approximately 214,400 registered users of the PN System Interface will submit an average of 8.33 prior notices annually, for a total of 1,785,952 prior notices received annually through the PN System Interface. FDA estimates the reporting burden for a prior notice submitted through the PN System Interface to be 23 minutes, or 0.384 hours, per notice, for a total burden of 685,806 hours.

FDA received no cancellations of prior notices through ABI/ACS during December 2003; 16,624 during 2004; and 21,720 during 2005. Based on this experience, FDA estimates that approximately 6,500 users of ABI/ACS will submit an average of 3.34 cancellations annually, for a total of 21,710 cancellations received annually through ABI/ACS. FDA estimates the reporting burden for a cancellation submitted through ABI/ACS to be 15 minutes, or 0.25 hours, per cancellation, for a total burden of 5,428 hours.

FDA received 1,539 cancellations of prior notices through the PN System Interface during December 2003; 64,918 during 2004; and 65,491 during 2005. Based on this experience, FDA estimates that approximately 214,400 registered users of the PN System Interface will submit an average of 0.31 cancellations annually, for a total of 66,464 cancellations received annually through the PN System Interface. FDA estimates the reporting burden for a cancellation submitted through the PN System Interface to be 15 minutes, or 0.25 hours, per cancellation, for a total burden of 16,616 hours.

FDA has not received any requests for review under §§ 1.283(d) or 1.285(j) in the last 3 years (December 2003 through 2005); therefore, the agency estimates no more than one request for review will be submitted annually. FDA estimates that it will take a requestor about 8 hours to prepare the factual and legal information necessary to prepare a request for review. Thus, FDA has estimated a total reporting burden of 8 hours.

FDA has not received any post-hold submissions under § 1.285(i) in the last 3 years (December 2003 through 2005); therefore, the agency estimates no more than one post-hold submission will be submitted annually. FDA estimates that it will take about 1 hour to prepare the written notification described in § 1.285(i)(2)(i). Thus, FDA has estimated a total reporting burden of 1 hour.

In cases where a regulation implements a statutory information collection requirement, only the additional burden attributable to the regulation, if any, has been included in FDA's burden estimate.

Dated: December 13, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6–21737 Filed 12–19–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2003D–0478]**

### Marketed Unapproved Drugs; Public Workshop; Change of Meeting Location and Time

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a change of location and time for the upcoming public workshop on marketed unapproved drugs. Registration for the public workshop is closed. A new address and time are given for those persons who have previously registered with FDA.

**DATES:** The public workshop will be held on January 9, 2007, from 8:30 a.m. to 4:30 p.m.

**ADDRESSES:** The public workshop will be held in the Universities at Shady Grove, Conference Center Auditorium, bldg. 1, 9640 Gudelsky Dr., Rockville, MD. Directions and information on parking, hotels, and transportation options can be found at *http://www.shadygrove.umd.edu/conference*. The agenda for the workshop will be posted at *http://www.fda.gov/cder/drug/unapproved_drugs*.

**FOR FURTHER INFORMATION CONTACT:** Karen Kirchberg, Center for Drug Evaluation and Research (HFD–330), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–8916, e-mail: *Karen.Kirchberg@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

In the **Federal Register** of November 1, 2006 (71 FR 64284), FDA issued a notice announcing a public workshop on issues related to the application process for seeking approval for marketed unapproved drugs. The November 1, 2006, notice invited individuals interested in attending the workshop to register and submit topics for discussion by November 15, 2006. Registration for the workshop is closed. Attendance at the workshop is limited to those persons who have previously registered with FDA.

Because of a greater than anticipated response for attending the public workshop, FDA is announcing in this notice a new location and time.

#### II. New Location and Time for the Public Workshop

The new location will be the Universities at Shady Grove, Conference Center Auditorium (see **ADDRESSES**). Directions and information on parking, hotels, and transportation options can be found at *http://www.shadygrove.umd.edu/conference*. The new time will be 8:30 a.m. to 4:30 p.m.

Dated: December 14, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6–21738 Filed 12–19–06; 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.

#### Production, Recovery and Purification Process for Plasmid DNA Clinical Manufacturing

*Description of Technology:* Available for licensing from NIH is a method for large scale production, recovery, and purification process for plasmid DNA manufacturing meeting human clinical trial requirements. DNA plasmid