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-2020-N-1675

FROM: Heather Buck, Division of Pediatric and Maternal Health

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

APPLICATION: IND 130531

DRUG: Rifampin

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

PURPOSE: To open Public Docket FDA-2020-N-1675 and announce the 30-day open public comment period for the pediatric studies of rifampin that were conducted in accordance with section 409I of the PHS Act and submitted to NIH and FDA.

BACKGROUND:
Section 4091 of the Public Health Service Act, also known as the Best Pharmaceuticals for Children Act (BPCA), mandates the National Institutes of Health (NIH) to prioritize therapeutic areas in critical need for pediatric labeling; to sponsor pediatric clinical trials; and to submit these data to FDA for consideration for labeling changes. Under the BPCA, the National Institute of Child Health and Human Development (NICHD) awarded a contract to Duke University, which established the Pediatric Trials Network (PTN) through its Duke Clinical Research Institute (DCRI). Rifampin was identified as a drug for which there are gaps in knowledge when used in the pediatric population.

The DCRI conducted the NICHD-2012-STA01 study entitled, “Pharmacokinetics of Antistaphylococcal Antibiotics in Infants” under IND 115396.

SUMMARY OF STUDIES:
NICHD-2012-STA01 was a multicenter, open-label, multiple-dose pharmacokinetic (PK) study. The primary objective of the study was to characterize the PK of rifampin, ticarcillin-clavulanate, and clindamycin in infants with systemic infection. The secondary objective was to

describe the safety profile of rifampin, ticarcillin-clavulanate, and clindamycin in infants. Only the results for rifampin were reported and discussed here.

Twenty-seven participants were enrolled. Overall, a total of 86 plasma concentrations, from 22 participants, were collected and used to construct a population PK model. There were no serious adverse events or adverse events related to rifampin reported.

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 following studies were published June 23, 2020, on the NICHD Data Specimens Hub (DASH) website: https://dash.nichd.nih.gov/study/226673

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-2020-N-1675.