

Office of Orphan Products Development (OOPD)/FDA Resources and Links

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Guidances:

- [Rare Diseases: Common Issues in Drug Development](#)
- [Human Gene Therapy for Rare Diseases](#)
- [Cellular & Gene Therapy Guidances](#)
- [Rare Pediatric Disease Priority Review Vouchers](#)
- [Humanitarian Use Device \(HUD\) Designations](#)
- [Humanitarian Device Exemption \(HDE\) Program](#)

Webinar:

- [Recommended Tips for Creating an Orphan Drug Designation Application](#)

Additional Resources:

- [Office of Orphan Products Development](#)
- [Designating an Orphan Product](#)
- [Searchable Database for Designated Products](#)
- [OOPD Grant Funding Opportunities \(including Clinical Trial Grants and Natural History Grants\)](#)
- [Code of Federal Regulations](#)
- [Patient Affairs Staff at FDA](#)
- [FDA Patient Engagement Opportunities](#)

Still have questions?

- Email me at lewis.fermaglich@fda.hhs.gov