Montana Department of
ENVIRONMENTAL QUALITY
Brian Schweitzer, Governor
P. O. Box 200901 Helena, MT 59620-0901 (406) 444-2544 Website: www.deq.mt.gov

March 3, 2011

Mr. Michael Covarrubias
Corixa Corporation d/b/a GlaxoSmithKline Biologicals, NA
553 Old Corvallis Road
Hamilton, MT 59840

Dear Mr. Covarrubias:

Montana Air Quality Permit #4460-01 is deemed final as of March 3, 2011, by the Department of Environmental Quality (Department). This permit is for a pharmaceutical preparations facility. All conditions of the Department's Decision remain the same. Enclosed is a copy of your permit with the final date indicated.

For the Department,

Vickie Walsh
Air Permitting Program Supervisor
Air Resources Management Bureau
(406) 444-9741

Deanne Fischer, P.E.
Environmental Engineer
Air Resources Management Bureau
(406) 444-3403

VW:DF
Enclosure

Montana Department of Environmental Quality
Permitting and Compliance Division

Montana Air Quality Permit #4460-01

Corixa Corporation
d/b/a GlaxoSmithKline Biologicals, NA
553 Old Corvallis Road
Hamilton, MT 59840

March 3, 2011

MONTANA AIR QUALITY PERMIT

Issued To: Corixa Corporations d/b/a
GlaxoSmithKline Biologicals, NA
553 Old Corvallis Road
Hamilton, MT 59840

MAQP: #4460-01
Application Complete: 10/19/2010
Additional Information Received: 12/17/2010
Preliminary Determination Issued: 01/26/2011
Department Decision Issued: 02/15/2011
Permit Final: 03/03/2011
AFS #: 081-0010

A Montana Air Quality Permit (MAQP), with conditions, is hereby granted to Corixa Corporation, d/b/a, GlaxoSmithKline Biologicals, NA (GSK), pursuant to Sections 75-2-204 and 211 of the Montana Code Annotated (MCA), as amended, and Administrative Rules of Montana (ARM) 17.8.740, *et seq*., as amended, for the following:

SECTION I: Permitted Facilities

A. Plant Location

GSK's Hamilton Montana Facility is located at 553 Old Corvallis Road in Hamilton, at 46.28567 Latitude, 114.14296 Longitude, and within the S ½ of Section 7, Township 6 North, Range 20 West, Ravalli County, Montana.

B. Current Permit Action

GSK operates a stationary pharmaceutical preparations facility. On October 19, 2010 the Department of Environmental Quality – Air Resources Management Bureau (Department) received a request from GSK to make the following modifications to the facility's Montana Air Quality Permit (MAQP). The request was further justified in a letter of additional information received by the Department on December 17, 2010

1. GSK proposed to change the process for producing product in Building 12 from the High Density process to the Low Density process.

2. GSK determined that the cooling water temperature supplied to the condensation emission control systems in Building 5 is slightly higher than presented in the original permit application. Also the chilled water temperature supplied to the condensation emission control systems in Building 12 is higher than presented in the original permit application. These changes in water temperature increase the volatile organic compounds (VOC) and hazardous air pollutants (HAP) emissions from both buildings slightly, and should be noted in the permit.

3. GSK proposed to change the method of monitoring the operation of the condensation emission control systems for both Building 5 and Building 12. Instead of measuring the exhaust gas temperature from each condenser, as outlined in Section II.A of the permit, the inlet cooling water and inlet chilled water temperatures would be measured.

4. GSK also noted that the there was a misrepresentation of the number of laboratory hoods included as point sources in the emissions inventory in the previous permit. This modification would correct the emissions inventory calculations.

In conclusion, this modification includes the changes in the manufacturing process in Building 12, modifies the inlet water temperature to, and the method used to monitor the performance of the condensers in Buildings 5 and 12, recalculates the estimated VOC and HAP emissions from Buildings 5 and 12, corrects the number of vent hoods included as point sources in the emissions inventory, and updates the permit to reflect the current permit language and rule references used by the Department.

SECTION II: Conditions and Limitations

A. Emission Limitations

1. GSK shall install, operate, and maintain condensation control technology equipment to control emissions from Building 5 and Building 12 pharmaceutical manufacturing operations (ARM 17.8.752).

2. GSK shall operate the condensation emissions control system for Building 5 manufacturing operations such that the maximum 1 hour average cooling water temperature is 17° Celsius (ARM 17.8.752).

3. GSK shall operate the condensation emissions control system for Building 12 manufacturing operations such that the maximum 1 hour average chilled water temperature is 7° Celsius (ARM 17.8.752).

4. GSK may operate up to three diesel engines EGEN1, EGEN2, and EGEN3 to power electric generators named G1, G2, and G3 respectively. The engines shall not exceed 2012 horsepower (hp), 2682 hp, and 671 hp, respectively (ARM 17.8.749).

5. The operation of the three diesel engines/generators shall not exceed 500 hours each per rolling 12-month time period (ARM 17.8.749 and ARM 17.8.752).

6. GSK may operate up to three natural gas fired boilers, Boiler 1, Boiler 2 and Boiler 3; the maximum rated heat input capacity for Boiler 1 and Boiler 2 shall not exceed 16.329 million British thermal units per hour (MMBtu/hr) each and the maximum rated heat input capacity of Boiler 3 shall not exceed 30.659 MMBtu/hr (ARM 17.8.749).

