Request for HUD designation received by OOPD

OOPD Review and Analysis:
- What disease/condition, or orphan subset of a disease/condition, does the device treat/diagnose?
- Is the target population <8,000 per year?
- Is the scientific rationale for the device appropriate?

Are designation criteria met in the HUD request?

Applicant considers the following:
- Whether the disease/condition is different from that identified by OOPD
- Whether an orphan subset of the disease/condition can be shown based on features of the device
- Whether recalculation of the target population is appropriate or needed
- Whether additional scientific rationale is needed

Amendment to HUD designation application

OOPD requests additional information from applicant or disapproves HUD request

Withdrawal and/or other device marketing pathways

Key
HDE - Humanitarian Device Exemption
HUD - Humanitarian Use Device
OOPD - Orphan Products Development