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Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: August 13, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 02–21262 Filed 8–20–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0337]

Draft Guidance for Industry on Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation; 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation.'' This guidance provides recommendations to applicants on the chemistry, manufacturing, and controls (CMC); human pharmacokinetics and bioavailability; and labeling documentation for liposome drug products submitted in new drug applications (NDAs).

DATES: Submit written or electronic comments on the draft guidance by November 19, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Liang Zhou, Center for Drug Evaluation and Research (HFD–180), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7471.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation.''

Liposome drug products are defined as drug products containing drug substances (active pharmaceutical ingredients) encapsulated in liposomes. A liposome is a microvesicle composed of a bilayer of lipid amphipathic molecules enclosing an aqueous compartment. Liposome drug products are formed when a liposome is used to encapsulate a drug substance within the lipid bilayer or in the interior aqueous space of the liposome. A drug substance in a liposome formulation is intended to exhibit a different pharmacokinetic and/or tissue distribution (PK/TD) profile from the same drug substance (or active moiety) in a nonliposomal formulation given by the same route of administration. The complete characterization of the PK/TD profile of a new liposome drug product is essential to establish the safe and effective dosing regimen of the product.

The guidance provides recommendations to applicants on the CMC, human pharmacokinetics and bioavailability, and labeling documentation for liposome drug products submitted in NDAs. The guidance does not provide recommendations on: (1) Clinical efficacy and safety studies, (2) nonclinical pharmacology and/or toxicology studies, (3) bioequivalence studies or those to document sameness, (4) liposomal formulations of vaccine adjuvants or biologics, or (5) drug-lipid complexes.

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 liposome drug products: CMC, human pharmacokinetics and bioavailability, and labeling documentation. 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 Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch 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 either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: August 13, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 02–21263 Filed 8–20–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Rural Assistance Center

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

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration announces up to $600,000 in FY 2002 funds is available to fund a single competitive

cooperative agreement to support the development of a Rural Assistance Center (RAC) demonstration project. The RAC will assist rural communities and individual rural citizens in building and sustaining high-quality rural health care delivery systems.

Eligibility is open to any public or private entity. Faith-based organizations are eligible to apply for these funds. Awards will be made under the program authority of Section 301 of the Public Health Service Act. Funds for this award were appropriated under Public Law 107–116. The award will be for a period of three years. Additional funding of up to $600,000 annually in the second or third years is contingent on the availability of funds and grantee performance.

DATES: Applicants for this program are requested to notify the Office of Rural Health Policy by September 1, 2002. Notification of intent to apply can be made in one of three ways: telephone: 301–443–0835; e-mail *shirsch@hrsa.gov;* mail, Office of Rural Health Policy, Room 9A–55, 5600 Fishers Lane, Rockville, MD 20857. The deadline for receipt of grant applications is September 16, 2002. Applications will be considered on time if received on or before this date.

ADDRESSES: To receive a complete application kit, applicants may telephone the HRSA Grants Application Center at 1–877–477–2123 (1–877–HRSA–123) beginning August 16, 2002, or register on-line at: *http://www.hrsa.gov/,* or by accessing *http://www.hrsa.gov/g_order3.htm* directly. This program uses the standard Form PHS 5161–1 (rev. 7/00) for applications (approved under OMB No. 0920–0428). Applicants must use the Catalog of Federal Domestic Assistance (CFDA) number 93.223 when requesting application materials. The CFDA is a Government wide compendium of enumerated Federal programs, projects, services, and activities that provide assistance. An original and paper copies of applications should be mailed to: HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg MD, telephone: 1–877–HRSA–123 (477–2123), E-mail: *hrsagac@hrsa.gov.*

This application guidance and the required form for the Rural Assistance Center Program may also be downloaded in either Microsoft Word or Adobe Acrobat format (.pdf) from the ORHP Homepage at *http://www.ruralhealth.hrsa.gov.* Please contact Steve Hirsch at 301–443–0835 or *shirsch@hrsa.gov* if you need technical assistance in accessing the ORHP Home Page via the Internet.

SUPPLEMENTARY INFORMATION:

Program Background and Objectives

For the 65 million people living in rural America, the U.S. Department of Health and Human Services' mission to protect health and to provide assistance for those in need is especially relevant. Health care and social service programs in rural communities provide needed support of communities' well-being and represent a significant segment of the local economies. These programs, however, frequently lack adequate funds, personnel and support network.

For more than a decade, the Office of Rural Health Policy has supported activities that assist states, localities and rural citizens as they work to build and sustain high-quality rural health care delivery systems. One component of that support has been the Rural Information Center Health Service (RICHS). The intent of the RAC is to demonstrate that this activity can be expanded and enhanced to better serve rural communities by identifying private and public resources, collecting and sharing information about models that work, and serving as a technical resource for a wide range of health and social service issues.

In July of 2001, Secretary of Health and Human Services Tommy G. Thompson created a rural task force to assess how the Department serves rural communities. Among the key findings of this year-long initiative is that DHHS operates more than 220 discrete programs that affect rural communities. As part of the rural initiative, the Department's Rural Task Force also collected more than 450 public comments on a variety of issues affecting rural communities. One of the key themes that emerged from these public comments is the need to reach out to rural communities and help them identify how best to access the broad range of health and social services programs that are available to rural communities.

