the functions under Sections 8 & 15 of the Small Business Act. The OSDBU provides leadership, policy, guidance and supervision, as well as coordinating short- and long-range strategic planning to assure that small business vendors have a fair opportunity to compete for and receive business with the Department. The Office also provides technical assistance to the Department's OPDIVs and STAFFDIVs; reviews and evaluates planned procurements to ensure that small businesses are given thorough consideration; evaluates effectiveness of the small business programs and processes; develops pertinent HHS-wide policies, guidance, and performance standards; maintains Departmental small business reports; and conducts special Departmental initiatives related to small and socio-economic business concerns. The OSDBU manages the development and implementation of appropriate outreach programs aimed at heightening the awareness of the small business community to the contracting opportunities available within HHS. The OSDBU provides input for coordinated Department positions on proposed legislation and Government regulations on matters affecting cognizant small socioeconomic business programs. It also serves as the focal point for coordinating ASFR's response to cross-cutting Freedom of Information Act (FOIA) requests, audits, and activities related to small business related efforts and programs.

Dated: November 2, 2011.

E.J. Holland, Jr.,

Assistant Secretary for Administration.

[FR Doc. 2011–28964 Filed 11–8–11; 8:45 am]

BILLING CODE 4150–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0797]

Agency Information Collection Activities; Proposed Collection; Comment Request; State Enforcement Notifications

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 reporting requirements contained in existing FDA regulations governing State enforcement notifications.

DATES: Submit either electronic or written comments on the collection of information by January 9, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* 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: Denver Presley, II, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–3793.

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.

State Enforcement Notifications—21 CFR 100.2(d) (OMB Control Number 0910–0275)—Extension

Section 310(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 337(b)) authorizes States to enforce certain sections of the FD&C Act in their own names but provides that States must notify FDA before doing so. Section 100.2(d) (21 CFR 100.2(d)) sets forth the information that a State must provide to FDA in a letter of notification when it intends to take enforcement action under the FD&C Act against a particular food located in the State. The information required under § 100.2(d) will enable FDA to identify the food against which the State intends to take action and advise the State whether Federal action has been taken against it. With certain narrow exceptions, Federal enforcement action precludes State action under the FD&C Act.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
100.2(d)	1	1	1	10	10

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

The estimated reporting burden for § 100.2(d) is minimal because enforcement notifications are seldom used by States. During the last 3 years, FDA has not received any new enforcement notifications; therefore, the Agency estimates that one or fewer notifications will be submitted annually. Although FDA has not received any new enforcement notifications in the last 3 years, it believes these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing FDA when it intends to take enforcement action under the FD&C Act against a particular food located in the State.

Dated: November 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–29058 Filed 11–8–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

The Development and Evaluation of Human Cytomegalovirus Vaccines; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration, Center for Biologics Evaluation and Research, the National Institutes of Health, the National Institute of Allergy and Infectious Diseases, the Centers for Disease Control and Prevention, and the National Vaccine Program Office are announcing a public workshop entitled ''The Development and Evaluation of Human Cytomegalovirus Vaccines.'' The purpose of the public workshop is to identify and discuss key issues related to the development and evaluation of human cytomegalovirus (HCMV) vaccines. The public workshop will include presentations on HCMV disease and pathogenesis and issues related to vaccine development.

Date and Time: The public workshop will be held on January 10 and January 11, 2012, from 8:30 a.m. to 5:30 p.m.

Location: The public workshop will be held at Lister Hill Center Auditorium, National Institutes of Health, Bldg. 38A, 8600 Rockville Pike, Bethesda, MD 20894. Pre-registered participants will receive additional information on parking and public transportation with their email registration confirmation.

Contact Person: Manen Bishop, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, (301) 827–2000, FAX: (301) 827–3079, email: *CBERTraining@fda.hhs.gov* (Subject line: HCMV Vaccine Workshop).

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone, and fax numbers) to Manen Bishop (see *Contact Person*) or email to *CBERTraining@fda.hhs.gov* (Subject line: HCMV Workshop Registration) by December 12, 2011. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Manen Bishop (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: HCMV, also known as human herpesvirus 5, infects approximately half of the U.S. population by adulthood. While most infections are without symptoms, the infection is lifelong. However, the disease may become apparent in children who were infected during gestation (congenital HCMV) and in infected individuals with weakened immune systems. Congenital HCMV infection causes mental retardation, learning disabilities, hearing loss, vision loss, and other disabilities. Patients undergoing stem cell or solid-organ transplants are at particularly high risk for severe disease or death from HCMV infection.

An effective vaccine could have a significant impact on rates of congenital anomalies and severe infections caused by HCMV. However, efforts to develop a vaccine against HCMV have not yet been successful.

The public workshop will focus on the status of knowledge about HCMV biology and epidemiology and on vaccine development strategies. Topics for discussion will include: (1) HCMV epidemiology and diagnosis, (2) HCMV immunology and virology, (3) manufacturers' and regulators' perspectives, (4) target populations for a HCMV vaccine, (5) design of clinical trials to study HCMV vaccines in the setting of congenital HCMV and transplants, and (6) next steps toward development of HCMV vaccines.

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible at: *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm.* Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: November 3, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–29006 Filed 11–8–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Application for Collaboration With the NIH Center for Translational Therapeutics (NCTT)

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 (insert name of NIH Institute or Center), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Application for collaboration with the NIH Center for Translational Therapeutics (NCTT). *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* Programs at the NCTT provide opportunities to partner with and gain access to both common and specifically rare and neglected disease through a variety of programs delivering assay development, screening, hit to lead chemistry, lead optimization, chemical biology studies, drug development capabilities, expertise, and clinical/regulatory resources in a collaborative environment with the goal of moving promising therapeutics into human clinical trials. NCTT uses an application and evaluation process to select collaborators. Selected investigators provide the drug project starting points and ongoing biological/disease expertise throughout the project. *Frequency of Response:* Four per year. *Affected Public:* Research scientists. *Type of Respondents:* Academic scientists, industry, not-for-profits, government