recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records administration at the following Internet address: *www.access.gpo.gov/nara/cfr-table-search.html*.

The following additional requirements apply to this project:

- AR–7 Executive Order 12372.
- AR–10 Smoke-Free Workplace Requirements.
- AR–11 Healthy People 2010.
- AR–12 Lobbying Restrictions.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm*.

VI.3. Reporting Requirements

You must provide CDC with a signed original and two copies of the following reports:

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application for the subsequent year, and must contain the following elements:

a. Current Budget Period Activities Objectives—(1) A description of accomplishments and progress in achieving objectives within the planned budget during the first six months of the current budget period, (2) reasons for not achieving established objectives and what will be done to meet unmet objectives, (3) Current budget period financial progress, (4) new budget period proposed program activities and objectives, (5) Detailed line-item budget and justification, (6) If contracts are proposed, provide the name of the contractor(s), method of selection, period of performance, scope of work, and itemized budget and budget justification/narrative.

2. Financial status report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: (770) 488–2700.

For program technical assistance, contact: Ron Stoddard, Project Officer, Program Development Branch, Division of Diabetes Translation, Centers for Disease Control and Prevention, 4770 Buford Highway, MS K–10, Atlanta, Georgia 30341–3717, Telephone: (770) 488–5013, E-mail: *rrs1@cdc.gov*.

For budget assistance in the states, contact: Tiffney Esslinger, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: (770) 488–2686, E-mail: *tde2@cdc.gov*.

For budget assistance in the territories, contact: Vincent Falzone, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: (770) 488–2763, E-mail: *vcf6@cdc.gov*.

Dated: April 20, 2004.

William P. Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04–9372 Filed 4–23–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0176]

Preparation for the International Conference on Harmonization Meetings in Washington, DC; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Preparation for ICH meetings in Washington, DC'' to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in Washington, DC. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Experts Working Groups meetings in Washington, DC, June 7–10, 2004, at which discussion of the topics underway and the future of ICH will continue.

Date and Time: The meeting will be held on May 17, 2004, from 1:30 to 4:30 p.m.

Location: The meeting will be held at 5600 Fishers Lane, 3d floor, Potomac Conference Room, Rockville, MD 20857. For security reasons, all attendees are asked to arrive no later than 1:30 p.m., as you will be escorted from the front entrance of 5600 Fishers Lane to the Potomac Conference Room.

Contact Person: Sema Hashemi, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3050, FAX: 301–480–0716, e-mail: *Sema.Hashemi@fda.hhs.gov*.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to the contact person by May 7, 2004.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

If you need special accommodations due to a disability, please contact Sema Hashemi 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 the following 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 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 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. Oral presentations from the public will be scheduled between approximately 3:45 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 May 7, 2004, and submit a brief statement of the general nature of the evidence or arguments they which to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be made available on May 3, 2004, via the Internet at *http://www.fda.gov/cder/meeting/ICH__05172004.htm.*

Dated: April 19, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–9323 Filed 4–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999D–0529]

Guidance for Industry on Changes to an Approved New Drug Application or Abbreviated New Drug Application; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of April 8, 2004 (69 FR 18768). The document announced the availability of a revised guidance for industry entitled ''Changes to an Approved NDA or ANDA.'' The document was published with inadvertent errors. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Joyce A. Strong, Office of Policy and Planning (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 04–7533, appearing on page 18768 in the **Federal Register** of Thursday, April 8, 2004, the following corrections are made:

1. On page 18768, in the first column, under the **FOR FURTHER INFORMATION CONTACT** section, the contact information is corrected to read ''David J. Cummings, Center for Drug Evaluation and Research (HFD–357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5187.''

2. On page 18768, in the third column, the second full paragraph is removed.

Dated: April 19, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–9324 Filed 4–23–04; 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.

Reactivity of Human Sera in a Sensitive, High Throughput Pseudovirus-Based Papillomavirus Neutralization Assay for HPV 16 and HPV 18

John Schiller (NCI), Douglas Lowy (NCI), Chris Buck (NCI),

Diana Pastrana (NCI), Richard Roden (EM), DHHS Reference No. E–137–2004/0—Research Material

Licensing Contact: Peter Soukas; (301) 435–4646; *soukasp@mail.nih.gov.*

This invention is a research tool for measuring protective antibody responses generated by prophylactic Human Papilloma Virus (HPV) vaccines. Sensitive high-throughput neutralization assays, based upon pseudoviruses carrying a secreted alkaline phosphatase (SEAP) reporter gene, were developed and validated by the inventors for HPV 16, HPV 18, and bovine papillomavirus 1 (BPV1). In a 96-well plate format, the assay was reproducible and appears to be as sensitive as, but more specific than, a standard papillomavirus-like particle (VLP)-based enzyme-linked immunosorbent assay (ELISA). The SEAP pseudovirus-based neutralization assay should be a practical method for quantifying potentially protective antibody responses in HPV natural history and prophylactic vaccine studies.

This assay is available nonexclusively through a biological materials license. The assay is further described in Pastrana *et al.*, ''Reactivity of human sera in a sensitive, high-throughput pseudovirus-based papillomavirus neutralization assay for HPV16 and HPV18,'' *Virology.* 2004 Apr 10;321(2):205–16.