

## Life Sciences Industry Extra: Federal Funding Opportunity for Orphan Products

1/12/2009

As part of its ongoing effort to support the development of orphan products, the Food and Drug Administration (FDA) announced the availability of research grants for up to \$400,000 per year for FY 2010 and FY 2011. These grants are available to support clinical research programs for drugs, biologics, medical devices (including diagnostics), and foods for medical purposes that are indicated for a disease or condition that affects fewer than 200,000 people in the United States, and for which no current therapy exists or the proposed product will be superior to the existing product. A diagnostic or a vaccine will qualify for orphan status if the U.S. population to which it will be administered is no more than 200,000 people per year.

Administered through the FDA's Office of Orphan Product Development (OPD), this funding is available to foreign or domestic, public or private, and for-profit or nonprofit entities, including state and federal government entities and federal agencies that are not part of Health and Human Services, and to certain individuals, once they successfully complete the application procedure and are awarded a grant.

Under the OPD program, grants of up to \$200,000 may be awarded for phase 1, 2 or 3 studies, with larger grants (up to \$400,000) considered for studies continuing in phase 2 or 3. Up to \$14.1 million has been earmarked for FY 2010. Subject to the availability of funds, OPD expects that about \$10 million will be set aside for continuing grants, leaving approximately \$4 million available to fund 10 to 12 new projects.

Applications must include documentation to support the estimated prevalence of the orphan disease or condition and an explanation of how the proposed study will either help gain product approval or provide essential data. For vaccines and diagnostics, the applicant must provide support for the estimate of how many people will be administered the product annually. Other requirements apply depending on the nature of the product.

Organizations interested in applying for the OPD grants should review the detailed information in the [Federal Register](#) notice announcing the availability of the grants.

Applicants should apply electronically at [www.grants.gov](http://www.grants.gov), following the instructions under "Apply for Grants." Applications for the grants will be accepted between January 4 and February 4, 2009 for FY 2010 and January 3 and February 3, 2010 for FY 2011.

The attorneys in Mintz Levin's Life Sciences and FDA Practice Groups can assist you in understanding and applying for these OPD grants. Please contact us for more information.

---

*For assistance in this area, please contact the attorney listed below or any member of your Mintz Levin client service team.*

**Linda D. Bentley**  
(617) 348-1784  
[LDBentley@mintz.com](mailto:LDBentley@mintz.com)

---

© 1994-2009 Mintz, Levin, Cohn, Ferris, Glovsky and Popeo P.C. All Rights Reserved.

This website may constitute attorney advertising. Prior results do not guarantee a similar outcome. Any correspondence with this website does not constitute a client/attorney relationship. Neither the content on this web site nor transmissions between you and Mintz Levin Cohn Ferris Glovsky and Popeo PC through this web site are intended to provide legal or other advice or to create an attorney-client relationship. Images or photography appearing on this website may not be actual attorneys or images associated with Mintz Levin.