Regulations (ICCR) Meeting in Brussels, Belgium'' to provide information on the process and receive comments on issues that may be relevant to discussions being held at the ICCR meeting in Brussels, Belgium. The purpose of the meeting is to solicit public input prior to the first meeting of this group in Brussels on September 27, 2007.

Date and Time: The meeting will be held on Tuesday, August 28, 2007, from 2 p.m. to 3:30 p.m.

Location: The meeting will be held at 5600 Fishers Lane, 3rd fl., Chesapeake Conference Room, Rockville, MD 20857. For security reasons, all attendees must preregister and are asked to arrive no later than 1:50 p.m., as you will be escorted from the front entrance of 5600 Fishers Lane to the Chesapeake Conference Room.

Contact Person: All participants must register with Michelle Limoli, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, by e-mail: *michelle.limoli@fda.hhs.gov* or FAX: 301–827–0003.

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 August 21, 2007.

If you need special accommodations due to a disability, please contact Michelle Limoli at least 7 days in advance.

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. 6–30, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

SUPPLEMENTARY INFORMATION: The ICCR is a voluntary international group of cosmetics regulatory authorities from the United States, Japan, the European Union, and Canada. It should be noted that the definition and regulatory classification of ''cosmetics'' in the different countries/regions is not identical. For this reason, the ICCR will consider some U.S. over-the-counter drugs that are regulated as ''cosmetics'' outside the United States. ICCR members are: the Food and Drug Administration of the United States of America; the Ministry of Health, Labour, and Welfare of Japan; the European Commission Directorate General Enterprise; and Health Canada. This multilateral framework was created to identify ways to remove regulatory obstacles among the regions, while maintaining the highest level of global consumer protection. The first meeting of the group will occur in Brussels, Belgium, September 27, 2007.

The ICCR will operate on a consensus basis whereby all decisions of the representatives of the regulatory members and subsequent actions must be taken by consensus. Members agree to take steps as appropriate to implement the items that have reached consensus within the boundaries of their legal and institutional constraints. In this respect, they agree to promote the documents reflecting the consensus within their own jurisdictions and to seek convergence of regulatory policies and practices.

The members' responsibilities will include providing overall strategic guidance and direction to activities of ICCR; defining subject areas for ICCR activities and deciding on future topics for activity; exchanging information on regulatory, trade, and market developments of interest; determining policies related to the ICCR process, administration, and external communications; appointing ad-hoc working groups to carry out technical work as needed; adopting guidelines and policy statements, including those developed by the ad-hoc working groups; and taking on any other initiatives that contribute to achieving ICCR objectives.

It is recognized that successful implementation requires the input of a constructive dialogue with the cosmetics' industry trade associations and other relevant stakeholders, hence the scheduling of this public meeting.

The industry trade associations of each region will gather input in order to represent all affected industry sectors on specific issues at ICCR meetings. Prior to ICCR meetings, well in advance to allow adequate time for preparation, industry will suggest items for priority actions to be consider by ICCR members. During the ICCR meeting, industry trade associations will enter in a constructive dialogue with the members and give their opinion and directions for future work.

According to specific needs, ICCR working groups may be established with a precise mandate on an ad-hoc and temporary basis by the members. Working groups are created primarily for the purpose of developing proposed guidelines and policy statements for adoption by the members. The working group participants are appointed by consensus of the members. Outside technical experts may be invited on an as-needed basis.

The ICCR will meet at least once per year, but may alter the frequency of meetings if considered necessary to ensure progress. The venue of meetings rotates among the territory of the four members.

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 p.m. and 3:30 p.m. Time allotted for oral presentations may be limited by the numbers requesting to speak; however no more than 10 minutes will be allotted per speaker. Those desiring to make oral presentations should notify the contact person by August 24, 2007, and submit a brief statement of the general nature of the evidence or arguments they wish 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.

Dated: August 8, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–3954 Filed 8–9–07; 1:38 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission of OMB Review; Comment Request; Drug Accountability Record

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, the National Cancer Institute (NIH) will publish periodic summaries to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Drug Accountability Record (Form NIH 2564).

Type of Information Collection Request: Extension, with no Changes OMB No. 0925–0240, Expiration Date 11/30/07.

