Authority: Section 330 of the Public Health Service Act, 42 U.S.C. 245b.

CFDA Number: 93.703.

Justification for the Exception to Competition

Under the original grant applications approved by HRSA, Regional Health Care Affiliates (RHCA) was identified as the provider of health care services on behalf of the Trover Health System, while Trover Health System was to serve in an administrative capacity for the grants. After the awards were issued, Trover Health System and RHCA notified HRSA that RHCA's organizational structure had changed to enable it to carry out both administrative and programmatic requirements. The two parties requested that full responsibility for the grants be transferred from Trover Health System to RHCA. RHCA provided documentation that it meets Section 330 statutory and regulatory requirements as well as applicable grant management requirements.

Regional Health Care Affiliates will directly initiate primary health care services in Webster and McLean Counties to the more than 5,250 low income, underserved and uninsured individuals in the original service area, Webster and McLean Counties, KY, as had been proposed in funded grant applications.

Regional Health Care Affiliates can provide primary health care services immediately, is located in the same geographical area where the Trover Health System's primary health care services have been provided, and will be able to provide continuity of care to patients of the former grantee.

This underserved target population has an immediate need for vital primary health care services and would be negatively impacted by any delay caused by a competition. As a result, in order to ensure that critical primary health care services are available to the original target population in a timely manner, these replacement awards will not be competed.

FOR FURTHER INFORMATION CONTACT: Marquita Cullom-Stott via e-mail at *MCullom-Stott@hrsa.gov* or 301–594–4300.

Dated: December 10, 2009.

Mary K. Wakefield,

Administrator.

[FR Doc. E9–30010 Filed 12–16–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0573]

International Conference on Harmonisation; Draft Guidance on Addendum to International Conference on Harmonisation S6; Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals S6(R1); Availability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 ''Addendum to ICH S6: Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals S6(R1).'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance provides recommendations on nonclinical studies to support the safety of clinical trials and marketing applications for biotechnology-derived pharmaceuticals. The draft guidance is intended to clarify and provide greater detail to the nonclinical recommendations in the ICH guidance entitled ''S6 Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals'' (ICH S6) published in the **Federal Register** of November 18, 1997 (62 FR 61515).

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 electronic or written comments on the draft guidance by February 1, 2010.

ADDRESSES: Submit electronic comments on the draft guidance to *http://www.regulations.gov*. 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 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; or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Anne M. Pilaro, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 2324, Silver Spring, MD 20993–0002, 301–796–2320; or Mercedes A. Serabian, Center for Biologics Evaluation and Research (HFM–760), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5377.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics

Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In October 2009, the ICH Steering Committee agreed that a draft guidance entitled ''Addendum to ICH S6: Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals S6(R1)'' should be made available for public comment. The draft guidance is the product of the Safety (S6) Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the ICH S6 Safety Expert Working Group.

The draft document provides guidance on nonclinical studies to support the safety of clinical trials and marketing applications for biotechnology-derived pharmaceuticals. Biotechnology-derived pharmaceuticals include protein therapeutic, diagnostic, and prophylactic products derived from cell-culture systems such as bacteria, yeast, and eukaryotic cells, including organisms produced by recombinant DNA technology. The draft guidance specifically provides clarification of and greater detail to the nonclinical recommendations in ICH S6 regarding the topics of species selection, study design, and recommendations for immunogenicity, carcinogenicity, and reproductive and developmental toxicity testing of biotechnology-derived pharmaceuticals. ICH S6 was published more than 10 years ago and much knowledge relevant to the safety evaluation of biopharmaceuticals has been gained since that original publication. This draft guidance seeks to incorporate this new knowledge within the established framework of ICH S6 and is intended to enable the development of safe and effective biopharmaceuticals. In addition, this draft guidance harmonizes approaches given in both ICH S6 and the ICH guidance ''M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals.''

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 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. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments on the draft 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

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

Dated: December 11, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–29991 Filed 12–16–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0579]

International Conference on Harmonisation; Draft Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 11 on Capillary Electrophoresis General Chapter; 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 ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 11: Capillary Electrophoresis General Chapter.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance provides the results of the ICH Q4B evaluation of the Capillary Electrophoresis General Chapter harmonized text from each of the three pharmacopoeias (United States, European, and Japanese) represented by the Pharmacopoeial Discussion Group (PDG). The draft guidance conveys recognition of the three pharmacopoeial methods by the three ICH regulatory regions and provides specific information regarding the recognition. The draft guidance is intended to recognize the interchangeability between the local regional pharmacopoeias, thus avoiding redundant testing in favor of a common testing strategy in each regulatory region. This draft guidance is the 11th annex to the core Q4B guidance, which was made available in the **Federal Register** of February 21, 2008 (73 FR 9575).

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 February 16, 2010.

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; or 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. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the 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:

Regarding the guidance: Robert H. King, Sr., Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4150, Silver Spring, MD 20993–0002,