7. GSK shall operate and maintain low oxides of nitrogen (NO_x) burner and flue gas recirculation systems to control NO_x emissions from Boiler 1, Boiler 2 and Boiler 3 (ARM 17.8.752).

8. GSK shall combust only pipeline quality natural gas to control SO_2 emissions from Boiler 1, Boiler 2 and Boiler 3 (ARM 17.8.752).

9. GSK shall use good combustion practices to control CO, PM_{10}, VOC and HAP emissions from Boiler 1, Boiler 2 and Boiler 3 (ARM 17.8.752).

10. GSK shall not cause or authorize emissions to be discharged into the outdoor atmosphere from any sources installed after November 23, 1968, that exhibit an opacity of 20% or greater averaged over 6 consecutive minutes (ARM 17.8.304).

11. GSK shall not cause or authorize the use of any street, road, or parking lot without taking reasonable precautions to control emissions of airborne particulate matter (ARM 17.8.308).

12. GSK shall treat all unpaved portions of the haul roads, access roads, parking lots, or general plant area with water and/or chemical dust suppressant as necessary to maintain compliance with the reasonable precautions limitation in Section II.A.10 (ARM 17.8.749).

13. GSK shall comply with all applicable standards and limitations, and the reporting, recordkeeping and notification requirements contained in 40 CFR 60, Subpart Dc, *Standards of Performance for Small Industrial, Commercial, Institutional Steam Generating Units* (ARM 17.8.340 and 40 CFR 60, Subpart Dc).

14. GSK shall comply with all applicable standards and limitations, and the reporting, recordkeeping and notification requirements contained at 40 CFR 60, Subpart IIII, *Standards of Performance for Stationary Compression Ignition Internal Combustion Engines* (ARM 17.8.752, ARM 17.8.340, and 40 CFR 60, Subpart IIII).

15. GSK shall comply with all applicable standards and limitations, and the reporting, recordkeeping, and notification requirements contained in 40 CFR 63, Subpart ZZZZ, *National Emissions Standards for Hazardous Air Pollutants for Stationary Reciprocating Internal Combustion Engines*, for any applicable diesel engine (ARM 17.8.752, ARM 17.8.342, and 40 CFR 63, Subpart ZZZZ).

B. Testing Requirements

1. The Department of Environmental Quality (Department) may require further testing (ARM 17.8.105).

2. All compliance source tests shall conform to the requirements of the Montana Source Test Protocol and Procedures Manual (ARM 17.8.106).

C. Monitoring Requirements

GSK shall install, calibrate, maintain, and operate continuous monitoring and recording equipment on the condensation emission control systems for Building 5 and Building 12 manufacturing operations to measure the chilled/cooling water temperatures. The chilled/cooling water temperatures shall be recorded in hourly averages (ARM 17.8.749).

D. Operational Reporting Requirements

1. GSK shall supply the Department with annual production information for all emission points, as required by the Department in the annual emission inventory request. The request will include, but is not limited to, all sources of emissions identified in the emission inventory contained in the permit analysis.

Production information shall be gathered on a calendar-year basis and submitted to the Department by the date required in the emission inventory request. Information shall be in the units required by the Department. This information may be used to calculate operating fees, based on actual emissions from the facility, and/or to verify compliance with permit limitations (ARM 17.8.505).

2. GSK shall notify the Department of any construction or improvement project conducted, pursuant to ARM 17.8.745, that would include ***the addition of a new emissions unit***, change in control equipment, stack height, stack diameter, stack flow, stack gas temperature, source location, or fuel specifications, or would result in an

increase in source capacity above its permitted operation. The notice must be submitted to the Department, in writing, 10 days prior to startup or use of the proposed de minimis change, or as soon as reasonably practicable in the event of an unanticipated circumstance causing the de minimis change, and must include the information requested in ARM 17.8.745(l)(d) (ARM 17.8.745).

3. All records compiled in accordance with this permit must be maintained by GSK as a permanent business record for at least 5 years following the date of the measurement, must be available at the plant site for inspection by the Department, and must be submitted to the Department upon request (ARM 17.8.749).

4. GSK shall document, by month, the hours of operation of each of the three diesel engines/generators. By the 25th day of each month, GSK shall total the hours of operation of the three diesel engines/generators for the previous month. The monthly information will be used to verify compliance with the rolling 12-month limitation in Section II.A.4. The information for each of the previous months shall be submitted along with the annual emission inventory (ARM 17.8.749).

SECTION III: General Conditions

A. Inspection – GSK shall allow the Department's representatives access to the source at all reasonable times for the purpose of making inspections or surveys, collecting samples, obtaining data, auditing any monitoring equipment (CEMS, CERMS) or observing any monitoring or testing, and otherwise conducting all necessary functions related to this permit.

B. Waiver – The permit and the terms, conditions, and matters stated herein shall be deemed accepted if GSK fails to appeal as indicated below.

C. Compliance with Statutes and Regulations – Nothing in this permit shall be construed as relieving GSK of the responsibility for complying with any applicable federal or Montana statute, rule, or standard, except as specifically provided in ARM 17.8.740, *et seq*. (ARM 17.8.756).

D. Enforcement – Violations of limitations, conditions and requirements contained herein may constitute grounds for permit revocation, penalties, or other enforcement action as specified in Section 75-2-401, *et seq*., MCA.

