availability of a guidance for industry entitled "Process Validation: General Principles and Practices." This guidance provides information for the pharmaceutical industry on the elements of process validation for the manufacture of human and animal drug and biological products, including active pharmaceutical ingredients (APIs). The guidance is intended to provide clear and consistent communication of regulatory expectations and to promote voluntary compliance with current FDA requirements. This guidance revises and replaces the guidance for industry entitled "Guideline on General Principles of Process Validation," dated May 1987.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your requests. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance 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.

FOR FURTHER INFORMATION CONTACT:

Brian Hasselbalch, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4364, Silver Spring, MD 20993–0002, 301–796–3279; or

Grace McNally, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4374, Silver Spring, MD 20993–0002, 301–796–3286; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210; or

Dennis Bensley, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8268.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Process Validation: General Principles and Practices." This guidance document provides guidance to the pharmaceutical industry on the elements of process validation for the manufacture of human and animal drug and biological products, including APIs.

This guidance describes process validation activities in three stages:

- In Stage 1, Process Design, the commercial process is defined based on knowledge gained through development and scale-up activities.
- In Stage 2, Process Qualification, the process design is evaluated and assessed to determine if the process is capable of reproducible commercial manufacturing.
- In Stage 3, Continued Process Verification, ongoing assurance is gained during routine production that the process remains in a state of control.

In addition to discussing activities typical of each stage of process validation, the guidance provides recommendations regarding appropriate documentation and analytical methods to be used during process validation.

In the **Federal Register** of November 18, 2008 (73 FR 68431), FDA announced the availability of a draft guidance of the same title and gave interested persons the opportunity to submit comments by January 20, 2009. In the **Federal Register** of February 13, 2009 (74 FR 7237), the Agency reopened the comment period to March 16, 2009. The Agency received public comments from a broad spectrum of the pharmaceutical industry. In response to comments received on the draft guidance, the Agency added a glossary of terms and clarified or added more specific guidance on certain issues.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the general principles and practices of process validation. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information requested in the guidance are covered under FDA regulations at 21 CFR part 211, 21 CFR 314.70, and 21 CFR 601.12 and are approved under OMB control numbers 0910–0139, 0910–0001 and 0910–0338, respectively.

III. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm,* or *http://www.regulations.gov.*

Dated: January 19, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1437 Filed 1–24–11; 8:45 am]

BILLING CODE 4160–01–P

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 Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: HRSA AIDS Drug Assistance Program Quarterly Report—(OMB No. 0915–0294): Extension

HRSA's AIDS Drug Assistance Program (ADAP) is funded through Part B of Title XXVI of the Public Health Service Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (The Ryan White HIV/AIDS Program), which provides grants to states and territories. ADAP provides medications for the treatment of HIV disease. Program funds may also be used to purchase health insurance for eligible clients or for services that enhance access, adherence, and monitoring of drug treatments.

Each of the 50 states, the District of Columbia, Puerto Rico, and several territories receive ADAP grants. As part of the funding requirements, ADAP Grantees submit quarterly reports that include information on patients served, pharmaceuticals prescribed, pricing, sources of support to provide AIDS medication treatment, eligibility requirements, cost data, and coordination with Medicaid. Each quarterly report requests updates from programs on the number of patients served, type of pharmaceuticals prescribed, and prices paid to provide medication. The first quarterly report of each ADAP fiscal year (due in July of each year) also requests information that only changes annually (*e.g.,* state funding, drug formulary, eligibility criteria for enrollment, and cost-saving strategies including coordination with Medicaid).

The quarterly report represents the best method for HRSA to determine how ADAP Grants are expended and to provide answers to requests from Congress and other organizations.

The estimated annual burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
1st Quarterly Report	57	1	57	3	171
2nd, 3rd, & 4th Quarterly Reports	57	3	171	1.5	256.5
Total	57	.....	228	.....	427.5

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 19, 2011.

Robert Hendricks,

Director, Division of Policy and Information Coordination.

[FR Doc. 2011–1457 Filed 1–24–11; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

[Docket No. TSA–2004–19515]

Extension of Agency Information Collection Activity Under OMB Review: Air Cargo Security Requirements

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), OMB control number 1652–0040, abstracted below, to the Office of Management and Budget (OMB) for renewal in compliance with the Paperwork Reduction Act. The ICR describes the nature of the information collection and its expected burden. TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of this collection of information on October 14, 2010, 75 FR 63192. TSA has not received any comments. The collections of information that make up this ICR involve five broad categories affecting airports, passenger aircraft operators, foreign air carriers, indirect air carriers operating under a security program, and all-cargo carriers. These five categories are: Security programs, security threat assessments (STA), known shipper data via the Known Shipper Management System (KSMS), cargo screening reporting, and evidence of compliance recordkeeping.

DATES: Send your comments by February 24, 2011. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Comments may be mailed or delivered to Joanna Johnson, PRA Officer, Office of Information Technology, TSA–11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20596–6011. Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to Desk Officer, Department of Homeland Security/TSA, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Joanna Johnson, Office of Information Technology, TSA–11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6011; telephone (571) 227–3651 or e-mail *joanna.johnson@dhs.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation is available at *http://www.reginfo.gov.* Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological