previous dose of hepatitis A vaccine should not get another dose.

• Anyone who has a severe (life threatening) allergy to any vaccine component should not get the vaccine. Tell your doctor if you have any severe allergies. All hepatitis A vaccines contain alum and some hepatitis A vaccines contain 2-phenoxyethanol.

• Anyone who is moderately or severely ill at the time the shot is scheduled should probably wait until they recover. Ask your doctor or nurse. People with a mild illness can usually get the vaccine.

• Tell your doctor if you are pregnant. The safety of hepatitis A vaccine for pregnant women has not been determined. But there is no evidence that it is harmful to either pregnant women or their unborn babies. The risk, if any, is thought to be very low.

4. What are the risks from hepatitis A vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of hepatitis A vaccine causing serious harm, or death, is extremely small.

Getting hepatitis A vaccine is much safer than getting the disease.

Mild problems.

• Soreness where the shot was given (about 1 out of 2 adults, and up to 1 out of 6 children).

• Headache (about 1 out of 6 adults and 1 out of 25 children).

• Loss of appetite (about 1 out of 12 children).

• Tiredness (about 1 out of 14 adults).

If these problems occur, they usually last 1 or 2 days.

Severe problems.

• Serious allergic reaction, within a few minutes to a few hours of the shot (very rare).

5. What if there is a moderate or severe reaction?

What should I look for?

• Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

• Call a doctor, or get the person to a doctor right away.

• Tell your doctor what happened, the date and time it happened, and when the vaccination was given.

• Ask your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS Web site at *http://www.vaers.hhs.gov*, or by calling 1–800–822–7967.

VAERS does not provide medical advice.

6. The National Vaccine Injury Compensation Program

In the event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call 1–800–338–2382 or visit their Web site at *http://www.hrsa.gov/vaccinecompensation*.

7. How can I learn more?

• Ask your doctor or nurse. They can give you the vaccine package insert or suggest other sources of information.

• Call your local or state health department.

• Contact the Centers for Disease Control and Prevention (CDC):

—Call 1–800–232–4636 (1–800–CDC-INFO)

—Visit CDC Web sites at: *http://www.cdc.gov/hepatitis* or *http://www.cdc.gov/nip*

Department of Health and Human Services, Centers for Disease Control and Prevention, National Immunization Program.

Vaccine Information Statement, Hepatitis A (3/21/06), 42 U.S.C. 300aa–26.

Dated: May 20, 2006.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention.

[FR Doc. E6–8350 Filed 5–30–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0202]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's regulations requiring that the agency receive prior notice before food is imported or offered for import into the United States.

DATES: Submit written or electronic comments on the collection of information by July 31, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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) 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.

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 PNSI						
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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section No.	FDA Form No.	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
Prior notice cancelled through PNSI						
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 that one or fewer requests 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 that one or fewer post-hold submissions 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: May 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–8311 Filed 5–30–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committe Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4), and 552b(c)(6), Title 5 U.S.C., as amended. The cooperative agreement applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the cooperative agreement application review, the disclosure of which would