**Annual Report**

**Orphan Drug Designation # 11-1111**

**Drug XY for use in Indication YZ**

Sponsor:

Name of Sponsor, MD PhD

Professor, Department

DUKE UNIVERSITY

Date of Submission

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*Orphan Drug Designation Annual Repots must be submitted within 14 months after the date on which a drug was designated as an orphan drug* a*nd annually thereafter until marketing approval (21 CFR 316.30):*

[*http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=0e737d105ef9a1632b19a1e713b93cc4&mc=true&n=pt21.5.316&r=PART&ty=HTML#se21.5.316\_130*](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=0e737d105ef9a1632b19a1e713b93cc4&mc=true&n=pt21.5.316&r=PART&ty=HTML#se21.5.316_130)

# Pre-Clinical and Clinical Development

*A short account of the progress of drug development including a review of preclinical and clinical studies initiated, ongoing, and completed and a short summary of the status or results of such studies.*

# Investigational Plan for the Coming Year

*A description of the investigational plan for the coming year, as well as any anticipated difficulties in development, testing, and marketing.*

# Orphan Drug Status

*A brief discussion of any changes that may affect the orphan-drug status of the product. For example, for products nearing the end of the approval process, sponsors should discuss any disparity between the probable marketing indication and the designated indication as related to the need for an amendment to the orphan-drug designation pursuant to §316.26.*