



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2023-012; FRL-12634-01-OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget 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 (EPA ICR Number 1781.10, 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 February 28, 2025. Public comments were previously requested via the *Federal Register* on May 18, 2023 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: 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-OAR-2023-012** to EPA online using www.regulations.gov (our preferred method), by email to a-and-r-docket@epa.gov or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460.

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.

Submit written comments and recommendations to OMB for the proposed information

collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Muntasir Ali, Sector Policies and Program Division, Office of Air Quality Planning and Standard, D243-05, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (919) 541-0833; email address: ali.muntasir@epa.gov.

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through February 28, 2025. 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.

Public comments were previously requested via the *Federal Register* on May 18, 2023 during a 60-day comment period (88 FR 31748). This notice allows for an additional 30 days for public comments. 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) 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.

Form Numbers: None.

Respondents/affected entities: Owners and operators of pharmaceuticals manufacturing operations.

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

Estimated number of respondents: 27 (total).

Frequency of response: Semiannually

Total estimated burden: 44,300 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: \$5,750,000 (per year), which includes \$174,000 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is no change in hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This is due to two considerations. First, the regulations have not changed over the past three years and are not anticipated to change over the next three years. Second, the growth rate for this industry is very low or non-existent, so there is no significant change in the overall burden. There is also an increase in O&M costs due to an adjustment to increase from 2007 \$ to 2022 \$ using the CEPCI Equipment Cost Index.

Courtney Kerwin,

Director, Information Engagement Division.

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