DD Month 20YY

Food and Drug Administration

Janet Maynard, MD, MHS

Director, Office of Orphan Products Development

10903 New Hampshire Avenue

WO32-5295

 Silver Spring, MD 20993

**RE: Orphan Drug Designation Request**

Dear Dr. Maynard:

Please find enclosed an Orphan Drug Designation Request Form FDA 4035. This Orphan Drug Designation Request is for *Drug XY* for use in *ZW Syndrome*.

If there are any questions regarding this submission, please contact me. If I cannot be reached, you may contact *Jane Doe* at 919-668-xxxx or *janedoe@duke.edu*. *Dr. Doe* is authorized to communicate with the FDA on issues relating to this Orphan Drug Designation request.

Sincerely,

John Doe, MD, PhD

Associate Professor

Duke University

Phone: 1-919-xxx-xxxx

Email: john.doe@duke.edu