E. Appeals – Any person or persons jointly or severally adversely affected by the Department's decision may request, within 15 days after the Department renders its decision, upon affidavit setting forth the grounds therefor, a hearing before the Board of Environmental Review (Board). A hearing shall be held under the provisions of the Montana Administrative Procedures Act. The filing of a request for a hearing does not stay the Department's decision, unless the Board issues a stay upon receipt of a petition and a finding that a stay is appropriate under Section 75-2-211(11)(b), MCA. The issuance of a stay on a permit by the Board postpones the effective date of the Department's decision until conclusion of the hearing and issuance of a final decision by the Board. If a stay is not issued by the Board, the Department's decision on the application is final 16 days after the Department's decision is made.

F. Permit Inspection – As required by ARM 17.8.755, Inspection of Permit, a copy of the air quality permit shall be made available for inspection by the Department at the location of the source.

G. Permit Fee – Pursuant to Section 75-2-220, MCA, failure to pay the annual operation fee by GSK may be grounds for revocation of this permit, as required by that section and rules adopted thereunder by the Board.

H. Duration of Permit – Construction or installation must begin or contractual obligations entered into that would constitute substantial loss within 3 years of permit issuance and proceed with due diligence until the project is complete or the permit shall expire (ARM 17.8.762).

Permit Analysis
Corixa Corporations d/b/a
GlaxoSmithKline Biologicals, NA
MAQP #4460-01

I. Introduction/Process Description

Corixa Corporation, d/b/a, GlaxoSmithKline Biologicals, NA (GSK) owns and operates a pharmaceutical preparations manufacturing plant and research and development (R&D) facility located in Hamilton, Montana. The GSK facility is located at 553 Old Corvallis Road in Hamilton, at 46.28567 Latitude, 114.14296 Longitude, and within the S ½ of Section 7, Township 6 North Range 20 West, Ravalli County, Montana.

The facility consists of two proprietary pharmaceutical manufacturing operations and supporting equipment. The manufacturing operations are called "Building 5 Manufacturing Operations" and "Building 12 Manufacturing Operations" and supporting equipment and emitting units include three boilers, three emergency generators, one fire pump, two fuel storage tanks and a waste solvent storage tank.

A. Permitted Equipment

The following emitting units are included on the site:

- Boilers: Two 16.329 million British thermal units per hour (MMBtu/hr) and one 30.659 MMBtu/hr Cleaver-Brooks natural gas-fired boilers each equipped with low oxides of nitrogen (NO_x) burners. The boilers satisfy the facility's process and space-heating needs. The two 16.329 MMBtu/hr boilers were manufactured in 2004 and the 30.659 MMBtu/hr boiler was manufactured in 2006.

- Diesel-powered emergency engines/generators (EGENs), limited to 500 hours per year operation each:

    - G1 – One 2012-horsepower (hp)/2169-brake horsepower (bhp) engine driving a 1500-kiloWatt (kW) generator, manufactured by Caterpillar in 2001

    - G2 – One 2682-hp/2937-bhp engine driving a 2000-kW generator, manufactured by Caterpillar in 2007

    - G3 – One 671-hp/757-bhp engine driving a 500-kW generator, manufactured by Caterpillar in 2007

- One diesel-fired fire pump rated at 110 bhp manufactured in February 2007.

- Four identical Aerco natural gas-fired hot water heaters, each rated at 2 MMBtu/hr.

- Two above-ground diesel fuel storage tanks (ASTs) with rated capacities of 2,000 gallons and 6,000 gallons to supply fuel oil to the EGENs.

- One 10,000-gallon AST for storing waste solvents for offsite disposal.

- Approximately 70 laboratory fume hoods of which 40 serve the R&D and Quality Control (QC) operations and 30 serve manufacturing operations.

- Building 5 and Building 12 batch manufacturing operations, which consist of various unit operations, including extraction, purification, and regeneration.

B. Source Description

The facility consists of two proprietary pharmaceutical manufacturing operations and supporting equipment. The GSK site sits on approximately 35 acres and contains various buildings occupying 176,800 square feet of manufacturing, R&D, QC, administration, and utility operations. The manufacturing process operations utilize organic solvents, primarily chloroform and methanol with minor amounts of ethanol and other solvents, in the purification and extraction operations that go on in Building 5 and Building 12.

C. Permit History

On January 28, 2010 GSK was issued **MAQP #4460-00** for the operation of a pharmaceutical preparation manufacturing plant and research and development (R&D) facility and associated equipment.

D. Current Permit Action

The current permit action is a modification of MAQP #4460-00. On October 19, 2010, the Department of Environmental Quality – Air Resources Management Bureau (Department) received a request from GSK for a modification to MAQP #4460-00 to include the following changes. The request was further justified in a letter of additional information received by the Department on December 17, 2010:

- GSK proposed to change the process for producing product in Building 12 from the High Density process to the Low Density process.

- GSK determined that the cooling water temperature supplied to the condensation emission control systems in Building 5 is slightly higher than presented in the original permit application. Also the chilled water temperature supplied to the condensation emission control systems in Building 12 is higher than presented in the original permit application. These changes in water temperature increase the volatile organic compounds (VOC) and hazardous air pollutants (HAP) emissions from both buildings slightly, and should be noted in the permit.

- GSK proposed to change the method of monitoring the operation of the condensation emission control systems in both Building 5 and Building 12. Instead of measuring the exhaust gas temperature from each condenser, as outlined in Section II.A. of the permit, the inlet cooling water and inlet chilled water temperatures would be measured.

- GSK also noted that the there was a misrepresentation of the number of laboratory hoods included as point sources in the emissions inventory in the previous permit. This modification would correct the emissions inventory calculations.

In conclusion, this modification includes the changes in the manufacturing process in Building 12, modifies the inlet water temperature to, and the method used to monitor the performance of the condensers in Buildings 5 and 12, recalculates the estimated VOC and HAP emissions from Buildings 5 and 12, corrects the number of vent hoods included as point sources in the emissions inventory, and updates the permit to reflect the current permit language and rule references used by the Department. **MAQP #4460-01** replaces MAQP #4460-01.

E. Response to Public Comments

Person/Group Commenting	Permit Reference	Comment	Department Response
IES Engineers (Letter dated February 4, 2011)	4460-01	Correct the potential/allowable VOC and HAP emissions for Buildings 5 and 12 Manufacturing Operations.	Typographical error in emissions inventory was corrected.

F. Additional Information

Additional information, such as applicable rules and regulations, Best Available Control Technology (BACT)/Reasonably Available Control Technology (RACT) determinations, air quality impacts, and environmental assessments, is included in the analysis associated with each change to the permit.

II. Applicable Rules and Regulations

The following are partial explanations of some applicable rules and regulations that apply to the facility. The complete rules are stated in the Administrative Rules of Montana (ARM) and are available, upon request, from the Department. Upon request, the Department will provide references for location of complete copies of all applicable rules and regulations or copies where appropriate.

A. ARM 17.8, Subchapter 1 – General Provisions, including but not limited to:

1. ARM 17.8.101 Definitions. This rule includes a list of applicable definitions used in this chapter, unless indicated otherwise in a specific subchapter.

2. ARM 17.8.105 Testing Requirements. Any person or persons responsible for the emission of any air contaminant into the outdoor atmosphere shall, upon written request of the Department, provide the facilities and necessary equipment (including instruments and sensing devices) and shall conduct tests, emission or ambient, for such periods of time as may be necessary using methods approved by the Department.

3. ARM 17.8.106 Source Testing Protocol. The requirements of this rule apply to any emission source testing conducted by the Department, any source or other entity as required by any rule in this chapter, or any permit or order issued pursuant to this chapter, or the provisions of the Clean Air Act of Montana, 75-2-101, *et seq.*, Montana Code Annotated (MCA).

   GSK shall comply with the requirements contained in the Montana Source Test Protocol and Procedures Manual, including, but not limited to, using the proper test methods and supplying the required reports. A copy of the Montana Source Test Protocol and Procedures Manual is available from the Department upon request.

4. ARM 17.8.110 Malfunctions. (2) The Department must be notified promptly by telephone whenever a malfunction occurs that can be expected to create emissions in excess of any applicable emission limitation or to continue for a period greater than 4 hours.

5. ARM 17.8.111 Circumvention. (1) No person shall cause or permit the installation or use of any device or any means that, without resulting in reduction of the total amount of air contaminant emitted, conceals or dilutes an emission of air contaminant that would

otherwise violate an air pollution control regulation. (2) No equipment that may produce emissions shall be operated or maintained in such a manner as to create a public nuisance.

B. ARM 17.8, Subchapter 2 – Ambient Air Quality, including, but not limited to the following:

1. ARM 17.8.204 Ambient Air Monitoring
2. ARM 17.8.210 Ambient Air Quality Standards for Sulfur Dioxide
3. ARM 17.8.211 Ambient Air Quality Standards for Nitrogen Dioxide
4. ARM 17.8.212 Ambient Air Quality Standards for Carbon Monoxide
5. ARM 17.8.213 Ambient Air Quality Standard for Ozone
6. ARM 17.8.214 Ambient Air Quality Standard for Hydrogen Sulfide
7. ARM 17.8.220 Ambient Air Quality Standard for Settled Particulate Matter
8. ARM 17.8.221 Ambient Air Quality Standard for Visibility
9. ARM 17.8.222 Ambient Air Quality Standard for Lead
10. ARM 17.8.223 Ambient Air Quality Standard for PM_{10}

GSK must maintain compliance with the applicable ambient air quality standards.

C. ARM 17.8, Subchapter 3 – Emission Standards, including, but not limited to:

1. ARM 17.8.304 Visible Air Contaminants. This rule requires that no person may cause or authorize emissions to be discharged into the outdoor atmosphere from any source installed after November 23, 1968, that exhibit an opacity of 20% or greater averaged over 6 consecutive minutes.

2. ARM 17.8.308 Particulate Matter, Airborne. (1) This rule requires an opacity limitation of less than 20% for all fugitive emission sources and that reasonable precautions be taken to control emissions of airborne particulate matter. (2) Under this rule, GSK shall not cause or authorize the use of any street, road, or parking lot without taking reasonable precautions to control emissions of airborne particulate matter.

3. ARM 17.8.309 Particulate Matter, Fuel Burning Equipment. This rule requires that no person shall cause, allow, or permit to be discharged into the atmosphere particulate matter caused by the combustion of fuel in excess of the amount determined by this rule.

4. ARM 17.8.310 Particulate Matter, Industrial Process. This rule requires that no person shall cause, allow, or permit to be discharged into the atmosphere particulate matter in excess of the amount set forth in this rule.

