6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2013–0349; FRL – 9910-93-OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Pharmaceuticals Production (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), "NESHAP for Pharmaceuticals Production (Renewal)" (EPA ICR No. 1781.07, OMB Control No. 2060-0358), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq*). This is a proposed extension of the ICR, which is currently approved through June 30, 2014. Public comments were previously requested via the *Federal Register* 78 FR 35023 on June 11, 2013 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2013–0349, to: (1) EPA online, using www.regulations.gov (our preferred method), or by email to: docket.oeca@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460; and (2) OMB via email to oira_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without

change including any personal information provided, unless the comment includes: profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (202) 564-2970; fax number: (202) 564-0050; email address: yellin.patrick@epa.gov.

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov/, or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit: http://www.epa.gov/dockets.

Abstract: The NESHAP for Pharmaceuticals Production were proposed on April 2, 1997, and promulgated on September 21, 1998. In general, all NESHAP standards require initial notifications, performance tests, and periodic reports. Owners or operators are also required to maintain records of the occurrence and duration of any malfunctions in the operation of an affected facility or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance and, in general, are required of all sources subject to NESHAP. This information is used by the Agency to identify sources subject to the standards to insure that the maximum achievable control technologies are being applied. Semiannual summary reports are also required.

Form Numbers: None.

Respondents/affected entities: Pharmaceutical manufacturing operations.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart GGG).

Estimated number of respondents: 27 (total).

Frequency of response: Initially, occasionally, quarterly and semiannually.

Total estimated burden: 44,266 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $4,442,518 (per year), includes $112,266 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is no change in the labor hours in this ICR compared to the previous ICR. This is due to two considerations: 1) the regulations have not changed since the publication of the 2011 final rule, which was covered in the last ICR renewal; and 2) the growth rate for the industry is very low, negative or non-existent. However, there is an increase in industry cost as the burden calculations in this ICR, including affirmative defense, have been updated to use more recent labor rates.

Dated: May 27, 2014.

Erin Collard, Acting Director, Collection Strategies Division.

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