Qualification Determination Letter

DDTBMQ000014

August 15, 2018

John-Michael Sauer, PhD
Critical Path Institute
Predictive Safety Testing Consortium (PSTC)
1730 E. River Road, Tucson, AZ 85718

Re: Biomarker Qualification Determination

Dear Dr. Sauer:

Please refer to your Full Qualification Package for biomarker qualification DDTBMQ000014 dated and fully completed January 22, 2018, and reviewed under the legacy qualification process prior to establishment of the section 507 process of the Federal Food, Drug, and Cosmetic Act (FD&C).

The Biomarker Qualification Program (BQP) has completed its review of your submission and is qualifying the following biomarker for the listed context of use (COU):

Biomarker: biomarker panel interpreted via a Composite Measure (CM) of the following six urinary biomarkers: Clusterin (CLU), Cystatin-C (CysC), Kidney Injury Molecule-1 (KIM-1), N-acetyl-beta-D-glucosaminidase (NAG), Neutrophil Gelatinase-Associated Lipocalin (NGAL), and Osteopontin (OPN)

Context of Use: A safety composite biomarker panel to be used in conjunction with traditional measures to aid in the detection of kidney tubular injury in phase 1 trials in healthy volunteers when there is an a priori concern that a drug may cause renal tubular injury in humans.

For full details regarding this qualification determination, including specific information about how this qualified biomarker can be used in drug development programs and clinical trials, please refer to the following information on the BQP website[1].

If you have any questions, please contact the Biomarker Qualification Program at CDER-BiomarkerQualificationProgram@fda.hhs.gov.

[1]https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/BiomarkerQualificationProgram

Sincerely,

Chris Leptak, MD/PhD
Director, CDER Biomarker Qualification Program
CDER/Office of New Drugs, Immediate Office

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