

The Food and Drug Administration's (FDA) Office of Orphan Products Development (OOPD) is pleased to announce the availability of funds for fiscal year (FY) 2009 and FY 2010 grant awards to support clinical trials on the safety and effectiveness of products for rare diseases and conditions. Contingent on availability of FY 2009 and FY 2010 funds, it is anticipated that \$14.2 million will be available for new applications, competing awards, and non competing continuation awards. For FY 2009, the application receipt date is February 6, 2008, and for FY 2010, the application receipt date is February 4, 2009.

These studies are intended to provide acceptable data to the FDA that will substantially contribute to the approval of new products, or new indications for already marketed products. In the FDA OOPD grants program, products for rare diseases and conditions (orphan products) are defined as drugs, biologics, medical devices, and medical foods indicated to treat or diagnose a rare disease or condition with a prevalence of fewer than 200,000 people in the United States.

A complete text of the FDA request for applications (RFA) is available in the *Federal Register* (FR) notice, dated July 3, 2007, or at <http://www.fda.gov/orphan/grants/2009RFA.html>. FDA will support the clinical studies covered by this notice under section 301 of the Public Service Act (42 U.S.C. 241). Regarding the administrative and financial management aspects of this notice, please contact Dianna Jessee, Grants Management Specialist, Division of Contracts and Grants Management (HFA-500), FDA, 5630 Fishers Lane, Room 2141, Rockville, Maryland 20857; 301-827-7177; e-mail: dianna.jessee@fda.hhs.gov. Regarding the program aspects of this notice, please contact: Debra Y. Lewis, O.D., M.B.A., Director, OOPD Grants Program (HF-35); FDA, 5600 Fishers Lane, Rockville, Maryland 20857; 301-827-0059; e-mail: debra.lewis@fda.hhs.gov. To request a copy of the July 3, 2007 FR notice, please phone the OOPD office at 301-827-3666/1-800-300-7469 or send a fax request to 301-827-0017.

Information by E-Mail/Website

Subscribers to the FDA orphan products information listserv receive relevant *Federal Register* notices, up-to-date lists of orphan designations and approvals, and newsworthy items of interest to the orphan products community. Subscribe at: <http://list.nih.gov/archives/orphanprodinfo.html>

For more information regarding the Office of Orphan Products Development please visit the following website: <http://www.fda.gov/orphan>