DD Month 20YY

Center for Tobacco Products

Food and Drug Administration

Document Control Center

10903 New Hampshire Avenue

Building 71, Room G335

Silver Spring, MD 20993-0002

Attn: Matthew R. Holman, PhD

Director, Office of Science

**RE: Proposed Use of an Investigational Tobacco Product**

Dear Dr. Holman:

Please find enclosed a request to use an Investigational Tobacco Product (ITP) in a clinical investigation. We are asking to administer [brand name/sub-brand name of investigational tobacco product] in a well-controlled investigation under IRB oversight. The initial study protocol for use under this ITP is entitled “Investigational Tobacco Product Study Title.”

The following products will be used in the study: [Identify the product by category (e.g., cigarette, smokeless tobacco) and product subcategory (e.g., snus or dissolvables)].

Reference is made to the following FDA submissions: [List FDA submission tracking number]

I, Dr. John Duke, am a Professor of Medicine at Duke University School of Medicine. I am the sponsor-investigator of the proposed investigation and will be responsible for monitoring the conduct and progress of the study, as well as the review and evaluation of information relevant to the effects of the investigational tobacco product.

If there are any questions regarding this submission, please contact myself or Jacob Durham, at (919) 668-xxxx or at jdurham@notes.duke.edu. Mr. Durham is authorized to communicate with the FDA on issues relating to this ITP.

Sincerely,

John Duke, MD

Professor, Department

Duke University

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