5. ARM 17.8.322 Sulfur Oxide Emissions--Sulfur in Fuel. This rule requires that no person shall burn liquid, solid, or gaseous fuel in excess of the amount set forth in this rule.

6. ARM 17.8.324 Hydrocarbon Emissions--Petroleum Products. (3) No person shall load or permit the loading of gasoline into any stationary tank with a capacity of 250 gallons or more from any tank truck or trailer, except through a permanent submerged fill pipe, unless such tank is equipped with a vapor loss control device as described in (1) of this rule.

7. ARM 17.8.340 Standard of Performance for New Stationary Sources and Emission Guidelines for Existing Sources. This rule incorporates, by reference, 40 CFR Part 60, Standards of Performance for New Stationary Sources (NSPS). GSK is considered an NSPS-affected facility under 40 CFR Part 60 and is subject to the requirements of the following subparts.

a. 40 CFR 60, Subpart A – General Provisions apply to all equipment or facilities subject to an NSPS Subpart as listed below:

b. 40 CFR 60, Subpart Dc – Standards of Performance for Small Industrial, Commercial, Institutional Steam Generating Units. This subpart applies to industrial, commercial, and institutional boilers with rated heat inputs between 10 and 100 MMBtu/hr that were constructed after June 9, 1989. The water heaters at the GSK facility each have heat input ratings of 2 MMBtu/hr, which is less than 10 MMBtu/hr, so they are exempt from this rule. However, the three boilers were installed in 2004 and 2006, and have rated heat inputs of 16.329 and 30.659 MMBtu/hr. Therefore, the three boilers are subject to the requirements of this standard.

c. 40 CFR 60, Subparts VV and VVa - Standards of Performance for Equipment Leaks of VOC in the Synthetic Organic Chemical Manufacturing Industry. These rules apply to listed equipment types at facilities in the synthetic organic chemical manufacturing industry. GSK is not engaged in the manufacture of synthetic organic chemicals. Therefore, these rules do not apply.

d. 40 CFR 60, Subpart III - Standards of Performance for Equipment Leaks of VOC Emissions in the Synthetic Organic Chemical Manufacturing Industry Air Oxidation Processes. This rule applies to any facility producing one or more of 36 listed chemicals as a product, co-product, by-product, or intermediate. None of the listed chemicals are produced by GSK; therefore, the rule does not apply.

e. 40 CFR 60, Subpart NNN - Standards of Performance for Equipment Leaks of VOC Emissions in the Synthetic Organic Chemical Manufacturing Industry Distillation Operations. This rule applies to any facility producing one or more listed chemicals as a product, co-product, by-product, or intermediate. The chemical list includes chloroform and methanol, which are used (but not produced) by GSK as a product, co-product, by-product, or intermediate. Therefore, the rule does not apply.

f. 40 CFR 60, Subpart RRR - Standards of Performance for Equipment Leaks of VOC Emissions in the Synthetic Organic Chemical Manufacturing Industry Air Oxidation Processes. This rule applies to any facility producing one or more listed chemicals as a product, co-product, by-product, or intermediate. The chemical list includes chloroform and methanol, which are used (but not produced) by GSK as a product, co-product, by-product, or intermediate. In addition, batch reactors are exempt. GSK does not operate any continuous reactor processes. Therefore, this rule does not apply.

g. 40 CFR 60, Subpart IIII – Standards of Performance for Stationary Compression Ignition Internal Combustion Engines. This standard applies to internal combustion engines with displacement less than 30 liters per cylinder, that are constructed (ordered) after July 11, 2005, and manufactured after April 1, 2006 (except fire pump engines, for which the key date is July 1, 2006). The 2012-hp engine that drives the 1500-kW generator (G1) at the Hamilton facility was installed in 2001, so it is not subject to this rule. However, the 2682-hp and the 671-hp engines that drive the 2,000-kW and 500-kW generators (G2 and G3, respectively) were installed in 2007 and are therefore subject to this rule. The Fire Pump was manufactured in 2007, and is likewise subject to this rule.

8. ARM 17.8.342 National Emission Standards for Hazardous Air Pollutants (NESHAPs) for Source Categories. The source, as defined and applied in 40 CFR Part 63, shall comply with the requirements of 40 CFR Part 63, as listed below:

   a. 40 CFR 63, Subpart A – General Provisions apply to all equipment or facilities subject to an NESHAP Subpart as listed below:

   b. 40 CFR 63, Subpart F – NESHAP for Synthetic Organic Chemical Manufacturing Industry. This rule applies to facilities that are major sources of HAPs that manufacture one or more listed chemicals. The chemical list includes chloroform and methanol, both of which are used (but not manufactured) by GSK. In addition, GSK is not a major source of HAPs; therefore, this rule does not apply to GSK.

   c. 40 CFR 63, Subpart G – NESHAP for Synthetic Organic Chemical Manufacturing Industry for Process Vents, Storage Vessels, Transfer Operations, and Wastewater. In accordance with 40 CFR 63.100(b), the applicability provisions of Subpart F also apply to Subparts G and H. Since Subpart F does not apply to GSK, as shown above, Subpart G also does not apply to GSK.

   d. 40 CFR 63, Subpart H – NESHAP for Synthetic Organic Chemical Manufacturing Industry for Equipment Leaks. In accordance with 40 CFR 63.100(b), the applicability provisions of Subpart F also apply to Subparts G and H. Since Subpart F does not apply to GSK, as shown above, Subpart H also does not apply to GSK.

   e. 40 CFR 63, Subpart ZZZZ – NESHAPs for Stationary Reciprocating Internal Combustion Engines (RICE). As an area source, the diesel RICE will be subject to this rule. However, although diesel RICE engines are an affected source, per 40 CFR 63.6590(b)(3) they do not have any requirements unless they are new or reconstructed after June 12, 2006. Therefore, all of the emergency engines operated by GSK would be affected sources under this rule; however, only EGEN G2 and EGEN G3 would be subject to substantive requirements under this Subpart.

D. ARM 17.8, Subchapter 5 – Air Quality Permit Application, Operation, and Open Burning Fees, including, but not limited to:

1. ARM 17.8.504 Air Quality Permit Application Fees. This rule requires that an applicant submit an air quality permit application fee concurrent with the submittal of an air quality permit application. A permit application is incomplete until the proper application fee is paid to the Department. GSK submitted the appropriate permit application fee for the current permit action.

2. ARM 17.8.505 Air Quality Operation Fees. An annual air quality operation fee must, as a condition of continued operation, be submitted to the Department by each source of air contaminants holding an air quality permit (excluding an open burning permit) issued by the Department. The air quality operation fee is based on the actual or estimated actual amount of air pollutants emitted during the previous calendar year.

   An air quality operation fee is separate and distinct from an air quality permit application fee. The annual assessment and collection of the air quality operation fee, described above, shall take place on a calendar-year basis. The Department may insert into any final permit issued after the effective date of these rules, such conditions as may be necessary to require the payment of an air quality operation fee on a calendar-year basis, including provisions that prorate the required fee amount.

E. ARM 17.8, Subchapter 7 – Permit, Construction, and Operation of Air Contaminant Sources, including, but not limited to:

1. ARM 17.8.740 Definitions. This rule is a list of applicable definitions used in this chapter, unless indicated otherwise in a specific subchapter.

2. ARM 17.8.743 Montana Air Quality Permits--When Required. This rule requires a person to obtain an air quality permit or permit modification to construct, modify, or use any air contaminant sources that have the potential to emit (PTE) greater than 25 tons per year of any pollutant. GSK has a PTE greater than 25 tons per year of NO_x; therefore, an air quality permit is required.

3. ARM 17.8.744 Montana Air Quality Permits--General Exclusions. This rule identifies the activities that are not subject to the Montana Air Quality Permit program.

4. ARM 17.8.745 Montana Air Quality Permits--Exclusion for De Minimis Changes. This rule identifies the de minimis changes at permitted facilities that do not require a permit under the Montana Air Quality Permit Program.

5. ARM 17.8.748 New or Modified Emitting Units--Permit Application Requirements. (1) This rule requires that a permit application be submitted prior to installation, modification, or use of a source. GSK submitted the required permit application for the current permit action. (7) This rule requires that the applicant notify the public by means of legal publication in a newspaper of general circulation in the area affected by the application for a permit. GSK submitted an affidavit of publication of public notice for the October 12, 2010, issue of the *Ravalli Republic*, a newspaper of general circulation in the Town of Hamilton in Ravalli County, as proof of compliance with the public notice requirements.

6. ARM 17.8.749 Conditions for Issuance or Denial of Permit. This rule requires that the permits issued by the Department must authorize the construction and operation of the facility or emitting unit subject to the conditions in the permit and the requirements of this subchapter. This rule also requires that the permit must contain any conditions necessary to assure compliance with the Federal Clean Air Act (FCAA), the Clean Air Act of Montana, and rules adopted under those acts.

7. ARM 17.8.752 Emission Control Requirements. This rule requires a source to install the maximum air pollution control capability that is technically practicable and economically feasible, except that BACT shall be utilized. The required BACT analysis is included in Section III of this permit analysis.

8. ARM 17.8.755 Inspection of Permit. This rule requires that air quality permits shall be made available for inspection by the Department at the location of the source.

9. ARM 17.8.756 Compliance with Other Requirements. This rule states that nothing in the permit shall be construed as relieving GSK of the responsibility for complying with any applicable federal or Montana statute, rule, or standard, except as specifically provided in ARM 17.8.740, *et seq*.

10. ARM 17.8.759 Review of Permit Applications. This rule describes the Department's responsibilities for processing permit applications and making permit decisions on those permit applications that do not require the preparation of an environmental impact statement.

11. ARM 17.8.760 Additional Review of Permit Applications. This rule describes the Department's responsibilities for processing permit applications and making permit decisions on those applications that require an environmental impact statement.

12. ARM 17.8.762 Duration of Permit. An air quality permit shall be valid until revoked or modified, as provided in this subchapter, except that a permit issued prior to construction of a new or modified source may contain a condition providing that the permit will expire unless construction is commenced within the time specified in the permit, which in no event may be less than 1 year after the permit is issued.

13. ARM 17.8.763 Revocation of Permit. An air quality permit may be revoked upon written request of the permittee, or for violations of any requirement of the Clean Air Act of Montana, rules adopted under the Clean Air Act of Montana, the FCAA, rules adopted under the FCAA, or any applicable requirement contained in the Montana State Implementation Plan (SIP).

