Drugs." This public workshop is intended to provide a forum for discussing potential approaches toward a track and trace system and obtaining input from supply chain partners on attributes and standards for the identification, authentication, and tracking and tracing of prescription drug packages, and to further the Agency's goal of protecting public health by securing the drug supply chain against the introduction of counterfeit and other substandard drugs.

DATES: The public workshop will be held on February 15 and 16, 2011, from 9 a.m. to 5 p.m. Submit electronic or written comments on the posted information or on the workshop to the docket by April 16, 2011.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, room 1503, Silver Spring, MD 20993. To register for the public meeting, e-mail your registration information to *drug.trackandtrace@fda.hhs.gov.* See section III of this document for registration details. Submit electronic comments to *http://www.regulations.gov.* Submit written comments 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 the brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Connie Jung, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–4830, e-mail: *connie.jung@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Since the formation of the first Counterfeit Drug Task Force in 2003, FDA has strongly advocated for a multi-layered approach to securing the supply chain and protecting consumers from the threats posed by counterfeit drugs. The ability to track and trace finished drug products in the supply chain plays a significant role in providing transparency and accountability in the drug supply chain. On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85) was signed into law. Section 913 of this legislation created section 505D of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), which requires the Secretary of Health and Human Services (the Secretary) to develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs. In addition, section 505D of the FD&C Act directs the Secretary to consult with specific entities to prioritize and develop standards for identification, validation, authentication, and tracking and tracing of prescription drugs.

In March 2010, FDA issued a final guidance for industry which describes the Agency's current recommendation for standardized numerical identification (also known as serialization) for prescription drug packages (Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for Prescription Drug Packages, Guidance for Industry—Final Guidance [1]). This guidance is intended to be the first of several steps that FDA may take to implement section 505D of the FD&C Act and further improve the security of the drug supply chain. As FDA continues to work on developing additional standards for securing the drug supply chain, the agency is seeking public input to ensure that we consider information regarding all supply chain participants.

II. Purpose of the Workshop

This public workshop is intended to explore approaches for achieving an effective and feasible track and trace system for finished prescription drug products from the supply chain stakeholder's point of view, including industry and the public, and to obtain views on system attributes and standards that would facilitate identification, authentication, and tracking and tracing of prescription drug packages. We intend to discuss with stakeholders the necessary elements to accomplish effective authentication and identify desirable features of a track and trace system. Participants will not be asked to develop consensus opinions during the discussion, but rather to provide their individual perspectives.

By February 4, 2011, FDA will post information on our Web site *(http://www.fda.gov/Drugs/DrugSafety/ucm169828.htm)* under "Standards Development for Prescription Drug Supply Chain Security." as follows:

- Workshop agenda,
- Workshop discussion topics.

III. How To Register for the Workshop

To register for the workshop either: (1) E-mail your registration information to *drug.trackandtrace@fda.hhs.gov* or (2) mail your registration information to the contact person (*see* **FOR FURTHER INFORMATION CONTACT**). Registration information should include registrant name, company or organization, address, phone number, and email address. Registration requests should be received by February 1, 2011. Registration is free. Seats are limited. FDA may limit the numbers of participants from each organization based on space limitations. Registrants will receive confirmation upon acceptance for participation in the workshop. Onsite registration on the day of the meeting will be based on space availability on the day of the event starting at 8 a.m. If registration reaches maximum capacity, FDA will post a notice closing meeting registration for the workshop on FDA's Web site at: *http://www.fda.gov/Drugs/DrugSafety/ucm169828.htm.* If you need special accommodations due to a disability, please contact Connie Jung (*see* **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

IV. Parking Information

If you are driving to FDA's White Oak Campus, you should proceed to the South East Surface Parking Lot to park your vehicle. Shuttle service is available from the bus shelters in the South East Lot to Building 1. The FDA campus is a Federal facility, therefore all meeting attendees must enter through Building 1 and follow security procedures.