Need and Use of Information Collection: Food and Drug Administration (FDA) regulations require investigators to establish a record of the receipt, use and disposition of all investigational agents. The National Cancer Institute, (NCI) as a sponsor investigational drug trials, has the responsibility to assure the FDA that investigators in its clinical trials program are maintaining systems for drug accountability. In order to fulfill

these requirements, a standard Investigational Drug Accountability Report Form (NIH 2564) was designed to account for drug inventories and usage by protocols. The data obtained from the drug accountability record will be used to keep track of the dispensing of investigational anticancer agents to patients. It is used by NCI management to ensure that investigational drug supplies are not diverted for inappropriate protocol or patient use. The information is also compared to patient flow sheets (protocol reporting forms) during site visits conducted for each investigator once every three years. All comparisons are done with the intention of ensuring protocol, patient and drug compliance for patient and drug compliance for patient safety and protections.

Frequency of Response: Daily.

Affected Public: State or local governments, businesses or other for-profit. Federal agencies or employees, non-profit institutions, and small business or organizations.

Type of Respondents: Investigators, pharmacist, nurses, pharmacy technicians, data manager. The annual reporting burden is divided into two major areas. These are the audits of Drug Accountability Forms by Government and its contractors and the use of the forms by clinical research sites. The burden is as follows:

Federal Burden: 1,700 audits are conducted of clinical research sites, a minimum of three Drug Accountability Forms are reviewed at the audit. Each form requires a ½ hour to review.

Number of Respondents: 1,700.

Number of Responses per Respondent: 3.

Average Burden per Response: 0.5 hours.

Annual Burden Hours: 2,250 hours.

Clinical Trial Site Burden: The annualized respondents' burden for recordkeeping is estimated to require 6,240 hours. The recordkeeping burden represents an average time required for multiple entries (4 minutes or 0.1 hour per entry) on the drug accountability form, the average number of forms maintained by each recordkeeper and the number of recordkeepers.

Drug Accountability Forms

Number of Record Keepers: 3,990.

Number of Responses per Respondent: 16.

Average Burden per Response: 0.1.

Annual Burden Hours: 6,240 hours.

There are no Capital Costs, Operating Costs, and Maintenance Cost to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information; including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

For Further Information Contact: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Charles L. Hall, Jr., Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division of the Cancer Treatment and Diagnosis, and Centers, National Cancer Institute, Executive Plaza North, Room 7148, 9000 Rockville Pike, Bethesda, MD 20892 or call non-toll-free number 301–496–5725 or e-mail your request, including your address to: *Hallch@mail.nih.gov.*

Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days following the date of this publication.

Dated: August 3, 2007.

Ann E. Duane,

Acting NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. E7–15750 Filed 8–10–07; 8:45 am]

BILLING CODE 4140–01–P

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.

An Improved Chromosomal Comparative Genomic Hybridization (CGH) Microarray for the Detection of Cancer Associated Genome Amplification and Deletion Events

Description of Technology: The progression and therapeutic response of cancer is closely associated with chromosomal instability (i.e. genomic amplifications and deletions). The most widely used technique to detect these small changes in the genome is CGH. CGH utilizes nucleic acid hybridization to oligonucleotide features corresponding to specific, predetermined regions of the genome to detect DNA copy number changes. Due to the size of the human genome, it is necessary to have high-density features to detect small amplification and deletion events within the genome.

The current invention is based on a CGH microarray with oligonucleotide features that provides a high-density coverage. More specifically, the inventors have used 60-mer oligonucleotide features within a previously shown set of 36 tumor associated genes/genomic regions and have successfully detected small changes in DNA copy number with high density coverage (1 feature per 400bp). Furthermore, the inventors have used a fade-out design for coverage of the flanking regions and cover the remainder of the genome at an average density of 1 feature per 100kb.

Applications:

1. CGH microarray can be used to detect small regions of genomic instability within cancer associated genes, while larger events can also be detected with similar efficacy.

2. Gene amplification and deletion profiles of patient samples can be used in diagnosis and therapeutic decision making.

Advantages:

1. Easy to use, CGH microarray technique, based on current technology.

2. Technology detects small changes in tumor associated genomic instability