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.

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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.