1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sakineh Walther, Center for Drug Evaluation and Research (HFD–316), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–8964.

SUPPLEMENTARY INFORMATION:

I. Background

In the United States, as many as several thousand drug products are marketed illegally without required FDA approval. The manufacturers of these drugs have neither received FDA approval to legally market their drugs, nor have the drugs been marketed in accordance with a final OTC drug monograph. The drug approval and OTC monograph processes play an essential role in ensuring that all drugs are both safe and effective. Manufacturers of new drugs that lack required approval, including those that are not marketed in accordance with an OTC drug monograph, have not provided FDA with evidence demonstrating that their products are safe and effective. Therefore, FDA has an interest in taking steps to encourage the manufacturers of these products either to obtain the required evidence and comply with the approval provisions of the Federal Food, Drug, and Cosmetic Act or to remove the products from the market. FDA wants to achieve these goals without adversely affecting public health, imposing undue burdens on consumers, or unnecessarily disrupting the market.

In general, in recent years, FDA has employed a risk-based enforcement approach to marketed unapproved drugs that includes efforts to identify illegally marketed drugs, prioritization of those drugs according to potential public health concerns or other impacts on the public health, and subsequent regulatory followup. Some of the specific actions the agency has taken have been precipitated by evidence of safety or effectiveness problems that has come to our attention either during inspections or through outside sources.

II. The Guidance

FDA is announcing the availability of a guidance entitled ''Marketed Unapproved Drugs—Compliance Policy Guide.'' In the **Federal Register** of October 23, 2003 (62 FR 60702), FDA announced the availability of a draft guidance of the same title and gave interested persons an opportunity to submit comments by December 22, 2003. In response to comments received, the agency revised the guidance to include editorial corrections and clarification of policies, including clarification of when and how we intend to exercise our enforcement discretion. The revisions also clarify the discussion of ''grandfather'' status and expressly state that no part of the guidance is a finding as to the legal status of any particular drug product.

This document supersedes section 440.100 entitled ''Marketed New Drugs Without Approved NDAs or ANDAs'' (CPG 7132c.02) of the CPG. It applies to any new drug required to have FDA approval for marketing, including new drugs covered by the OTC review.

The goals of the guidance are to address the following issues: (1) Clarify for FDA personnel and the regulated industry how the FDA intends to exercise its enforcement discretion regarding unapproved drugs and (2) emphasize that illegally marketed drugs must obtain FDA approval.

The guidance reflects the agency's desire to address these issues with policies that are predictable, reasonable, and supportive of the public health. The agency's approach encourages companies to comply with the drug approval process, but it also seeks to minimize disruption to the marketplace and to safeguard consumer health when there are potential safety risks. The guidance explains that FDA will continue to give priority to enforcement actions involving unapproved drugs with potential safety risks, that lack evidence of effectiveness, and that constitute health fraud. It also explains how the agency intends to address those situations in which a firm obtains FDA approval to sell a drug that other firms have long been selling without FDA approval. It confirms that the agency will continue longstanding policies regarding firms making unapproved drugs who are violating the act in other respects and clarifies how the agency plans to address formulation changes made to evade an enforcement action.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on 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. 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 document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: June 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–9032 Filed 6–8–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

DNA Influenza Vaccine

Description of Technology: The FDA is pleased to announce a single vector DNA vaccine against influenza as available for licensing. The single vector

expresses both hemagglutinin (HA) and matrix (M) proteins, generating both humoral and cellular immune responses. The vaccine candidate completely protected mice against homologous virus challenge and significantly improved survival against heterologous virus challenge. A robust and reliable vaccine supply is widely recognized as critical for seasonal or pandemic influenza preparedness. The advantages offered by this vaccine make it an excellent candidate for further development.

Advantages: (1) DNA vaccines are easy to produce and store; (2) Vaccine candidate improved survival against heterologous virus challenge; (3) No risk of reversion to pathogenic strain as with live-attenuated virus vaccines; (4) Can be administered to immuno-compromised individuals, increasing potential market size; (5) HA and M proteins encoded by single vector, ensuring uniform delivery of immunogen; (6) More efficient to boost synergistic effects on both HA and M specific immune responses than a mixture of individual plasmids; (7) M protein not subject to antigenic drift, which allows advanced manufacturing and overcomes the need for strain monitoring; (8) DNA vaccines elicit cellular immune response, essential for efficient virus clearance.

Inventors: Zhiping Ye *et al.* (FDA).

Patent Status: U.S. Provisional Application No. 60/786,747 filed 27 Mar 2006 (HHS Reference No. E–300–2005/0–US–01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Susan Ano, Ph.D.; 301/435–5515; *anos@mail.nih.gov.*

Collaborative Research Opportunity: The Food and Drug Administration is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact the inventor, Zhiping Ye at 301/435–5197 or Beatrice Droke at 301/827–7008 for more information.

Method for Improved Phase Contrast MRI Resolution

Description of Technology: This invention is a method to significantly improve the temporal or spatial resolution in a phase contrast MRI (PC–MRI) study. In general, conventional PC–MRI involves encoding the motion information of spins in the phase of the image. The velocity of the spin motion can be extracted by calculating the phase difference between two consecutive images acquired with two different bipolar encoding gradients. Two scans are required in order to reconstruct flow velocity data, resulting in an increase in image acquisition and reconstruction time by a factor of two compared to that of a standard anatomical image. As a means of reducing the PC–MRI scan time, the inventors propose a method of acquiring only a fraction of k-space data. The k-space is sampled using an under-sampled spiral or single projection, radial scheme. Subsequently, the two data sets in the PC–MRI are subtracted to extract the motion information from undersampled data without any aliasing artifacts. This method of partial-field of view acquisition and reconstruction of PC-MRI results in an increased temporal resolution, while maintaining high spatial resolution. The increase in image acquisition efficiency could be used to increase the spatial resolution while maintaining the temporal resolution.

Inventors: Reza Nezafat *et al.* (NHLBI).

Patent Status: U.S. Patent Application No. 11/227,406 filed 14 Sep 2005 (HHS Reference No. E–134–2005/0-US–01).

Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: Chekesha Clingman, PhD; 301/435–5018; clingmac@mail.nih.gov.

Image Guided Systems and Methods for Organ Viability Assessment

Description of Technology: The number of patients for organ transplants continues to grow, without an increase in the number of organs available for transplant. This has increased interest in transplanting organs from non-traditional sources, such as donations after cardiac death. However, there are currently no methods to objectively measure the effects of resuscitation and ischemia damage on organ viability.

The present invention relates to systems and methods for evaluating the status and characterization of organs, determining their suitability for transplants, as well as restoring the viability of organs intended for transplants. Particularly, this method is based on using optical (infrared or near infrared) imaging to guide the resuscitation of the donor organs and predict the recovery of grafts challenged with several hours of preservation. This method allows for localization of ischemic areas and guiding targeted resuscitation of the organ.

For example, the inventors have shown that by combining a kidney reperfusion system with infrared imaging equipment, it is possible to differentiate between ischemic and non-ischemic tissue and restore the viability of the kidney. This method can potentially be used to evaluate the viability of any body part or organ intended for transplantation, such as extremities, heart, lungs, and liver. This approach can lead to the utilization of donation-after-cardiac-death organs and can substantially increase the donor pool of organs. Hence, this new method can identify organs that may be considered unsuitable for transplant, and help prevent transplantation of organs whose function may be considered impaired, as well as help guide resuscitation efforts.

Inventors: Alexander M. Gorbach (ORS), Allan D. Kirk (NIDDK), Eric Elster (NIDDK).

Patent Status: U.S. Provisional Application No. 60/778,785 filed 03 Mar 2006 (HHS Reference No. E–098–2005/0–US–01).

Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: Chekesha Clingman, PhD; 301/435–5018; *clingmac@mail.nih.gov.*

Dated: June 5, 2006.

David R. Sadowski,

Acting Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E6–9018 Filed 6–8–06; 8:45 am]

BILLING CODE 4140–01–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 rant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Small Grants for Behavioral Research in Cancer Control.

Date: June 26–27, 2006.

Time: 9 a.m. to 5 p.m.

Agenda: To review an evaluate grant applications.