DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

TO: Docket FDA-2018-N-2986

FROM: Heather Buck, Division of Pediatric and Maternal Health

SUBJECT: Notice of data availability and announcement of open public comment period

APPLICATION: IND 073884

DRUG: Lithium

SPONSOR: Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

INDICATION: Acute and maintenance treatment for pediatric bipolar disorder

PURPOSE: To open Public Docket FDA-2018-N-2986 and announce the 30-day open public comment period for the pediatric studies of lithium that were conducted in accordance with section 409I of the PHS Act and submitted to NIH and FDA.

BACKGROUND:
Section 409I of the Best Pharmaceuticals for Children Act (BPCA) requires the National Institutes of Health (NIH) in collaboration with FDA and experts in pediatric research, develop and publish a priority list of therapeutic areas in critical need of pediatric research. These data are to be submitted to FDA for consideration for labeling changes. The coordination of this work was delegated to NICHD. FDA and NICHD prioritized lithium as a drug in need of improved pediatric labeling under this BPCA prioritization process.

NICHD sponsored two multi-phase lithium studies and final clinical study reports were submitted to IND 73822 on November 12, 2015 (COLT1) and December 11, 2015 (COLT2) and are currently under FDA review for consideration of improved pediatric labeling.

SUMMARY OF STUDIES:
NCT00442039 (COLT1): Pediatric Pharmacokinetic and Tolerability Study of Lithium for

the Treatment of Pediatric Mania Followed by an Open Label Long-Term Safety Period, Discontinuation Phase, and Re-stabilization Period.

NCT01166425 (COLT2): A Randomized, Double-Blind, Placebo Controlled Study of the Efficacy of Lithium for the Treatment of pediatric Mania Followed by an Open Label Long-Term Safety Period, Double-Blind, Placebo-Controlled Discontinuation Phase, and Open Label Re-stabilization Period.

AVAILABILITY OF DATA:
For studies conducted under the BPCA, the FDA Reauthorization Act of 2017 included new mandates for public sharing of CSRs on NIH websites. In fulfillment of these mandates, CSRs for the COLT1 and COLT2 studies were published February 28, 2018, on the NICHD Data Specimens Hub (DASH) website:

- COLT1: https://dash.nichd.nih.gov/study/16018
- COLT2: https://dash.nichd.nih.gov/study/16020

To protect participant confidentiality, protected health information (PHI) and other confidential information were redacted from the CSRs that were published on DASH. Researchers who would like to request de-identified data from the studies should make requests through the DASH website.

PUBLIC COMMENT PERIOD:
Public comments will be gathered for 30 days from the time of this posting. To provide comments, visit www.Regulations.gov and search for Docket FDA-2018-N-2986.