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