TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Part 3	43	1	43	24	1,032

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

Dated: December 13, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–21636 Filed 12–19–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0202]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 19, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002—21 CFR 1.278 to 1.285 (OMB Control Number 0910–0520)—Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) added section 801(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(m)), which requires that FDA receive prior notice for food, including food for animals, that is imported or offered for import into the United States. Sections 1.278 to 1.282 of FDA's regulations (21 CFR 1.278 to 1.282) set forth the requirements for submitting prior notice; §§ 1.283(d) and 1.285(j) (21 CFR 1.283(d) and 1.285(j)) set forth the procedure for requesting FDA review after an article of food has been refused admission under section 801(m)(1) of the act or placed under hold under section 801(l) of the act; and § 1.285(i) (21 CFR 1.285(i)) sets forth the procedure for post-hold submissions. Advance notice of imported food allows FDA, with the support of the Bureau of Customs and Border Protection (CBP), to target import inspections more effectively and help protect the nation's food supply against terrorist acts and other public health emergencies.

Any person with knowledge of the required information may submit prior notice for an article of food. Thus, the respondents to this information collection may include importers, owners, ultimate consignees, shippers, and carriers.

FDA's regulations require that prior notice of imported food be submitted electronically using CBP's Automated Broker Interface of the Automated Commercial System (ABI/ACS) (§ 1.280(a)(1)) or the FDA Prior Notice (PN) System Interface (Form FDA 3540) (§ 1.280(a)(2)). The term ''Form FDA 3540'' refers to the electronic system known as the FDA PN System Interface, which is available at *http://www.access.fda.gov*. Prior notice must be submitted electronically using either ABI/ACS or the FDA PN System Interface. Information collected by FDA in the prior notice submission includes: The submitter and transmitter (if different from the submitter); entry type and CBP identifier; the article of food, including complete FDA product code; the manufacturer, for an article of food no longer in its natural state; the grower, if known, for an article of food that is in its natural state; the FDA Country of Production; the shipper, except for food imported by international mail; the country from which the article of food is shipped or, if the food is imported by international mail, the anticipated date of mailing and country from which the food is mailed; the anticipated arrival information or, if the food is imported by international mail, the U.S. recipient; the importer, owner, and ultimate consignee, except for food imported by international mail or transshipped through the United States; the carrier and mode of transportation, except for food imported by international mail; and planned shipment information, except for food imported by international mail (§ 1.281).

Much of the information collected for prior notice is identical to the information collected for FDA's importer's entry notice, which has been approved under OMB control number 0910–0046. The information in FDA's importer's entry notice is collected electronically via CBP's ABI/ACS at the same time the respondent files an entry for import with CBP. To avoid double-counting the burden hours already counted in the importer's entry notice information collection, the burden hour analysis in table 1 of this document reflects the reduced burden for prior notice submitted through ABI/ACS in the column labeled ''Hours per Response.''

In addition to submitting a prior notice, a submitter should cancel a prior notice and must resubmit the information if information changes after FDA has confirmed a prior notice submission for review (e.g., if the identity of the manufacturer changes) (§ 1.282). However, changes in the estimated quantity, anticipated arrival information, or planned shipment information do not require resubmission of prior notice after FDA has confirmed a prior notice submission for review (§ 1.282(a)(1)(i) to 1.282(a)(1)(iii)). In the event that an article of food has been refused admission under section 801(m)(1) of the act or placed under

hold under section 801(l) of the act, §§ 1.283(d) and 1.285(j) set forth the procedure for requesting FDA review and the information required to be included in a request for review. In the event that an article of food has been placed under hold under section 801(l) of the act, § 1.285(i) sets forth the procedure for and the information to be included in a post-hold submission.

In the **Federal Register** of May 31, 2006 (71 FR 30940), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received two timely letters in response, each containing one or more comments. To the extent that the comments suggest changes to the requirements of the prior notice interim final rule (21 CFR Part 1, subpart I), such a request is outside the scope of the four collection of information topics on which the notice solicits comments and, thus, will not be addressed here. The interim final rule established a 75-day comment period. In order to ensure that those commenting on the interim final rule had the benefit of FDA's outreach and educational efforts and had experience with the systems, timeframes, and data elements of the prior notice system, FDA reopened the comment period for 30 days on April 14, 2004 (69 FR 19763), and for an additional 60 days on May 18, 2004 (69 FR 28060), for a total of 165 days. The prior notice final rule currently is being developed and will publish in the near future. The agency's responses to the comments received in response to the 60-day notice published May 31, 2006, reference provisions found in the prior notice interim final rule and will not address any changes being considered for the final rule.

