and monitors most ORR discretionary grants; recommends grantee allocation; coordinates with the grants management office to review the financial expenditures under discretionary grant programs; provides data in support of apportionment requests; and provides technical assistance on discretionary grants operations. The Division coordinates and provides liaison with the Department and other Federal agencies on discretionary grant operational issues and other activities as specified by the Director or required by Congressional mandate. The Division responds to unanticipated refugee and entrant arrivals or significant increases in arrivals to communities where adequate or appropriate services do not exist through supplemental initiatives. The Division works to promote economic independence among refugees through social services, educational services, and intensive case management and community development initiatives.

D. Division of Children's Services supports services to unaccompanied children, who are referred to ORR for care as refugees, asylees, Cuban and Haitian entrants, children granted Special Immigrant Juvenile Visas and those pending immigration status or identified as victims of trafficking. The Division implements intake and placement decisions for all unaccompanied refugee and alien children. The Division supports specialized care through grants, contracts and state administered unaccompanied minors programs. The Division conducts monitoring and inspections of facilities and placement locations in which unaccompanied children reside. The Division also maintains statistical information and data on each child and any actions concerning the child while the child is under the Director's care.

The Division ensures consideration of the child's best interest in care and custody decisions. The Division coordinates all decisions related to sponsor reunification, background checks, home assessments, follow-up services, medical assessment and treatment, sponsorship breakdowns, repatriation and movement of children into the Unaccompanied Refugee Minors (URM) Program.

The Division develops policy to ensure all children's programs are administered in a manner that ensures the best interest of the child and that services are administered in a manner that supports child welfare standards of care and services to include; training, accreditation, legal services, assessment and trauma related initiatives. The Division administers the pro bono legal services and child advocate program and compiles a state-by-state list of professionals or entities qualified to provide the children with a guardian and attorney representational services.

E. Division of Anti-Trafficking in Persons is responsible for implementing certain provisions of the Trafficking Victims Protection Act. The Division coordinates the certification of, and services to, victims of severe forms of trafficking, promotes public awareness on human trafficking, and increases identification of potential victims of severe forms of trafficking. The Division manages these activities through grants and contracts. It also coordinates with other Federal Government agencies on certification activities and policy issues related to the trafficking laws. The Division certifies victims of severe forms of trafficking following consultation with appropriate Federal and State Government agencies and social service agencies. The Division coordinates with the appropriate entities for the determination and placement of identified and certified unaccompanied minor victims of trafficking. It maintains statistical information and data on each victim, including certification documentation and services provided. The Division compiles an annual report, in coordination with other Federal agencies, on the number of certifications issued to and services accessed by identified victims.

F. Division of Refugee Health provides direction for assuring that refugees are provided medical assistance and mental health services through the State-administered program and alternative programs such as the Wilson/Fish projects. The Division ensures the quality of medical screening and initial medical treatment of refugees through its administration of grant programs, technical assistance and interagency agreements in support of comprehensive medical and mental health services. The Division supports coordination of services to refugees under the Affordable Care Act. The Division also supports mental health services to victims of torture.

The Division works closely with State Refugee Health Coordinators in the planning and provision of medical and mental health services to meet the individual needs of incoming populations. The Division tracks all state costs related to refugee medical assistance and screening.

Dated: November 1, 2011.

George H. Sheldon,

Acting Assistant Secretary for Children and Families.

[FR Doc. 2011–29075 Filed 11–9–11; 8:45 am]

BILLING CODE 4120–27–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0787]

Draft Guidance for Industry and Food and Drug Administration Staff; Investigational Device Exemptions for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies.'' Through the approaches announced in this draft guidance, FDA intends to facilitate early feasibility studies of medical devices, using appropriate risk mitigation strategies, under the IDE requirements. Early feasibility studies allow for limited early clinical evaluations of devices to provide proof of principle and initial clinical safety data before the device design is finalized. This draft guidance addresses the information that should be provided to FDA in support of an early feasibility study IDE application and explains the requirements applicable to modifications to the device design or clinical protocol during the early feasibility study. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 8, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies'' to the Division of Small Manufacturers, International, and

Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to (301) 847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft 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: Dorothy Abel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1204, Silver Spring, MD 20993–0002, (301) 796–6366.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance is intended to provide assistance to FDA staff, clinicians, clinical innovators, and industry on the development and review of IDE applications (21 CFR 812.20) for early feasibility studies of significant risk devices. Early feasibility studies allow for early clinical evaluation of devices to provide proof of principle and initial clinical safety data in a limited number of subjects. During these studies, iterative device modifications are likely to be made based on clinical experience. Early feasibility studies may be appropriate early in device development when nonclinical testing methods are not available or adequate to provide the information needed to advance the developmental process, and clinical experience is thus necessary. As with all clinical studies, initiation of an early feasibility study must be justified by an appropriate risk-benefit analysis and adequate human subject protection measures.

This draft guidance discusses the key principles unique to the justification for, and design of, early feasibility studies, as well as outlines the general principles for preparing and reviewing early feasibility study IDE applications. This draft guidance is not intended to address all required elements of an IDE application generally or to provide a comprehensive tutorial on best clinical practices for investigational medical device studies.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on IDE for early feasibility studies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the solicitation of nominations from sponsors of innovative device technologies to participate in a pilot program for early feasibility study IDE applications, which implements the approaches announced in this draft guidance. The experience gained from the pilot program will be used to inform the final version this draft guidance.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*.

You may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of this draft guidance or send a fax request to (301) 847–8149 to receive a hard copy. Please use the document number 1782 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–29117 Filed 11–9–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0790]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations.'' This guidance document has been developed to promote the initiation of clinical investigations to evaluate medical devices under FDA's IDE regulations. In an effort to promote timely clinical investigations in a manner that protects study subjects, FDA has developed methods to allow a clinical investigation to begin under certain circumstances, even when there are outstanding issues regarding the IDE submission. These mechanisms, including approval with conditions, staged approval or staged approval with conditions, and communication of outstanding issues related to the IDE through future considerations, are described in this guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 8, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food