TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

CFR Sections	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
821.2 and 821.30(e)	4	1	4	12	48
821.25(a)	1	1	1	76	76
821.25(d)	22	1	22	2	44
821.30(a) and (b)	17,000	72	1,222,725	0.1666	203,706
821.30(c)(2)	1	1	1	28	28
821.30(d)	17,000	15	259,186	0.1666	43,180
Total					247,082

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

CFR Sections	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
821.25(b)	229	46,260	10,593,433	0.2899	3,071,036
821.25(c)	229	1	229	63.0	14,430
821.25(c)(3)	229	1,124	257,454	0.2899	74,636
TOTAL					3,160,102

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The annual hourly reporting burden for respondents involved in medical device tracking is estimated to be 247,082 hours, and the annual recordkeeping burden for these respondents is estimated to be 3,160,102 hours. These numbers have been rounded up. The burden estimates cited in tables 1 and 2 of this notice are based primarily upon the data and methods provided in FDA's assessment for fiscal year (FY) 1999 entitled ''A Cost Assessment of Medical Device Tracking.'' Using implantation procedures from the National Center for Health Statistics, FDA applied a 2-percent annual growth rate to estimate the number of procedures for tracked implant devices for FY 1997 through FY 2006. This assessment also used unit shipment data in combination with various growth rates to estimate annual sales distribution for the tracked l/s-l/s devices over the same time period. In addition, the assessment also estimated the burden on industry for developing and maintaining tracking systems for these medical devices for FY 1997 through FY 2006.

For the annual recordkeeping burden, the number of respondent medical device manufacturers subject to device tracking is estimated to be 229 and is based on data from FDA's manufacturers database. FDA issued tracking orders to 20 additional medical device manufacturers during the time period for FY 2002 through FY 2004. Under § 821.25(c), the additional medical device manufacturers collectively bear a one-time recordkeeping burden of 10,560 hours to develop a medical device tracking system. FDA's estimate of 17,000 medical device distributor respondents contained in this assessment, are derived from Dun & Bradstreet sources on medical equipment wholesalers, retailers, home care dealers, and rental companies. Health Forum, an American Hospital Association Company, provided statistics on hospitals.

Dated: April 15, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–8682 Filed 4–21–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee. This meeting was announced in the **Federal Register** of March 27, 2008 (73 FR 16314). The amendment is being made to reflect changes in the introductory paragraph and to add a portion entitled ''*Closed Committee Deliberations.*'' There are no other changes.

FOR FURTHER INFORMATION CONTACT: Teresa Watkins, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail:

Teresa.Watkins@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572) in Washington, DC area), codes 3014512529 and 3014512535. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 27, 2008, FDA announced that a meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee would be held on May 5 and 6, 2008.

On page 16314, in the third column, the introductory paragraph of the document is amended to read as follows:

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

On page 16315, the second column of the document is amended to add a portion entitled ''*Closed Committee Deliberations*'' to read as follows:

Closed Committee Deliberations: On May 5, 2008, from 8 a.m. to 9:15 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)). During this session, the committee will discuss the details of a proprietary research report and protocol addressing characteristics of different formulations.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: April 16, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–8683 Filed 4–21–08; 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.

Platform for the High Throughput Screening of Single Nucleotide Polymorphisms and Small Insertions and Deletions

Description of Technology: Available for licensing and commercial development is an oligoarray-based process for gene-specific single nucleotide polymorphism (SNP) genotyping based on comparative hybridization. This process can detect, even in heterozygous conditions, known and potentially flag unknown variants (point mutations, base insertion or deletion) along the complete sequence of a given gene while drastically cutting the time and costs compared to high-throughput direct sequencing without affecting sensitivity and specificity. The accuracy and efficiency of the invention was validated based on the BRCA–1 breast and ovarian cancer predisposing gene. This process can easily be custom designed to include within the same platform a relatively large number of genes relevant to a specific clinical condition and it is particularly useful for the screening of long genomic region with relatively infrequent but clinically relevant variants.

More specifically, the invention is made reliable by the development of two tailored algorithms: the first automatically designs the complete data set of gene-specific probes starting from the genomic sequence according to the user specification (size of the probes, relative position, etc.); and the other is based on an algorithm that flags gene variants in the test sample. This allows detecting unknown variants in the region in which only the reference hybridizes to the probes. These features drastically reduce the amount of sequencing (the gold standard for SNP detection) to small regions in which a discrepancy between test signal and reference signal is found. Moreover, there is no limit, other than the physical area of the slide, to the number of probes that can be added to the array and the number of genes that can be queried simultaneously. Thus, a repertoire of considerable size can be scanned in a single test for each sample with sensitivity and specificity comparable to direct sequencing.

Applications: The immediate clinical applications of this platform is a remarkable improvement of genetic testing by increasing the number of target genes that can be screened in a short time, at a minimal cost using an automated simplified analysis, such as the sequencing-grade screening for BRCA–1 variants and the detection of mutations in cancerous tissues. The method can be also applied to other human genes (coding and non-coding sequences), and other sequences from animals, bacterial and viruses.

Development Status: Method fully developed and validated.

Inventors: Ena Wang (CC), Alessandro Monaco (CC), Francesco M Marincola (CC), et al.

Patent Status: U.S. Provisional Application No. 61/068,182 filed 05 Mar 2008 (HHS Reference No. E–082–2008/0–US–01).

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

Licensing Contact: Cristina Thalhammer-Reyero, Ph.D., M.B.A.; 301–435–4507; *thalhamc@mail.nih.gov*.

Generation of Wild-Type Dengue Viruses for Use in Rhesus Monkey Infection Studies

Description of Technology: Dengue virus is a positive-sense RNA virus belonging to the *Flavivirus* genus of the family Flaviviridae. Dengue virus is widely distributed throughout the tropical and semitropical regions of the world and is transmitted to humans by mosquito vectors. Dengue virus is a leading cause of hospitalization and death in children in at least eight tropical Asian countries. There are four serotypes of dengue virus (DEN–1, DEN–2, DEN–3, and DEN–4) that annually cause an estimated 50–100 million cases of dengue fever and 500,000 cases of the more severe form of dengue virus infection known as dengue hemorrhagic fever/dengue shock syndrome (DHF/DSS). This latter disease is seen predominately in children and adults experiencing a second dengue virus infection with a serotype different than that of their first dengue virus infection and in primary infection of infants who still have circulating dengue-specific maternal antibody. A vaccine is needed to lessen the disease burden caused by dengue virus, but none is licensed.

Because of the association of more severe disease with secondary dengue