(Comment) One comment stated that prior notice information provided to FDA has no practical utility for goods transshipped through the United States, from one point in Canada to another point in Canada, when the goods are shipped by a Customs-Trade Partnership Against Terrorism (C-TPAT) or Partners In Protection (PIP) certified exporter, and carried by a C-TPAT certified carrier, with a C-TPAT approved bolt seal on the container. The comment argued that because these goods do not enter U.S. commerce and the parties responsible for the goods (the exporter and carrier) are classified as ''low risk,'' the shipments have already been determined to be ''low risk,'' and thus, prior notice review by FDA is not necessary and the prior notice information provided to FDA has no practical utility. The comment also noted that Free and Secure Trade (FAST) approved drivers are now accepted by the U.S. Department of Homeland Security for the transportation of dangerous goods (including explosives) into and through the United States and argued that FAST approved drivers for shipments of food products transshipped through the United States should make it unnecessary to provide prior notice information for the shipment.

(Response) FDA does not agree that obtaining prior notice information is unnecessary if shipments can be characterized as ''low risk.'' Prior notice is a statutory requirement under section 801(m) of the act. As explained in the prior notice interim final rule, section 801(m) of the act applies to all food imported or offered for import into the United States except as outlined in 21 CFR 1.277(b) (68 FR 58974 at 58993), including ''low-risk'' shipments.

(Comment) Another comment asserted that transhipments, including both those originating in Canada and entering the United States for purposes of export to a third country, as well as Canadian shipments routed through the United States and returned to Canada, are transported under bond and information about the transshipments is entered in ABI/ACS. This comment further asserted that ABI/ACS captures the information necessary to identify transhipments that may pose a risk as defined by FDA. The comment suggested that it would minimize the burden of the collection of information if exporters of transhipments through the United States would be required to provide only the information originally required in ABI/ACS and not be required to enter additional information for FDA prior notice purposes.

(Response) FDA disagrees. ABI/ACS information submitted during entry cannot substitute for the submission of prior notice because it does not meet the requirements of the Bioterrorism Act, such as providing FDA with certain specified information before the food arrives in the United States. As we explained in the prior notice interim final rule, entry may be made up to 15 days after a food arrives in the United States and does not contain all of the information required in a prior notice, such as the country from which the article is shipped (68 FR 58974 at 58975–58976). The information in a prior notice is necessary for FDA to determine whether it should examine the food at the U.S. port of arrival. Moreover, the comment implies that these shipments should be exempt from prior notice requirements because the shipments are under strict CBP control and are secured by a bond, i.e., that these shipments are low-risk. As we explained previously, section 801(m) of the act requires prior notice for all food imported or offered for import into the United States except as outlined in 21 CFR 1.277(b). FDA notes, however, the policy established in the March 2005 revision to the prior notice interim final rule CPG, which addresses imported food arriving from and exiting to the same country. It describes the situations and conditions under which FDA and CBP should typically consider not taking regulatory action despite the fact that prior notice is not submitted.

(Comment) One comment noted that ''Standard Manifest'' data elements must be transmitted to CBP prior to arrival in order to clear a regular shipment, and the ''Preferred Manifest'' data elements must be transmitted to CBP in order to clear a low risk FAST/C-TPAT shipment. In addition to these CBP transmissions, a separate prior notice transmission to FDA, with a different data set, is required to meet the prior notice requirements. The comment suggested that, to minimize the burden of the collection of information on respondents, FDA and CBP should work together to develop integrated data elements for both regular and FAST/C-TPAT shipments which would meet both FDA and CBP requirements, and the information required should be submitted once and then transferred to the other agency as required.