Dated: *January 3, 2011.*

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–72 Filed 1–6–11; 8:45 am]

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[1] *http://www.fda.gov/RegulatoryInformation/Guidances/ucm125505.htm.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the OMB for review under the Paperwork Reduction Act of 1995:

Proposed Project: Ryan White HIV/AIDS Program: Client-Level Data Reporting System: (OMB No. 0915–0323)—[Revision]

The Ryan White HIV/AIDS Program's client-level data reporting system, entitled the Ryan White HIV/AIDS Program Services Report or the Ryan White Services Report (RSR), was created in 2008 by the Health Resources and Services Administration (HRSA). It is designed to collect information from grantees, as well as their subcontracted services providers, funded under Parts A, B, C, and D, and the Part F Minority AIDS Initiative of the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Ryan White HIV/AIDS Program). The Ryan White HIV/AIDS Program provides Federal HIV/AIDS Programs in the Public Health Service (PHS) Act under Title XXVI with flexibility to respond effectively to the changing HIV epidemic, with an emphasis on providing life-saving and life-extending services for people living with HIV/AIDS across this country, as well as targeting resources to areas that have the greatest needs.

All parts of the Ryan White HIV/AIDS Program specify HRSA's responsibilities in the administration of grant funds, the allocation of funds, the evaluation of programs for the population served, and the improvement of the quality of care. Accurate records of the providers receiving Ryan White HIV/AIDS Program funding, the services provided, and the clients served, continue to be critical issues for the implementation of the legislation and are necessary for HRSA to fulfill its responsibilities.

The RSR provides data on the characteristics of Ryan White HIV/AIDS Program-funded grantees, their contracted service providers, and the clients being served with program funds. The Report is intended to support clinical quality management, performance measurement, service delivery, and client monitoring at the system and client levels. The reporting system consists of two online data forms, the Grantee Report and the Service Provider Report, as well as a data file containing the client-level data elements. Data are submitted annually.

The legislation specifies grantee accountability and linking performance to budget. The RSR is used to ensure compliance with the requirements of the legislation, to evaluate the progress of programs, to monitor grantee and provider performance, to measure the Government Performance and Results Act (GPRA) and the Performance Assessment Rating Tool (PART) goals, and to meet reporting responsibilities to the Department, Congress, and OMB.

In addition to meeting the goal of accountability to Congress, clients, advocacy groups, and the general public, information collected through the RSR is critical for HRSA, State and local grantees, and individual providers to assess the status of existing HIV-related service delivery systems to investigate trends in service utilization and to identify areas of greatest need.

The estimated average annualized hour burden is 17,975 hours per year. Burden estimates are broken down into burden to grantee respondents and burden to service provider respondents. Estimates for grantees and service providers are further divided by the RSR component. Estimates for grantees and providers are based on prior experience in collecting, maintaining, and reporting data using the RSR and interviews with volunteers from grantee agencies.

The response burden for grantees is estimated as:

Component	Source of funding	Number of respondents	Responses per grantee	Hours per response	Total hour burden
Grantee Report	Part A	56	1	2.04	114
	Part B	59	1	2.52	149
	Part C	354	1	0.32	113
	Part D	98	1	0.33	32
	Subtotal	567			408

The response burden for service providers is estimated as:

Component	Number of respondents	Responses per provider	Total responses	Hours per response	Total hour burden
Service Provider Report	*2,080	1	*2,080	2.30	4,784

*All providers, including providers of administrative support services and direct client services.

Component	Electronic data system	Number of respondents	Responses per provider	Total responses	Hours per response	Total hour burden
Client Report	No	56	1	56	106.25	5,950
	Yes	1,822	1	1,822	3.75	6,832.5
	Subtotal	**1,878		**1,878		12,783

**Providers of direct client services only.

Total Burden is 17,975.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this **Federal Register** Notice to the desk officer for HRSA, either by e-mail to *OIRA—submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: January 3, 2011.

Robert Hendricks,

Director, Division of Policy and Information Coordination.

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