14. ARM 17.8.764 Administrative Amendment to Permit. An air quality permit may be amended for changes in any applicable rules and standards adopted by the Board of Environmental Review (Board) or changed conditions of operation at a source or stack that do not result in an increase of emissions as a result of those changed conditions. The owner or operator of a facility may not increase the facility's emissions beyond permit limits unless the increase meets the criteria in ARM 17.8.745 for a de minimis change not requiring a permit, or unless the owner or operator applies for and receives another permit in accordance with ARM 17.8.748, ARM 17.8.749, ARM 17.8.752, ARM 17.8.755, and ARM 17.8.756, and with all applicable requirements in ARM Title 17, Chapter 8, Subchapters 8, 9, and 10.

15. ARM 17.8.765 Transfer of Permit. This rule states that an air quality permit may be transferred from one person to another if written notice of intent to transfer, including the names of the transferor and the transferee, is sent to the Department.

F. ARM 17.8, Subchapter 8 – Prevention of Significant Deterioration of Air Quality, including, but not limited to:

1. ARM 17.8.801 Definitions. This rule is a list of applicable definitions used in this subchapter.

2. ARM 17.8.818 Review of Major Stationary Sources and Major Modifications--Source Applicability and Exemptions. The requirements contained in ARM 17.8.819 through ARM 17.8.827 shall apply to any major stationary source and any major modification, with respect to each pollutant subject to regulation under the FCAA that it would emit, except as this subchapter would otherwise allow.

This facility is a listed source under the chemical process plant category; however, the GSK facility's PTE is below 100 tons per year of any pollutant (excluding fugitive emissions). Therefore, the GSK facility is not a major stationary source, and is not currently subject to Prevention of Significant Deterioration (PSD) permitting pursuant to this Subchapter.

G. ARM 17.8, Subchapter 12 – Operating Permit Program Applicability, including, but not limited to:

1. ARM 17.8.1201 Definitions. (23) Major Source under Section 7412 of the FCAA is defined as any source having:

a. PTE > 100 tons/year of any pollutant;

b. PTE > 10 tons/year of any one hazardous air pollutant (HAP), PTE > 25 tons/year of a combination of all HAPs, or lesser quantity as the Department may establish by rule; or

c. PTE > 70 tons/year of particulate matter with an aerodynamic diameter of 10 microns or less (PM_{10}) in a serious PM_{10} nonattainment area.

2. ARM 17.8.1204 Air Quality Operating Permit Program. (1) Title V of the FCAA amendments of 1990 requires that all sources, as defined in ARM 17.8.1204(1), obtain a Title V Operating Permit. In reviewing and issuing MAQP #4460-01 for GSK, the following conclusions were made:

a. The facility's PTE is less than 100 tons/year for any pollutant.

b. The facility's PTE is less than 10 tons/year for any one HAP and less than 25 tons/year for all HAPs.

c. This source is not located in a serious PM_{10} nonattainment area.

d. This facility is subject to current NSPS standards (40 CFR 60, Subpart Dc and Subpart IIII).

e. This facility is subject to area source provisions of a current NESHAP standard (40 CFR 63, Subpart ZZZZ).

f. This source is not a Title IV affected source, or a solid waste combustion unit.

g. This source is not an EPA designated Title V source.

Based on these facts, the Department determined that GSK will be a minor source of emissions as defined under Title V. However, if minor sources subject to NSPS are required to obtain a Title V Operating Permit, GSK will be required to obtain a Title V Operating Permit.

III. BACT Determination

A BACT determination is required for each new or modified source. GSK shall install on the new or modified source the maximum air pollution control capability which is technically practicable and economically feasible, except that BACT shall be utilized.

A BACT analysis was submitted by GSK in Permit Application #4460-01, and in the letter dated December 17, 2010, addressing available methods of controlling emissions from the manufacturing operations in Buildings 5 and 12. The Department reviewed these methods, as well as previous BACT determinations for similar sources. The following control options have been reviewed by the Department in order to make the following BACT determination.

Manufacturing Operations in Buildings 5 and 12

Manufacturing operations in Buildings 5 and 12 emit VOCs and HAPs. The following technologies were considered to control these emissions from the manufacturing operations: condensation, thermal oxidation, catalytic oxidation, activated carbon absorption, and wet scrubbing.

Condensation

Condensation is a technique that separates VOCs and organic HAPs from the exhaust gas stream by saturating the exhaust stream. Saturation is achieved in one of two ways: (1) by increasing the system pressure at a constant temperature, or (2) by reducing the system temperature at a constant pressure. Generally, condensation is performed using the latter method.

Operation of a condensation emission control system is dependent on the composition and amount of condensable and non-condensable compounds present in the exhaust gas stream. Condensation of the condensable compounds (solvents) will occur at their dew point where their partial pressure is equal to their vapor pressure. For more volatile compounds (i.e., a lower normal boiling point), additional cooling of the gas steam is required to condense the desired compounds.

GSK currently uses condensers on its process equipment. There are several advantages in using surface condensers for the control of VOCs from the reactors. They are:

(1) There is no combustion involved; therefore, there are less safety concerns.

(2) At the manufacturing operations, VOC emissions occur intermittently and when they do occur, the concentrations can vary very rapidly. For VOC reactions, the type of pollution control device can be of great concern. Surface condensers are very safe for these operations.

(3) The use of condensers to control these air contaminants from the manufacturing operations is a common practice in the industry.

The Department determined that the use of condensers for controlling VOC and HAP emissions from the manufacturing operations is technically feasible.

