information is necessary for the proper performance of functions of the
Reporting and Use of Information
Concerning Integrity and Performance of
Recipients of Grants and Cooperative
Agreements, whether it will have
practical utility; whether our estimate of
the public burden of this collection of
information is accurate, and based on
valid assumptions and methodology;
ways to enhance the quality, utility, and
clarity of the information to be
collected; and ways in which we can
minimize the burden of the collection of
information on those who are to
respond, through the use of appropriate
technological collection techniques or
other forms of information technology.

C. Annual Reporting Burden

Respondents: 10,000.
Responses per Respondent: 1.
Total annual responses: 10,000.
Hours per Response: .05.
Total Burden Hours: 500.

Obtaining Copies of Proposals:
Requesters may obtain a copy of the
information collection documents from
the General Services Administration,
Regulatory Secretariat Division (MVCB),
1800 F Street NW., 2nd Floor,
Washington, DC 20405–0001, telephone
202–501–4755. Please cite OMB Control
No. 3090–00XX, MyUSA, in all
correspondence.


Sonny Hashmi,
Chief Information Officer, Office of the Chief
Information Officer.

BILLING CODE 6820–34–P

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0012]

Clinical Studies of Safety and
Effectiveness of Orphan Products
Research Project Grant (R01)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug
Administration (FDA) is announcing the
availability of grant funds for the
support of FDA’s Office of Orphan
Products Development grant program.
The goal of FDA’s Orphan Products
Development (OPD) grant program is to
support the clinical development of
products for use in rare diseases or
conditions where no current therapy
exists or where the proposed product
will be superior to the existing therapy.

FDA provides grants for clinical studies
on safety and/or effectiveness that will
either result in, or substantially
contribute to, market approval of these
products. Applicants must include in
the application’s Background and
Significance section documentation to
support the assertion that the product to
be studied meets the statutory criteria to
qualify for the grant and an explanation
of how the proposed study will either
help support product approval or
provide essential data needed for
product development.

DATES: Important dates are as follows:

1. The application due dates are
   February 4, 2015; February 3, 2016;
   February 1, 2017; and February 7, 2018.

2. The submission due dates are
   October 15, 2015; October 14, 2016;
   October 16, 2017; and October 15, 2018.

3. The opening date is December 4,
   2014.

4. The expiration dates are February
   8, 2018, and October 16, 2018,
   (resubmission).

ADDRESSES: Submit electronic
applications to: http://www.grants.gov.
For more information, see section III of the
SUPPLEMENTARY INFORMATION
section of this notice.

FOR FURTHER INFORMATION AND
ADDITIONAL REQUIREMENTS CONTACT:
Katherine Needleman, Director, Orphan
Products Grants Program, Office of
Orphan Products Development, Food
and Drug Administration, 10903 New
Hampshire Ave., Bldg. 32, Rm. 5295,
Silver Spring, MD 20993–0002, 301–
796–8660, katherine.needleman@
fda.hhs.gov; or Vieda Hubbard, Grants
Management Specialist, Division of
Acquisition Support and Grants, Office
of Acquisitions & Grant Services, 5630
Fishers Lane, Rockville, MD 20857,
240–402–7588, vieda.hubbard@
fda.hhs.gov.

For more information on this funding
opportunity announcement (FOA) and
to obtain detailed requirements, please
refer to the full FOA located at http://
grants.nih.gov/grants/guide (select the
“Request for Applications” link),
http://www.grants.gov (see “For
Applicants” section), and http://
www.fda.gov/ForIndustry/Developing
ProductsforRareDiseasesConditions/
WhomtoContactaboutOrphanProduct
Development/ucm134580.htm.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

A. Background

The OPD was created to identify and
promote the development of orphan
products. Orphan products are drugs,
biologics, medical devices, and medical
foods that are indicated for a rare
disease or condition. The term “rare
disease or condition” is defined in
section 528 of the Federal Food, Drug,

FDA generally considers drugs, devices,
and medical foods potentially eligible
for grants under the OPD grant program
if they are indicated for a disease or
condition that has a prevalence, not
incidence, of fewer than 200,000 people
in the United States. Diagnostics and
vaccines are considered potentially
eligible for such grants only if the U.S.
population to whom they will be
administered is fewer than 200,000
people in the United States per year.

B. Research Objectives

The goal of FDA’s OPD grant program
is to support the clinical development of
products for use in rare diseases or
conditions where no current therapy
exists or where the proposed product
will be superior to the existing therapy.

