6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2013–0349; FRL – 9978-60-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.

The Environmental Protection Agency has submitted an information collection request (ICR) - NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Renewal), EPA ICR Number 1781.08, OMB Control Number 2060-0358 - to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through May 31, 2018. Public comments were previously requested via the *Federal Register* (82 FR 29552) on June 29, 2017 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 neither conduct nor 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 DATE OF 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 National Emission Standards for Hazardous Air Pollutants (NESHAP) for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) were proposed on April 2, 1997; promulgated on September 21, 1998; and amended on both April 21, 2011 and February 27, 2014. The 2014 amendment promulgated technical correction was made to allow for EPA Method 320 as an alternative to EPA Method 18 for demonstrating that a 'vent' is not a process vent. These regulations apply to existing and new pharmaceuticals manufacturing operations that are major sources of hazardous air pollutants (HAP). The affected facilities encompass all pharmaceuticals manufacturing operations that include process vents, storage tanks, equipment components, and wastewater systems. New facilities include those that commenced construction

or reconstruction after the date of proposal. This information is being collected to assure compliance with 40 CFR Part 63, Subpart GGG. In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction 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 are required of all affected facilities subject to NESHAP. Any owner/operator subject to the provisions of this part shall maintain a file containing these documents, and retain the file for at least five years following the generation date of such maintenance reports and records. All reports are sent to the delegated state or local authority. In the event that there is no such delegated authority, the reports are sent directly to the U.S. Environmental Protection Agency (EPA) regional office.

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: 44,300 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $4,760,000 (per year), which includes $112,000 in either annualized capital and/or operation & maintenance costs.

Changes in the Estimates: There is a reduction in the estimated number of responses, by one. The previous ICR included one response for affirmative defense. However, that item has subsequently been removed from this ICR as those provisions are outdated. There is an adjustment increase in the respondent labor hours as currently identified in the OMB Inventory

of Approved Burdens. This increase is not due to any program changes. The change in the burden and cost estimates occurred due to a change in assumption. In accordance with the Terms of Clearance, this ICR assumes all existing respondents will have to familiarize with the regulatory requirements each year. There is also a small adjustment decrease in the total capital and O&M costs as compared the previously-approved ICR. This decrease is not due to any program changes, but occurred because, in accordance with the terms of clearance, this ICR rounds totals to three significant figures.

Courtney Kerwin,

Director,

Regulatory Support Division.

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