SUPPORTING STATEMENT
ENVIRONMENTAL PROTECTION AGENCY

NESHAP for Pharmaceuticals Production (40 CFR part 63, subpart GGG) (Renewal)

1. Identification of the Information Collection

1(a) Title of the Information Collection

NESHAP for Pharmaceuticals Production (40 CFR part 63, subpart GGG) (Renewal)

1(b) Short Characterization/Abstract

The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Pharmaceuticals Production was proposed on April 2, 1997 and promulgated on September 21, 1998. These standards apply to facilities in pharmaceuticals productions 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 commencing construction, or reconstruction after the date of that proposal. This information is being collected to assure compliance with 40 CFR part 63, subpart GGG. HAP emissions are the pollutants regulated under this subpart.

In general, all NESHAP standards require initial notifications, performance tests, and periodic reports. Owners, or operators also are 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 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.

Any owner, or operator subject to the provisions of this part will maintain a file of these measurements, and retain the file for at least five years following the date of such measurements, 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 United States Environmental Protection Agency (EPA) regional office.

There is an annual average of 100 respondents that will be subject to the standard, and it is estimated that there will be no new growth in the industry over the next three years, though one of the existing sources per year will become subject to the standard over the next three years due to the reconstruction of an existing affected facility. The average annual cost to industry over the next three years of this Information Collection Request (ICR) is estimated to be $14,485,933.

The Office of Management and Budget (OMB) approved the currently active ICR without any “Terms of Clearance” (TOC).

The "Affected Public" as categorized in ICRAS is "Private Sector- Business, or other for- profit." The burden for the "Affected Public" may be found in Table 1: Annual Industry Burden for NESHAP for Pharmaceuticals Production (40 CFR part 63, subpart GGG). The burden for the Federal Government is attributed entirely to work performed by Federal employees, or government contractors and may be found in Table 2: Average Annual EPA Burden for NESHAP for Pharmaceuticals Production (40 CFR part 63, subpart GGG).

2. Need for and Use of the Collection

2(a) Need/Authority for the Collection

The EPA is charged under section 112 of the Clean Air Act, as amended, to establish standards of performance for each category, or subcategory of major sources and area sources of hazardous air pollutants. These standards are applicable to new, or existing sources of hazardous air pollutants and will require the maximum degree of emission reduction. In addition, section 114(a) states that the Administrator may require any owner, or operator subject to any requirement of this Act to:

> (A) Establish and maintain such records; (B) make such reports; (C) install, use, and maintain such monitoring equipment, and use such audit procedures, or methods; (D) sample such emissions (in accordance with such procedures or methods, at such locations, at such intervals, during such periods, and in such manner as the Administrator shall prescribe); (E) keep records on control equipment parameters, production variables or other indirect data when direct monitoring of emissions is impractical; (F) submit compliance certifications in accordance with Section 114(a)(3); and (G) provide such other information as the Administrator may reasonably require.

In the Administrator's judgment, HAP pollutant emissions from pharmaceuticals production (predominately methanol, methylene chloride and toluene) cause, or contribute to air pollution that may reasonably be anticipated to endanger public health, or welfare. Therefore, the NESHAP was promulgated for this source category at 40 CFR part 63, subpart GGG

2(b) Practical Utility/Users of the Data

The control of emissions of HAP from pharmaceuticals production required not only the installation of properly designed equipment, but also the operation and maintenance of that equipment. Emissions of HAP from pharmaceuticals production is the result of operation of the affected facilities. The subject standards are achieved by the reduction of HAP emissions using control technology and leak detection and repair procedures.

The recordkeeping and reporting requirements in the standards ensure compliance with

the applicable regulations which where promulgated in accordance with the Clean Air Act. The collected information also is used for targeting inspections and as evidence in legal proceedings.

Performance tests are required in order to determine an affected facility's initial capability to comply with the emission standards. Continuous emission monitors may be used to ensure compliance with the standards at all times. During the performance test a record of the operating parameters under which compliance was achieved may be recorded and used to determine compliance in place of a continuous emission monitor.

The notifications required in the standards are used to inform the Agency, or delegated authority when a source becomes subject to the requirements of the regulations. The reviewing authority may then inspect the source to ensure that the pollution control devices are properly installed and operated, that leaks are being detected and repaired, and that the standards are being met. The performance test also may be observed.

