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.