FDA provides grants for clinical studies
on safety and/or effectiveness that will
either result in, or substantially
contribute to, market approval of these
products. Applicants must include in
the application’s Background and
Significance section documentation to
support the assertion that the product to
be studied meets the statutory criteria to
qualify for the grant and an explanation
of how the proposed study will either
help support product approval or
provide essential data needed for
product development.

C. Eligibility Information

The grants are available to any foreign
or domestic, public or private, for-profit
or nonprofit entity (including State and
local units of government). Federal
Agencies that are not part of the
Department of Health and Human
Services (HHS) may apply. Agencies
that are part of HHS may not apply.
For-profit entities must commit to excluding
fees or profit in their request for support
to receive grant awards. Organizations
that engage in lobbying activities, as
described in section 501(c)(4) of the
Internal Revenue Code of 1968, are not
eligible to receive grant awards.

II. Award Information/Funds Available

A. Award Amount

Of the estimated Fiscal Year (FY)
2016 funding ($14.1 million),
approximately $10 million will fund
noncompeting continuation awards, and
approximately $4.1 million will fund 5 to 10 new awards, subject to availability of funds. It is anticipated that funding for the number of noncompeting continuation awards and new awards in FY 2017, FY 2018, and FY 2019 will be similar to FY 2016. Phase 1 studies are eligible for grants of up to $250,000 per year for up to 3 years. Phase 2 and 3 studies are eligible for grants of up to $500,000 per year for up to 4 years. Please note that the dollar limitation will apply to total costs (direct plus indirect). Budgets for each year of requested support may not exceed the $250,000 or $500,000 total cost limits, whichever is applicable.

B. Length of Support

The length of support will depend on the nature of the study. For those studies with an expected duration of more than 1 year, a second, third, or fourth year of noncompeting continuation of support will depend on the following factors: (1) Performance during the preceding year, (2) compliance with regulatory requirements of investigational new drug/investigational device exemption, and (3) availability of Federal funds.

III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at http://grants.nih.gov/grants/guide. (FDA has verified the Web site addresses throughout this document but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.) For all electronically submitted applications, the following steps are required.

- **Step 1**: Obtain a Dun and Bradstreet (DUNS) Number
- **Step 2**: Register With System for Award Management (SAM) (formerly Central Contractor Registration (CCR))
- **Step 3**: Obtain Username & Password on Grants.gov
- **Step 4**: Authorized Organization Representative (AOR) Authorization
- **Step 5**: Track AOR Status
- **Step 6**: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at http://www07.grants.gov/applicants/organization_registration.jsp. Step 6, in detail, can be found at https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp. After you have followed these steps, submit electronic applications to: http://www.grants.gov.


Leslie Kux,
Assistant Commissioner for Policy.

[Federal Register Document: 2014–19600 Filed 8–18–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0790]

Food and Drug Administration

Decisions for Investigational Device Exemption Clinical Investigations: Guidance for Sponsors, Clinical Investigators, Institutional Review Boards, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations.” This guidance document was developed to promote the initiation of clinical investigations to evaluate medical devices under FDA’s IDE regulations. The guidance is intended to provide clarification regarding the regulatory implications of the decisions that FDA may render based on review of an IDE and to provide a general explanation of the reasons for those decisions.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “FDA Decisions for Investigational Device Exemption Clinical Investigations” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:
Owen Faris, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1522, Silver Spring, MD 20993–0002, 301–796–6210; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA seeks to encourage medical device research and innovation to address important clinical needs and improve patient care. In many cases, device development and evaluation include clinical investigation. This guidance document has been developed to facilitate the initiation of clinical investigations to evaluate medical devices under FDA’s IDE regulations, part 812 (21 CFR part 812).

FDA approval of an IDE submission allows the initiation of subject enrollment in a significant risk clinical investigation of a medical device. This guidance is intended to provide clarification regarding the regulatory implications of the decisions that FDA may render based on review of an IDE and to provide a general explanation of the reasons for those decisions.

In an effort to promote timely initiation of subject enrollment in clinical investigations in a manner that protects study subjects, FDA has developed methods to allow a clinical investigation of a device to begin under certain circumstances, even when outstanding issues regarding the IDE submission remain. These mechanisms, including Approval with Conditions, Staged Approval, and communication of outstanding issues related to the IDE through Study Design Considerations and Future Considerations, are described in this guidance.

FDA’s decision-making process for IDEs was modified with passage of the