The Rural Assistance Center will serve as a focal point of information about the broad range of public and private opportunities that are available to support rural communities. The RAC will help rural communities navigate these opportunities, identify successful state and community models and provide links to existing private and public resources that support rural health care and social service delivery. This will, in turn, help rural communities build and enhance their rural services and strengthen their communities.

Authorization: Section 301 of the Public Health Service Act, 42 U.S.C. 241.

Purpose

The purpose of this cooperative agreement is to assist rural communities in developing and sustaining high-quality rural health care and social service delivery systems through an integrated assistance center. Specifically, through this cooperative agreement the RAC will:

(1) Serve as a support to rural communities and rural citizens to identify available programs for improving the ability of rural communities to provide high-quality health care and social services.

(2) Identify and synthesize information about the availability of existing private and public resources for enhancing rural health care and social service delivery.

(3) Identify and disseminate information about models that work in rural communities that have been able to sustain, enhance and improve their local health care and social service delivery systems.

(4) Promote collaboration among DHHS programs that serve rural communities to increase effectiveness and reduce duplication of effort.

Eligibility

Under section 301 of the Public Health Service Act, any public or private entity is eligible to apply. Under the President's initiative, community-based and faith-based organizations that are otherwise eligible and believe they can contribute to HRSA's program objectives are encouraged to consider this initiative.

Funding Levels/Project Periods

The administrative and funding instrument to be used for the RAC will be a cooperative agreement, in which substantial ORHP policy expertise and/or programmatic involvement with the awardee is anticipated during the performance of the project. There is no requirement for matching funds with this program. Under the terms of this cooperative agreement, in addition to the required monitoring and technical assistance, Federal responsibilities will include:

(1) Participation in meetings conducted during the period of the cooperative agreement.

(2) Ongoing review of activities and procedures to be established and implemented.

(3) Review of project information prior to dissemination.

(4) Review of information on project activities.

(5) Assistance with the establishment of contacts with Federal and State agencies, grant projects and other contacts that may be relevant to the project's mission and referrals to these agencies.

One project will be approved for three years. Up to $600,000 in fiscal year 2002 funds will be used to fund the first year. Additional funding of up to $600,000 annually in years two and three will be contingent on the availability of funds and grantee performance.

Review Criteria

Applications that are complete and responsive to the guidance will be evaluated by an objective review panel specifically convened for this solicitation and in accordance with HRSA grants management policies and procedures.

Applications will be reviewed using the following criteria:

1. Knowledge and Understanding of the Issues relating to Rural Health and Rural Social Services (Weight: 20%) and the Challenges Facing Providers and Beneficiaries in Rural Areas

- The degree of understanding of the evolution of rural health and social services and the historical challenges facing rural communities in terms of resources and demographics (including populations experiencing cultural and linguistic barriers to care).
- The degree of thoroughness in describing how the RAC will address information gaps for rural communities.
- The extent of applicant knowledge of rural health and social service issues.
- The extent of applicant knowledge of the individuals and organizations involved in the rural health and social services.

2. Soundness and Adequacy of Project Plan (Weight: 30%)

- The extent to which the project objectives address the program purpose and are measurable, time-framed, and appropriate in relation to both the program requirements and identified needs.
- The degree to which the program areas outlined in the grant guidance have been addressed, prioritized and justified.
- The quality and feasibility of the project plan or methodology and its relation to the project's goals and objectives.
- The extent to which the proposed approach identifies the resources that will be used to implement the strategies.
- The degree to which the approaches are technically sound and appropriate to the project goals and objectives.

3. Soundness of Implementation Plan (Weight: 10%)

- The soundness of the plan for creating and implementing the RAC.
- The extent to which the applicant describes how the project staff will determine the degree to which proposed activities are being successfully conducted and completed, based on the objectives outlined.

4. Applicant's Capability and Capacity (Weight: 30%)

- The extent to which the applicant has demonstrated expertise and its capability to oversee and successfully carry out the project.
- Evidence that a sufficient number of project personnel and resources are proposed. Biographical sketches/curricula vitae document education, skills and experience that are relevant and necessary for the proposed project.

5. Appropriateness of Budget (Weight: 10%)

- The extent to which the proposed budget is realistic, adequately justified, and consistent with the proposed project plan.
- The extent to which the costs of administration and monitoring/evaluation are reasonable and proportionate to the costs of service provision.
- The degree to which the costs of the proposed project are economical in relation to the proposed service utilization.

Additional criteria may be used in the review of applications for this competition. Any such criteria will be identified in the program guidance included in the application kit. Applicants should pay strict attention to addressing these criteria, in addition to those referenced above.

This program is not subject to the provision of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100). This program is also not subject to the Public Health Systems Reporting Requirements.

Paperwork Reduction Act

OMB approval for any data collection in connection with this cooperative agreement will be sought, as required under the Paperwork Reduction Act of 1995.

Dated: August 15, 2002.

Elizabeth M. Duke,

Administrator.

[FR Doc. 02–21340 Filed 8–20–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Development of High-Yield Technologies for Isolating Exfoliated Cells in Body Fluids.

Dated: September 18, 2002.

Time: 8 AM to 5 PM.

Agenda: To review and evaluate grant applications.

Place: 6130 Executive Boulevard, Executive Plaza North, Room H, Rockville, MD 20852.

Contact Person: Kenneth L. Bielat, PhD, Scientific Review Administrator, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 7147, Bethesda, MD 20892, (301) 496–7576, *bielatk@mail.nih.gov.*

Catalogue of Federal Domestic Assistance Program Nos. 93,392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: August 13, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–21234 Filed 8–20–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as