The required semiannual reports are used to determine periods of excess emissions, identify problems at the facility, verify operation/maintenance procedures and for compliance determinations.

3. Nonduplication, Consultations, and Other Collection Criteria

The requested recordkeeping and reporting are required under 40 CFR part 63, subpart GGG.

3(a) Nonduplication

If the subject standards have not been delegated, the information is sent directly to the appropriate EPA regional office. Otherwise, the information is sent directly to the delegated state, or local agency. If a state, or local agency has adopted its own similar standards to implement the Federal standards, a copy of the report submitted to the state, or local agency can be sent to the Administrator in lieu of the report required by the Federal standards. Therefore, no duplication exists.

3(b) Public Notice Required Prior to ICR Submission to OMB

An announcement of a public comment period for the renewal of this ICR was published in the Federal Register 71 FR 58853 on October 5, 2006. No comments were received on the burden published in the Federal Register.

3(c) Consultations

For this information collection, we referenced the most recent ICR, the preparer of the active ICR, and accessed the most recent data available on the Air Facility System (AFS) database as maintained by the Office of Compliance. We reviewed information available from the United States Census Bureau via the internet, and other websites covering pharmaceuticals production. We consulted with Randy McDonald at EPA's Office of Air Quality Planning and

Standards at 919-541-5402 and Ms. Sue Wise with Merck at 908-423-3181.

3(d) Effects of Less Frequent Collection

Less frequent information collection would decrease the margin of assurance that facilities are continuing to meet the standards. Requirements for information gathering and recordkeeping are useful techniques to ensure that good operation and maintenance practices are applied and emission limitations are met. If the information required by these standards was collected less frequently, the proper operation and maintenance of control equipment and the possibility of detecting violations would be less likely.

3(e) General Guidelines

These reporting and recordkeeping requirements do not violate any of the regulations promulgated by OMB under 5 CFR part 1320, section 1320.5.

These standards require the respondents to maintain all records, including reports and notifications for at least five years. This is consistent with the General Provisions as applied to the standards. EPA believes that the five year records retention requirement is consistent the Part 70 permit program and the five year statute of limitations on which the permit program is based. The retention of records for five years allows EPA to establish the compliance history of a source, discern any pattern of non-compliance, and determine the appropriate level of enforcement action. EPA has found that the most flagrant violators have violations extending beyond five years. In addition, EPA would be prevented from pursuing the violators due to the destruction or nonexistence of essential records.

3(f) Confidentiality

Any information submitted to the Agency for which a claim of confidentiality is made will be safeguarded according to the Agency policies set forth in title 40, chapter 1, part 2, subpart B - Confidentiality of Business Information (see 40 CFR 2; 41 FR 36902, September 1, 1976; amended by 43 FR 40000, September 8, 1978; 43 FR 42251, September 20, 1978; 44 FR 17674, March 23, 1979).

3(g) Sensitive Questions

The reporting, or recordkeeping requirements in the standard do not include sensitive questions.

4. The Respondents and the Information Requested

4(a) Respondents/SIC Codes

The respondents to the recordkeeping and reporting requirements are pharmaceuticals production manufacturing operations. The United States Standard Industrial Classification (SIC) codes for the respondents affected by the standards are SIC 2833 and 2834, which correspond to

the North American Industry Classification System (NAICS) 325411 and 325412 for pharmaceuticals production manufacturing operations.

4(b) Information Requested

(i) Data Items

In this ICR, all the data that is recorded or reported is required by the NESHAP for Pharmaceuticals Production (40 CFR part 63, subpart GGG).

A source must make the following reports:

Notifications and Reports	Standard Citation by Section
Change in area source status (as applicable)	63.1(c)(5)
Application and notification of construction/reconstruction	63.5(b)(4), 63.5(d), and 63.1260(c)
Notification of applicability	63.9(a), 63.1260(b)
Notification of initial startup	63.9(b), 63.9(d), and 63.1260(b)
Notification of initial performance test, submittal of test plan, request for waiver of performance test	63.7(b)(1), 63.7(b)(2), 63.7(c), 63.7(f), 63.7(h) and 63.9(e), 63.1257(b)(8), 63.1260(l)
Notification of delay (reschedule) of initial performance test	63.7(b)(2)
Notification of CMS performance evaluation and results	63.8(e)(2), 63.9(g)(1), 63.9(e)(5), 63.10(e)(2), and 63.1260(d)
Notification to continue use of alternative to relative accuracy testing has been exceeded	63.9(g)(3) , 63.1260(d)
Notification of compliance status report (NOCSR)	63.9(h), 63.1260(f)
Initial performance test results	63.10(d)(2), 63.7(g), 63.1260(f)
Request for compliance extension and progress reports for compliance extension (as applicable)	63.10(d)(4), 63.1250(f)(6), 63.1260(m)

Notifications and Reports	Standard Citation by Section
Reports of startup, shutdown, and malfunction (SS&M)	63.10(d)(5), and 63.1260(i)
Pre-compliance report (as applicable)	63.1260(e)
Notification of process change	63.1260(h)
Periodic Reports	63.1260(g)
Reports of leak detection and repair (LDAR)	63.1260(j), 63.1255(h)
Reports of emissions averaging	63.1260(k)

A source must keep the following records:

Recordkeeping	
Recordkeeping requirements	63.10(a), 63.1259(a)
All reports and notifications	63.10(b)(1), and 63.1259(a)(1)
Record of applicability	63.10(b)(3), and 63.1259(a)(2)
Records of SS&M and SS&M plan	63.1259(a)(3)
Records of sources with continuous monitoring systems (CMS)	63.10(c)(1)-(14), and 63.1259(a)(4)
Application for approval of construction/reconstruction	63.1259(a)(5)
Records of equipment operation	63.1259(b)
Records of operating scenarios	63.1259(c)
Records of LDAR program	63.1259(d), 63.1255(g)
Records of emissions averaging	63.1259(e)
Records of delay of repair	63.1259(f)
Records of wastewater stream or residual transfer	63.1259(g)
Records of extensions	63.1259(h)
Records of inspections	63.1259(i)

Recordkeeping	
Records should be retained for 5 years	63.10(b)(1), 63.1259(a)(1)

Electronic Reporting

Some of the respondents are using monitoring equipment that automatically records parameter data. Although personnel at the affected facility must still evaluate the data, internal automation has significantly reduced the burden associated with monitoring and recordkeeping at a plant site.

Also, regulatory agencies in cooperation with the respondents continue to create reporting systems to transmit data electronically. However, electronic reporting systems are still not widely used. At this time, it is estimated that approximately 20 percent of the respondents use electronic reporting.

(ii) Respondent Activities

Respondent Activities
Read instructions.
Plan compliance strategy (includes preparing implementation plans)
Perform initial performance test, Reference Methods 1, 2, 3, 4, 18, 25 and 26 test, and repeat performance tests if necessary.
Write the notifications and reports listed above.
Enter information required to be recorded above.
Submit the required reports developing, acquiring, installing, and utilizing technology and systems for the purpose of collecting, validating, and verifying information.
Develop, acquire, install, and utilize technology and systems for the purpose of processing and maintaining information.
Develop, acquire, install, and utilize technology and systems for the purpose of disclosing and providing information.

Currently, sources are using automated monitoring equipment that provides parameter data. Although personnel at the source still need to evaluate the data, this type of monitoring equipment has significantly reduced the burden associated with monitoring and recordkeeping.

5. The Information Collected: Agency Activities, Collection Methodology, and Information Management

5(a) Agency Activities

EPA conducts the following activities in connection with the acquisition, analysis, storage, and distribution of the required information:

Agency Activities
Review notifications and reports, including performance test reports, and excess emissions reports, required to be submitted by industry.
Audit facility records.
Input, analyze, and maintain data in the Air Facility System (AFS).

5(b) Collection Methodology and Management

Following notification of startup, the reviewing authority could inspect the source to determine whether the pollution control devices are properly installed and operated. Performance test reports are used by the Agency to discern a source's initial capability to comply with the emission standard. Data and records maintained by the respondents are tabulated and published for use in compliance and enforcement programs. The semiannual reports are used for problem identification, as a check on source operation and maintenance, and for compliance determinations.

Information contained in the reports is entered into the AFS which is operated and maintained by EPA's Office of Compliance. AFS is EPA's database for the collection, maintenance, and retrieval of compliance data for approximately 125,000 industrial and government-owned facilities. EPA uses the AFS for tracking air pollution compliance and enforcement by local and state regulatory agencies, EPA regional offices and EPA headquarters. EPA and its delegated Authorities can edit, store, retrieve and analyze the data.

The records required by this regulation must be retained by the owner/operator for five years.

5(c) Small Entity Flexibility

A majority of the affected facilities are large entities (e.g., large businesses). However, the impact on small entities (i.e., small businesses) was taken into consideration during the development of the regulation. Due to technical considerations involving the process operations and the types of control equipment employed, the recordkeeping and reporting requirements are the same for both small and large entities. The Agency considers these requirements the minimum needed to ensure compliance and, therefore, cannot reduce them further for small entities. To the extent that larger businesses can use economies of scale to reduce their burden, the overall burden will be reduced.

5(d) Collection Schedule

The specific frequency for each information collection activity within this request is shown in Table 1: Annual Industry Burden for NESHAP for Pharmaceuticals Production (40 CFR part 63, subpart GGG).

6. Estimating the Burden and Cost of the Collection

Table 1 documents the computation of individual burdens for the recordkeeping and reporting requirements applicable to the industry for the subpart included in this ICR. The individual burdens are expressed under standardized headings believed to be consistent with the concept of burden under the Paperwork Reduction Act. Where appropriate, specific tasks and major assumptions have been identified. Responses to this information collection are mandatory.

The 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.

6(a) Estimating Respondent Burden

The average annual burden to industry over the next three years from these recordkeeping and reporting requirements is estimated to be 163,525 hours. These hours are based on Agency studies and background documents from the development of the regulation, Agency knowledge and experience with the NESHAP program, the previously approved ICR, and any comments received.

6(b) Estimating Respondent Costs

(i) Estimating Labor Costs

This ICR uses the following labor rates:

Managerial	$105.36 ($50.17 + 110%)
Technical	$92.09 ($43.85 + 110%)
Clerical	$45.15 ($22.50 + 110%)

These rates are from the United States Department of Labor, Bureau of Labor Statistics, September 2006, “Table 2. Civilian Workers, by occupational and industry group.” The rates are from column 1, “Total compensation.” The rates have been increased by 110% to account for the benefit packages available to those employed by private industry.

(ii) Estimating Capital/Startup and Operation and Maintenance Costs

The type of industry costs associated with the information collection activities in the subject standards are both labor costs that are addressed elsewhere in this ICR and the costs associated with continuous monitoring. The capital/startup costs are one-time costs when a

facility becomes subject to the regulation. The annual operation and maintenance costs are the ongoing costs to maintain the monitors and other costs such as photocopying and postage.]

(iii) Capital/Startup vs. Operation and Maintenance (O&M) Costs

Capital/Startup vs. Operation and Maintenance (O&M) Costs						
(A) Continuous Monitoring Device	(B) Capital/Startup Cost for One Respondent	(C) Number of New Respondents	(D) Total Capital/Startup Cost, (B X C)	(E) Annual O&M Costs for One Respondent	(F) Number of Respondents with O&M	(G) Total O&M, (E X F)
Data-logger and Thermocouple	$4,400	0	$0	$4,158	100	$415,800

The total capital/startup costs for this ICR are zero. This is the total of column D in the above table.

The total operation and maintenance (O&M) costs for this ICR are $415,800. This is the total of column G.

The average annual cost for capital/startup and operation and maintenance costs to industry over the next three years of the ICR is estimated to be $415,800. The continuous monitoring costs that are included in this section consist only of those capital/start-up and O&M costs that a source incurs as a result of the standard. Some continuous monitoring costs may not be included in this section. For instance, if a particular industry typically utilizes a control device that must have a continuous monitor (e.g., temperature, pressure drop, etc.) to function properly, and the recordation of additional measurements beyond the minimum are required by the standard, then there is no capital/startup, or O & M cost, but there is a labor cost to record the additional readings. Such a cost would not appear in this section, but in the industry burden Section 6 (d) below.

6(c) Estimating Agency Burden and Cost

The only costs to the Agency are those costs associated with analysis of the reported information. EPA's overall compliance and enforcement program includes activities such as the examination of records maintained by the respondents, periodic inspection of sources of emissions, and the publication and distribution of collected information.

The average annual Agency cost during the three years of the ICR is estimated to be $242,257. Details upon which this estimate is based appear in Table 2: Average Annual EPA Burden for NESHAP for Pharmaceuticals Production (40 CFR part 63, subpart GGG), attached.

This cost is based on the average hourly labor rate as follows:

Managerial	$58.18	(GS-13, Step 5, $36.36 + 60%)
Technical	$43.17	(GS-12, Step 1, $26.98 + 60%)
Clerical	$23.36	(GS-6, Step 3, $14.60 + 60%)

These rates are from the Office of Personnel Management (OPM) "2007 General Schedule" which excludes locality rates of pay. The rates have been increased by 60% to account for the benefit packages available to government employees. These rates can be obtained from the OPM web site, http//www.opm.gov/oca/payrates/ index/htm.

6(d) Estimating the Respondent Universe and Total Burden and Costs

Based on our research for this ICR, on average over the next three years, approximately 100 existing respondents will be subject to the standard. It is estimated that no additional respondents per year will become subject, although one existing source will become subject to new source standards through reconstruction. There will be no net increase in the number of sources due to this change. The overall average number of respondents, as shown in the table below is 100 per year.

The number of respondents is calculated using the following table that addresses the three years covered by this ICR:

Number of Respondents					
	Respondents That Submit Reports		Respondents That Do Not Submit Any Reports		
Year	(A) Number of New Respondents [1]	(B) Number of Existing Respondents	(C) Number of Existing Respondents That Keep Records But Do Not Submit Reports	(D) Number of Existing Respondents That Are Also New Respondents	(E) Number of Respondents (E=A+B+C-D)
1	1	99	0	1	100
2	1	99	0	1	100
3	1	99	0	1	100
Average	1	99	0	1	100

[1] New respondents only include sources with reconstructed affected facilities, so there is no net change in the number of respondents (i.e., a reconstructed existing facility becomes a new affected facility).

Column D is subtracted to avoid double-counting respondents. As shown above, the average Number of Respondents over the three year period of this ICR is 100.

The total number of annual responses per year is calculated using the following table:

TOTAL ANNUAL RESPONSES				
(A) INFORMATION COLLECTION ACTIVITY	(B) NUMBER OF RESPONDENTS PER YEAR	(C) NUMBER OF OCCURRENCES PER RESPONDENT PER YEAR	(D) NUMBER OF EXISTING RESPONDENTS THAT KEEP RECORDS BUT DO NOT SUBMIT REPORTS	(E) TOTAL ANNUAL RESPONSES E=(BXC) +D
a. Read rule and instructions	0	1	0	0
b. Required Activities				
i. Initial Performance Test				
New	0	1	0	0
ii. Initial Performance Test				
Reconstructed	1	1	0	1
iii. Initial Performance Test				
Wastewater	0	1		0
iii. Initial CMS performance				
Evaluation	0	1	0	0
iv. Repeat Performance Test	0.2	1	0	0.2
c. Write Reports				
i. Notification of Construction/				
Reconstruction	1	1	0	1
ii. Notification of Process Change	100	3		300
iii. Notification of Actual				
Startup	0	1	0	0
iv. Performance Test				
Notification	1	1	0	1
v. Notification of Applicability	0	1	0	0
vi. Notification of Demonstration of CMS	0	1	0	0
vii. Notification of Compliance				
Status	0	1		0
viii. Emissions Averaging Plan	0	1		0
ix. Semi-annual Summary				
Report				
a. No Deviations	90	2	0	180
b. Deviations	10	2	0	20
c. SS&M Report	100	2	0	200
d. LDAR Report	100	2	0	200
e. Emission Averaging				
Report	10	2	0	20
Total Number of Annual Responses				923

The number of Total Annual Responses is 923. The total annual labor costs are $14,485,933. Details regarding these estimates may be found in Table 1: Annual Industry Burden for NESHAP for Pharmaceuticals Production (40 CFR part 63, subpart GGG), attached.

6(e) Bottom Line Burden Hours Burden Hours and Cost Tables

The detailed bottom line burden hours and cost calculations for the respondents and the Agency are shown in Tables 1 and 2, respectively, and summarized below.

(i) Respondent Tally

The total annual labor costs are $14,485,933. Details regarding these estimates may be found in Table 1: Annual Industry Burden for NESHAP for Pharmaceuticals Production (40 CFR part 63, subpart GGG), attached. Furthermore, the annual public reporting and recordkeeping burden for this collection of information is estimated to average 177 hours per response.

The total annual capital/startup and O&M costs to the regulated entity are $415,800. The cost calculations are detailed in Section 6(b)(iii), Capital/Startup vs. Operation and Maintenance (O&M) Costs.

(ii) The Agency Tally

The average annual Agency burden and cost over next three years is estimated to be 5,852 labor hours at a cost of $242,257. See Table 2: Average Annual EPA Burden for NESHAP for Pharmaceuticals Production (40 CFR part 63, subpart GGG), attached.

6(f) Reasons for Change in Burden

The increase in burden from the most recently approved ICR is due to adjustments, as follows.

Adjustments common to both Tables:

1. The number of sources should be 100. In the previous ICR, it was assumed that there was no growth in the industry, but that one existing source would become subject to new source standards through reconstruction. If this occurs, then there is no net increase in the number of the sources, because the existing source simply becomes a reconstructed source. The same assumptions on growth and reconstruction were made for this ICR, but the number of sources had to be adjusted from 101 to 100 to account for the previous error.

2. The labor rates were adjusted to account for the latest labor rates available.

Additional adjustments to Table 1:

1. The burden for the following items should be zero, because this burden is for new, greenfield construction only. The sources in this ICR which are subject to new source standards are reconstructed; therefore, these one-time burdens associated with new, greenfield construction do not apply (i.e., the existing source, prior to its reconstruction would have already performed these actions):

a. Read Instruction
b. Quality Control Plan for CMS
c. Develop Record System
d. Train Personnel
e. Notification of Actual Startup
f. Notification of Demonstration of CMS
e. Notification of Compliance Status Report

2. The burdens for "Notification of Anticipated Startup" and "Quarterly Reports of Excess Emissions" were removed, as they are not requirements in the NESHAP.

3. The burden for "Semiannual Reports" was divided into "No Deviations" and "Deviations" as the burden varies considerably depending on which level of detail must be submitted. Assumptions were made on the percentage of sources submitting each, based on experience with ICRs for similar source categories.

4. The number of occurrences per respondent per year for "Startup, Shutdown and Malfunction" (SS&M) reports was corrected to two times per year. Additionally, the number of respondents per year submitting SS&M reports was corrected to correlate with the number of sources keeping records of SS&M.

5. Burden items for "Emissions Averaging Reports" and "Calibration of CMS" and "LDAR" records were added to the Table, as these burden items were omitted in the previous ICR.

6. The burden item for "Records of Operating Conditions Exceeding Last Performance Test" was deleted, as this is included in the burden for "Records of Operating Parameters for Control Devices".

Additional adjustments to Table 2:

1. The burdens for "Notification of Anticipated Startup" and "Quarterly Reports of Excess Emissions and CMS Performance" were removed, as they are not requirements in the NESHAP.

2. The burden for the following items should be zero, because this burden is for new, greenfield construction only. The sources in this ICR which are subject to new source standards are reconstructed, therefore these one-time burdens associated with new, greenfield construction do not apply (i.e., the existing source, prior to its reconstruction would have already performed these actions):

a. Review Notification of Demonstration of CMS
b. Review Initial Notification of Compliance Status
c. Notification of Actual Startup

3. The burden associated with the "Initial Notification" was reduced, as it was

overstated in the previous ICR, based on experience with ICRs for similar source categories.

4. The burden associated with the "Notification of Compliance Status Report" was increased, as it was understated in the previous ICR, based on experience with ICRs for similar source categories.

5. Burden items for "SS&M Report", "LDAR Report", and "Emissions Averaging Report" were added as they were omitted in the previous ICR.

6. The burden associated with reviewing "Semiannual Reports" was divided into "No Deviations" and "Deviations" as the burden varies considerably depending on which level of detail must be reviewed. Assumptions were made on the percentage of sources submitting each, based on experience with ICRs for similar source categories.

The decrease in Capital/Startup cost is because the one reconstructed source would not be required to buy a new thermocouple to meet the data collection requirements. The source would have already bought the thermocouple to meet the existing source standards and will continue to use that thermocouple to meet the more stringent new source standards. The increase in Operation and Maintenance (O&M) Costs, as calculated in section 6(b)(iii), compared with the costs in the previous ICR is because the O&M costs are ongoing costs born by all of the affected facilities, not just new sources.

6(g) Burden Statement

The annual public reporting and recordkeeping burden for this collection of information is estimated to average 177 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose, or provide information to, or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit, or otherwise disclose the information.

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 OMB Control Numbers for EPA's regulations are listed at 40 CFR part 9 and 48 CFR chapter 15.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID Number EPA-HQ-OECA-2006-0713. An electronic version of the public docket is available at http://www.regulations.gov/ which may be used to obtain a copy of the draft

collection of information, submit, or view public comments, access the index listing of the contents of the docket, and to access those documents in the public docket that are available electronically. When in the system, select "search," then key in the docket ID number identified in this document. The documents are also available for public viewing at the Enforcement and Compliance Docket and Information Center in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1744, and the telephone number for the docket center is (202) 566-1927. Comments also may be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Officer for EPA. Please include the EPA Docket ID Number EPA-HQ- OECA-2006-0713 and OMB Control Number 2060-0358 in any correspondence.

Part B of the Supporting Statement

This part is not applicable because no statistical methods were used in collecting this information.

Table 1 - Annual Respondent Burden and Cost - NESHAP for Pharmaceuticals Production
40 CFR Part 63, Subpart GGG

Burden Item [(a)]	(A) Respondent Hours per Occurrence	(B) Number of Occurences Per Respondent Year	(C) Hours Per Respondent Per Year (C=AxB)	(D) Number of Respondents per year	(E) Technical hours per year @$92.09 (E=CxD)	(F) Management Hours Per year @$105.36 (F=E*0.05)	(G) Clerical Hours per year @ $45.15 (G=E*0.10)	(H) Total Annual Cost [a]
1. Applications	N/A							
2. Surveys and Studies	N/A							
3. Reporting Requirements								
New Sources [b]								
A. Read Instructions	1	1	1	0	0.00	0.00	0.00	0.00
B. Required Activities								
i. Initial Performance Test -								
New	480	1	480	0	0.00	0.00	0.00	0.00
Reconstructed	160	1	160	1	160.00	8.00	16.00	16,299.68
Wastewater	160	1	160	0	0.00	0.00	0.00	0.00
ii. Quality Control Plan for CMS	60	1	60	0	0.00	0.00	0.00	0.00
iii. Develop Record System	40	1	40	0	0.00	0.00	0.00	0.00
iv. Train Personnel	40	1	40	0	0.00	0.00	0.00	0.00
iv. Repeat Performance Test [c]	60	1	60	0.2	12.00	0.60	1.20	1,222.48
C. Write Reports								
i. Notification of Construction/								
Reconstruction	2	1	2	1	2.00	0.10	0.20	203.75
ii. Notification of Physical or								
Operational Changes[d]	8	3	24	100	2,400.00	120.00	240.00	244,495.20
iii. Notification of Actual								
Startup	2	1	2	0	0.00	0.00	0.00	0.00
iv. Notification of Initial								
Performance Test	2	1	2	1	2.00	0.10	0.20	203.75
v. Notification of Applicability	2	1	2	0	0.00	0.00	0.00	0.00
vi. Notifcation of Demonstration								

of CMS	2	1	2	0	0.00	0.00	0.00	0.00
vii. Notification of Compliance								
Status	120	1	120	0	0.00	0.00	0.00	0.00
viii.Precompliance Report								
(emissions averaging)[e]	180	1	180	0	0.00	0.00	0.00	0.00
ix. Startup, Shutdown								
and Malfunction	40	2	80	100	8,000.00	400.00	800.00	814,984.00
x . Semiannual Summary								
Report [f]								
a. No Deviations	8	2	16	90	1,440.00	72.00	144.00	146,697.12
b. Deviations	24	2	48	10	480.00	24.00	48.00	48,899.04
xi. LDAR Report [g]	432	2	864	100	86,400.00	4,320.00	8,640.00	8,801,827.20
xii. Emissions Averaging Report	20	2	40	10	400.00	20.00	40.00	40,749.20
Subtotal Reporting							113,730.40	10,074,832.22
4. Recordkeeping Requirements								
i. Records of operating								
parameters for control devices [h]	1	365	365	100	36,500.00	1,825.00	3,650.00	3,718,364.50
ii. Records of SS&M	2	26	52	100	5,200.00	260.00	520.00	529,739.60
iii. Calibration of CMS [i]	16	1	16	100	1,600.00	80.00	160.00	162,996.80
iv. LDAR	Included in 3.c.xi.							
Subtotal recordkeeping							49,795.00	4,411,101.00
Total Hours and Cost							163,525.40	14,485,933.22

[a] Assume that all tasks are to be performed by managerial, technical and clerical personnel.

This ICR uses the following labor rates: $105.36 for Managerial labor, $92.09 for Technical labor, and $45.15 for Clerical labor.

These rates are from the United States Department of Labor Bureau of Labor Statistics, September 2006, “Table 10. Private industry, by occupational and industry group.” The rates have been increased by 110% to account for the benefit packages available to those employed by private industry.

[b] Assume that there will be one reconstructed facility each year for the next three years.

[c] Assume that 20 percent of sources required to conduct a performance test will repeat performance testing each year due to failure.

[d] Assume each source will require an average of three processing changes per facility each year over the next three year period of this ICR.

[e] Assumes 10 percent of existing facilities will comply with emissions averaging requirements; new facilities are not allowed to use emissions averaging.
[f] All affected sources must sumbit Semiannual Reports. It is estimated that 10% will have deviations.
[g] Assumes that it will take respondents 432 hours to write the leak detection and repair report
[h] Assume that all sources are required to keep records of operating parameters for control devices
[i] Assume that 10 percent of source are required to keep records of operating conditions exceeding last performance tests.

Table 2 - Annual Agency Burden and Cost - NEHSAP for Pharmaceuticals Production

40 CFR Part 63, Subpart GGG

Burden Item	(A) Person Hours per occurance	(B) Annual Occurrence Per Respondent	(C) Annual Person Hours per Respondent	(D) Total Number of Respondents	(E) Technical Hours per year	(F) Managerial Hours Per year	(G) Clerical Hours per year	(H) Total Annual Cost[a]
1. Required Activities[b]								
i. Initial Performance Test[c]	2	1	2	1	2.00	0.10	0.20	95.21
ii. Repeat Performance Test[d]	24	1	24	0.2	4.80	0.24	0.48	228.51
2. Report Review - One Time								
i. Notification of Construction/								
Reconstruction[c]	2	1	2	1	2.00	0.10	0.20	95.21
ii. Notification of actual startup	2	1	2	0	0.00	0.00	0.00	0.00
iii. Notification of Initial								
CMS Demonstration	2	1	2	0	0.00	0.00	0.00	0.00
iv. Initial Notification	2	1	2	0	0.00	0.00	0.00	0.00
v. Notification of Compliance								
Status Report	40	1	40	0	0.00	0.00	0.00	0.00
vii. Precompliance Report[e]								
a. w/ Emissions Averaging[f]	20	1	20	0	0.00	0.00	0.00	0.00
b. w/o Emissions Averaging[f]	4	1	4	0	0.00	0.00	0.00	0.00
3. Report Review - On-going								
i. Semiannual Summary Report								
a. No Deviations[g]	2	2	4	90	360.00	18.00	36.00	17,138.16

b. Deviations[g]	8	2	16	10	160.00	8.00	16.00	7,616.96
ii. Notification Physical/								
Operational change[h]	8	3	24	100	2,400.00	120.00	240.00	114,254.40
iii. SS&M Report[i]	2	2	4	100	400.00	20.00	40.00	19,042.40
iv. LDAR Report[j]	8	2	16	100	1,600.00	80.00	160.00	76,169.60
v. Emission Averaging Report[f]	8	2	16	10	160.00	8.00	16.00	7,616.96
Total								242,257.41
Subtotal Hours					5,088.80	254.44	508.88	
Total Hours							5,852.12	

[a] The cost is based on an hourly labor rate of $42.45 for technical labor, $53.22 for managerial labor,and $22.96 for clerical labor. These rate are from the Office of Personnel Management (OPM) " 2007 General Schedule", which exludes locality rates of pay.

[b] Includes review of test plan and test results

[c] Assume that there will be one reconstructed facility each year for the next three years.

[d] Assume that 20 percent of sources required to conduct a performance test will repeat performance testing each year due to failure.

[e] Assumes 50 percent of new facilities will submit a precompliance report.

[f] Assumes 10 percent of existing facilities will comply with emissions averaging requirements; new facilities are not allowed to use emissions averaging.

[g] Assumes 90 percent of facilities will have no deviations, 10 percent will have deviations

[h] Assume each source will require an average of three processing changes per facility each year over the next three year period of this ICR

[i] Assumes all facilities will report actions taken during startup, shutdown, or malfunction that are consistent with the SS&M plan

[j] Assumes all facilities will report the specified information for processes subject to the equipment leak standards.