

Designating an Orphan Product: Drugs and Biological Products

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Supporting the development and evaluation of new treatments for rare diseases is a key priority for the FDA. The FDA has authority to grant orphan drug designation to a drug or biological product to prevent, diagnose or treat a rare disease or condition. Orphan drug designation qualifies sponsors for incentives including:

- Tax credits for qualified clinical trials
- Exemption from user fees
- Potential seven years of market exclusivity after approval

Sponsors seeking orphan drug designation for a drug must submit a request for designation to the agency. Sponsors requesting designation of the same drug for the same rare disease or condition as a previously designated product must submit their own data and information to support their designation request. Orphan drug designation is a separate process from seeking approval or licensing. Drugs for rare diseases go through the same rigorous scientific review process as any other drug for approval or licensing.

See the [Orphan Drug Designations and Approvals](#) database for more information.

Content current as of:
08/12/2024

Regulated Product(s)
Drugs

Law(s) & Regulation(s)
Orphan Drug Act

Feedback

How to Submit Orphan Drug Designation Requests

Portal for submitting orphan drug designation requests

Sponsors may submit orphan drug designation [requests](#) one of three ways:

1. Through the [CDER NextGen portal](#)
2. By emailing the required information to orphan@fda.hhs.gov
3. By mailing the required information to:

Office of Orphan Products Development
Attention: Orphan Drug Designation Program
Food and Drug Administration
WO32-5295
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

New users of the [CDER NextGen Portal](#) must register for an account. For additional information or support, visit the [NextGen Portal Help Center](#). Users who submitted a request through the CDER NextGen portal do not need to submit by email. For designation requests submitted by email, the agency recommends using automated read receipt to verify receipt of the email.

Soleno Therapeutics, Inc.
Exhibit 2078
Apotex v. Soleno
PGR2026-00034
Ex. 2078-001

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Sponsors and others who plan to email information to FDA that is private, sensitive, proprietary or commercial confidential are strongly encouraged to send it from an FDA-secured email address so the transmission is encrypted. The agency will assume the addresses of emails received or email addresses provided as a point of contact are secure when responding to those email addresses.

Sponsors and others can establish a secure email address link to FDA by sending a request to SecureEmail@fda.hhs.gov. There may be a fee to a commercial enterprise for establishing a digital certificate before encrypted emails can be sent to FDA.

Resources

- Webinar: [Recommended Tips for Creating an Orphan Drug Designation Application](#) | Duration 41m 08s
 - [slides](#) (PDF)
 - [script](#) (PDF)
- [Orphan Drug Final Rule of June 12, 2013](#) (PDF)
- [Orphan Drug Final Rule of December 29, 1992](#) (PDF)
- [21 Code Federal Regulations Part 316 - Orphan Drugs](#)
- [Public Law 97- 414](#) (PDF)
- [Summary of H.R. 5238 - 97th Congress \(1981-1982\) Orphan Drug Act](#)

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Ex. 2078-002

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