Training, NIEHS, P.O. Box 12233, Research Triangle Park, NC 27709 or call non-toll-free number (919) 541–0217 or E-mail your request, including your address to *wetp@niehs.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: September 9, 2009.

Christopher W. Long,

NIEHS Deputy Associate Director for Management.

[FR Doc. E9–22567 Filed 9–17–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Draft Policy Documents for Comment

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: This is a Notice of Availability and request for comments on a draft Agency Guidance (''Policy Information Notices'' (PINs)) to convey and clarify statutory and regulatory governance requirements for federally-funded health centers and Federally Qualified Health Center (FQHC) Look-Alikes. The PIN, ''Health Center Governance Requirements and Expectations'' is available on the Internet at http://bphc.hrsa.gov/draftsforcomment/governance/draftgovernancepin.htm.

DATES: Comments must be received by October 26, 2009.

ADDRESSES: Comments should be submitted to <*OPPDGeneral@hrsa.gov*> by close of business October 26, 2009.

SUMMARY: HRSA believes that community input is valuable to the development of policies and policy documents related to the implementation of HRSA programs, including the Health Center Program. Therefore, we are requesting comments on the PIN referenced above. Comments will be reviewed and analyzed, and a summary and general response will be published as soon as possible after the deadline for receipt of comments.

Background: HRSA administers the Health Center Program, which supports more than 7,500 health care delivery sites, including community health centers, migrant health centers, health care for the homeless centers, and public housing primary care centers. Health centers serve medically underserved communities, delivering preventive and primary care services to patients regardless of their ability to pay. The purpose of the recently published draft PIN is (a) To convey and clarify HRSA's policy regarding Health Center Program statutory and regulatory governance requirements for all Health Center Program grantees (*e.g.,* health centers funded under section 330(e), (g), (h) and (i) of the Public Health Service (PHS) Act, as amended) and FQHC Look-Alikes (per section 1905(l)(2)(B) and section 1861(aa)(4) of the Social Security Act.); (b) provide clarification regarding board requirements for public centers under co-applicant arrangements, including public centers funded or designated solely under sections 330(g), 330(h) and/or 330(i) of the PHS Act, as amended to serve special populations; and (c) outline the eligibility and qualifying expectations for HRSA approval of a governance waiver for the fifty-one percent consumer/patient majority governance requirement for eligible section 330 grantees and FQHC Look-Alikes. The PIN eliminates the monthly meeting requirement from waiver consideration.

FOR FURTHER INFORMATION CONTACT: For questions regarding this notice, please contact the Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, at 301–594–4300.

Dated: September 11, 2009.

Mary K. Wakefield,

Administrator.

[FR Doc. E9–22444 Filed 9–17–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0427]

Draft Guidance for Industry: Clinical Considerations for Therapeutic Cancer Vaccines; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Clinical Considerations for Therapeutic Cancer Vaccines'' dated September 2009. The draft guidance document provides recommendations to sponsors who wish to submit an Investigational New Drug application (IND) for a therapeutic cancer vaccine on critical clinical considerations for investigational studies of these products. The draft guidance applies to therapeutic cancer vaccines that are intended to be administered to patients with an existing cancer for the purpose of treatment. The draft guidance does not apply to products intended to be administered to patients to prevent or decrease the incidence of cancer and does not apply to adoptive immunotherapeutic products such as T cell or NK cell products.

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 17, 2009.

ADDRESSES: Submit written requests for single copies of the draft 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 draft 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 draft guidance document.

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*.

FOR FURTHER INFORMATION CONTACT: Lori Jo Churchyard, 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 draft document entitled ''Guidance for Industry: Clinical Considerations for Therapeutic Cancer Vaccines'' dated September 2009. The draft guidance document provides recommendations to sponsors who wish to submit an IND for a therapeutic cancer vaccine on critical clinical considerations for early and late phase investigational studies intended to support a biologics license application. Development of a therapeutic cancer vaccine can present different considerations for clinical trial design than development of a traditional cytotoxic drug or biological product, due to differences in the proposed

mechanisms of action. The draft guidance applies to therapeutic cancer vaccines intended to be administered to patients with an existing cancer for the purpose of treatment. It does not apply to products intended to be administered to patients to prevent or decrease the incidence of cancer. Also, it does not apply to adoptive immunotherapeutic products such as T cell or NK cell products.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 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 312 have been approved under OMB control number 0910–0014; and the collections of information in 21 CFR part 50 on informed consent have been approved under OMB control number 0910–0130.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding 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. A copy of the draft 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 draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *http://www.regulations.gov*.

Dated: September 15, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–22531 Filed 9–17–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0431]

Preparation for International Conference on Hamonization: Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Preparation for ICH meetings in St. Louis, Missouri'' to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in St. Louis, MO. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the public meeting is to solicit public input prior to the next Steering Committee and Expert Working Groups meetings in St. Louis, MO, October 24 to 29, 2009, at which discussion of the topics underway and the future of ICH will continue.

Date and Time: The public meeting will be held on Wednesday, October 14, 2009, from 2:30 p.m. to 4:30 p.m.

Location: The public meeting will be held at the Washington Room at the Hilton Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Mary Morrison, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, by e-mail: *Mary.morrison@fda.hhs.gov*, or FAX: 301–827–0003.

Registration and Requests for Oral Presentations: Mail or fax your registration information (including name, title, firm name, address, telephone and fax numbers), written material and requests to make oral presentations, to Mary Morrison (see *Contact Person*) by October 9, 2009.

If you need special accommodations due to a disability, please contact Mary Morrison (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

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 medical product development among regulatory agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization 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, Labor and Welfare, the Japanese Pharmaceutical Manufactures 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 Health Canada, the European Free Trade Area and the World Health Organization. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions.

The current ICH process and structure can be found at the following Web site: *http://www.ich.org*.

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Public oral presentations will be scheduled between approximately 2:30 p.m. and 4:30 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by October 9, 2009, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses,