III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: September 10, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–22380 Filed 9–16–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0293]

Guidance for Industry: Considerations for Allogeneic Pancreatic Islet Cell Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Considerations for Allogeneic Pancreatic Islet Cell Products'' dated September 2009. The guidance document provides recommendations to manufacturers, sponsors, and clinical investigators involved in the transplantation of allogeneic pancreatic islet cell products for clinical investigations of the treatment of type 1 diabetes mellitus. The guidance identifies the types of data and information obtained during investigational new drug studies that may be helpful in establishing the safety, purity, and potency of a biological product in a biologics license application (BLA). The guidance announced in this notice finalizes the draft guidance of the same title, dated May 2008.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Considerations for Allogeneic Pancreatic Islet Cell Products'' dated September 2009. The guidance document provides recommendations to manufacturers, sponsors, and clinical investigators involved in the transplantation of allogeneic pancreatic islet cell products for clinical investigations of the treatment of type 1 diabetes mellitus. The guidance identifies the types of data and information that may be obtained during investigational new drug studies to assist in establishing the safety, purity, and potency of a biological product in a BLA. However, the guidance is not intended to identify all of the product, preclinical, and clinical data that may be needed to successfully support a BLA.

In the **Federal Register** of May 22, 2008 (73 FR 29760), FDA announced the availability of the draft guidance of the same title, dated May 2008. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated May 2008.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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 statutes and regulations.

II. Paperwork Reduction Act of 1995

The 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 211 has been approved under 0910–0139; the collections of information in 21 CFR part 312 has been approved under 0910–0014; the collections of information in 21 CFR parts 601 and 610 have been approved under 0910–0338; and the collections of information in 21 CFR part 1271 has been approved under 0910–0543 and 0910–0559.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *http://www.regulations.gov*.

Dated: September 11, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–22426 Filed 9–16–09; 8:45 am]

BILLING CODE 4160–01–S