPH
Associate Director
Clinical Outcome Assessments Staff
Office of New Drugs
Center for Drug Evaluation and Research

Digitally signed by Elektra J. Papadopoulos -S
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ou=FDA, ou=People,
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cn=Elektra J. Papadopoulos -S
Date: 2017.11.27 11:58:32 -05'00'

Mitchell V.
Mathis Jr -S
Mitchell Mathis, MD
Director
Division of Psychiatry Products (DPP)
Office of New Drugs
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