(Response) FDA disagrees. FDA's Bioterrorism Act and CBP's Trade Act of 2002 have different statutory requirements. For example under section 801(m) of the act, FDA, not CBP, must receive prior notice. In implementing these laws, the agencies require different information and use different targeting and screening tools. FDA and CBP have discussed interfacing with the Automated Manifest System (AMS) (the module of ACS through which carriers, port authorities, or service bureaus transmit electronically the cargo declaration portion of the inward foreign manifest to CBP) for manifest data and determined that the general cargo data in AMS are not suitable to accommodate the detailed information requirements of section 801(m) of the act. For example, AMS does not collect the country of origin. In addition, its collection of the identities of the article of food and its manufacturer differs from the way those are collected under the prior notice interim final and final rules in such a way that the data would not meet our needs in carrying out the purpose of section 801(m) of the act. Therefore, the information collection burden may not necessarily be reduced as the comment suggests because manifest data could

not substitute for certain prior notice requirements.

(Comment) Another comment suggested that both the FDA and CBP systems be simplified to more efficiently enter data that are common to all products in the shipment. For instance, information such as importer and shipper, which is common to all products in a shipment, should only need to be entered once.

(Response) The Bioterrorism Act requires notice for each article of food and requires in that notice, for each article of food, certain information. As stated in the interim final rule, an ''article'' refers to a single food that is associated with the same complete FDA Product Code, the same package size, and the same manufacturer or grower (68 FR 58974 at 59003). This is consistent with how entry is filed with CBP. An article of food is a unique item related to a specific manufacturer or grower and a specific process or size. All of these pieces of information are critical for a risk-based assessment of the food. The ABI/ACS system provides the capability to submit information for multiple food items as lines in a single entry, when entry level information is consistent for a number of articles in a shipment. For example, shipment level information, such as estimated time of arrival, can be captured once for all articles within a shipment. The ability to minimize data entry by copying specific information from one article, or line, to another depends upon the sophistication of the software being used by the submitter to create the submission to CBP. The FDA PN System Interface allows for simplified submission of similar articles of food by allowing the submitter to easily repeat common information (e.g., FDA product code, manufacturer, etc.) while entering different quantities (e.g., amount and package size). Both systems thus significantly reduce the amount of repetitive entry.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section No.	FDA Form No.	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
Prior Notice Submissions						
Prior Notice submitted through ABI/ACS						
1.280 to 1.281	None	6,500	949.50	6,171,750	0.167	1,030,682[2]
Prior Notice submitted through PN System Interface						
1.280 to 1.281	FDA 3540[3]	214,400	8.33	1,785,952	0.384	685,806
New Prior Notice Submissions Subtotal						1,716,488
Prior Notice Cancellations						
Prior Notice cancelled through ABI/ACS						
1.282	FDA 3540	6,500	3.34	21,710	0.25	5,428
Prior Notice cancelled through PN System Interface						
1.282 and 1.283(a)(5)	FDA 3540	214,400	0.31	66,464	0.25	16,616
Prior Notice Cancellations Subtotal						22,044
Prior Notice Requests for Review and Post-hold Submissions						
1.283(d) and 1.285(j),	None	1	1	1	8	8
1.285(i)	None	1	1	1	1	1
Prior Notice Requests for Review and Post-hold Submissions Subtotal						9
Total Hours Annually						1,738,541

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

[2]To avoid double-counting, an estimated 396,416 burden hours already accounted for in the Importer's entry notice information collection approved under OMB control number 0910–0046 are not included in this total.

[3]The term ''Form FDA 3540'' refers to the electronic system known as the FDA PN System Interface, which is available at *http://www.access.fda.gov*.

This estimate is based on FDA's experience and the average number of prior notice submissions, cancellations, and requests for review received in the past 3 years.

FDA received 282,244 prior notices through ABI/ACS during December 2003; 6,865,722 during 2004; and 6,171,939 during 2005. Based on this experience, FDA estimates that approximately 6,500 users of ABI/ACS will submit an average of 949.5 prior notices annually, for a total of 6,171,750 prior notices received annually through ABI/ACS. FDA estimates the reporting burden for a prior notice submitted through ABI/ACS to be 10 minutes, or 0.167 hours, per notice, for a total burden of 1,030,682 hours. This estimate takes into consideration the burden hours already counted in the information collection approval for FDA's importer's entry notice, as previously discussed in this document.

FDA received 35,308 prior notices through the PN System Interface during December 2003; 1,425,825 during 2004; and 1,786,896 during 2005. Based on this experience, FDA estimates that

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