Date: September 9, 2009.

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Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0408]

Draft Guidance for Industry on Microbiological Data for Systemic Antibacterial Drug Products—Development, Analysis, and Presentation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Microbiological Data for Systemic Antibacterial Drug Products—Development, Analysis, and Presentation.'' The draft guidance informs industry of FDA's current thinking regarding the types of microbiological studies, assessments, and clinical trials needed to support an investigational new drug application (IND) and a new drug application (NDA) for a systemic antibacterial drug product. Recommendations in this guidance cover microbiological considerations in the three major areas of conducting general nonclinical studies; conducting animal and human studies and clinical trials; and establishing and updating in vitro susceptibility test methods, quality control (QC) parameters, and interpretive criteria. This guidance also recommends the content and format for presentation of microbiological data for antibacterial drug products in the Microbiology subsection of labeling.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by December 16, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Fred Marsik, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6108, Silver Spring, MD 20993–0002, 301–796–7956; or

Edward Cox, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6212, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Microbiological Data for Systemic Antibacterial Drug Products—Development, Analysis, and Presentation.'' This guidance provides recommendations on the type of information to provide in submissions to the clinical microbiology section of INDs and NDAs for systemic antibacterial drug products. The in vitro microbiological data and in vivo animal studies (e.g., spectrum of activity in vitro and in appropriate animal models of human disease) support the justification of testing in humans. Sponsors usually submit data from nonclinical investigations to provide proof of concept of clinical activity before commencing human phase 2 studies and clinical trials and to aid in the development of provisional interpretive criteria for use in phase 3 clinical trials. Microbiological data submitted to an NDA will be used to substantiate the microbiological information contained in the labeling.

Specific topics discussed in the guidance include validating in vitro susceptibility testing methods; mechanism of action studies; mechanism of resistance studies; use of animal models; clinical trial protocols; establishment of QC parameters and interpretive criteria; submission and placement of microbiology information in the NDA submission; format and content of the Microbiology subsection of the labeling; and revision of existing susceptibility testing methods, QC parameters, or interpretive criteria.

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 the microbiological data for systemic antibacterial drug products. 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. The 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).

(1) The draft guidance provides recommendations on the type of information to include in submissions of the clinical microbiology section of INDs and NDAs for systemic antibacterial drug products. The microbiology section of an NDA is required under 21 CFR 314.50(d)(4) and this information collection is approved under OMB Control Number 0910–0001. For INDs, this information is required under 21 CFR 312.23(a) and approved under OMB Control Number 0910–0014.

(2) The draft guidance also recommends the types of data that should be submitted in a labeling supplement to update the microbiology information in approved labeling if an application holder chooses to update this information without relying on a standard recognized by FDA. The submission of labeling supplements is required under 21 CFR 314.70(b)(2)(v) and 201.56(a)(2) and this information collection is approved under OMB Control Numbers 0910–0001 and 0910–0572, respectively.

(3) Appendix A of the draft guidance describes the content of the Microbiology subsection of labeling. This labeling is covered under 21 CFR 201.57(c)(13)(i) and the information collection is approved under OMB Control Number 0910–0572.

(4) The draft guidance also references the guidance for industry entitled ''Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices'' for updating labeling information. The information collection in this guidance has been approved under OMB Control Number 0910–0638.

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.

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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.

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