Thermal oxidation

Thermal oxidation converts organic vapors in the air stream to carbon dioxide and water and is a very effective COS and organic HAP control technique. A thermal oxidizer's efficiency is dependent on residence time, combustion temperature, and turbulence. Operating temperatures typically range from 1,400 °F to 1,800 °F, with a retention time between 0.5 and 2.0 seconds. Because of the high fuel requirements for thermal oxidation, heat recovery equipment is generally employed to lower the cost of operation.

The disadvantages of a thermal oxidizer system for GSK's manufacturing operations are:

(1) For such small-scale operations, where VOC emissions occur intermittently, a thermal oxidizer must be heated and cooled several times. Such frequent heating and cooling causes expansion and contraction of the system, stressing the system, and reducing its life.

(2) For operations in Buildings 5 and 12, the concentration of the VOCs in the exhaust gases varies over a wide range. Such variations raise safety concerns because it becomes difficult to maintain the concentration of the process gases in a safe range, i.e., less than the lower explosive limit (LEL) or greater than the upper explosive limit (UEL).

(3) When the concentration of the VOCs in the exhaust stream is very high, large amounts of dilution air have to be introduced to keep the concentration of the gases in the safer range to avoid the possibility of overheating or explosion. Such additions increase the volume of the gas that needs to be handled by the thermal oxidizer, thereby increasing the size of the system significantly.

(4) There is a high probability of flame "flash back" with thermal oxidizer systems that control emission from these types of operations. The possibility of flame "flash back" is a significant safety concern unless properly addressed.

(5) Thermal oxidizers generate NOx emissions.

(6) A thermal oxidizer has high capital cost and operating cost compared to condensation.

(7) A separate wet scrubbing system must be purchased to control acid gas emissions generated due to the combustion of chlorinated solvents.

Therefore, the Department determined that a thermal oxidizer is not technically feasible for controlling VOC and HAP emissions from the manufacturing operations, and therefore, does not constitute BACT.

Catalytic Oxidation

Catalytic oxidation uses a catalyst to accelerate the combustion reaction. Catalytic systems operate at lower temperatures (500 °F to 1,000 °F) and require a considerably shorter residence time than thermal oxidation systems. Solvents and oxygen absorb on the surfaces of the catalyst where they are covered to carbon dioxide and water. Typically, the process gas stream must be preheated to a temperature suitable for the activation for the combustion reaction over the catalyst.

The VOC destruction efficiency of a catalytic oxidizer system depends upon the operating temperature and the gas residence time in the catalyst bed.

The disadvantages of catalytic oxidation for GSK's manufacturing operations are:

(1) The presence of chlorinated compounds may poison the catalyst, making it ineffective.

(2) The presence of acid gases will reduce system life.

(3) The wide variation of VOC concentrations in the process gas stream can cause heat release in the catalyst bed, raising the temperature beyond the catalyst's safe range, which may damage the catalyst.

Because of these disadvantages, the Department determined that a catalytic oxidation system is not a technically feasible as an add-on control device for controlling VOCs and organic HAP emissions from the manufacturing operations.

Activated Carbon Adsorption System

Adsorption is a separation process based on the ability of certain solids to remove gaseous compounds preferentially from a waste stream. Activated carbon has a great affinity for hydrocarbon molecules and a low affinity for the nitrogen and oxygen molecules in air. The degree of adsorption is dependent on the gas temperature, adsorbent surface area, hydrocarbon concentration in the gas stream, hydrocarbon molecular weight, and relative humidity. The capacity of activated carbon is greater at high vapor concentration, higher molecular weight, high adsorbent surface area, and low relative humidity. As adsorption proceeds, a saturation state is reached. The saturated carbon is temporarily removed from service. The hydrocarbons are stripped from the carbon using steam regeneration.

The disadvantages of an activated carbon adsorption system for GSK's manufacturing operations are:

(1) The system's high capital cost.

(2) The presence of particulate or liquid droplets in the exhaust stream reduces the effectiveness of the carbon system.

(3) Costs for wastewater disposal add to the operating costs of the system.

(4) The VOC removal efficiency is limited to 90 percent.

Based on this information, the Department determined that an activated carbon adsorption system may be technically feasible, but may be a less effective option as an add-on control device for controlling VOCs and organic HAP emissions from the manufacturing operations.

Wet Scrubbing System

Wet scrubbers are effective in removing air contaminants that are very soluble in water. Since the manufacturing operations utilize chloroform, which is practically insoluble in water, the use of a wet scrubbing system would not be effective for controlling VOC and HAP emissions. In addition, a wet scrubber would generate wastewater that would need to be treated before it could be discharged into the sewer system.

BACT Determination – Buildings 5 and 12 Manufacturing Operations

Based on the above analysis and information, the Department concurs with GSK that condensation emission control systems constitute BACT for the Building 5 and Building12 manufacturing operations. The condensation emission control systems in Building 5 are designed to operate with a maximum cooling water inlet temperature of 17 degrees Celsius (°C), and the condensation emission control systems in Building 12 are designed to operate with a maximum chilled water inlet temperature of 7°C.

IV. Emission Inventory

Emitting Unit	PM	PM10	PM2.5	NOX	CO	SO2	VOC	HAP
	Tons/Year							
Boiler #1 (16.329 MMBtu/hr)	0.715	0.715	0.715	5.006	2.575	0.122	0.286	0.132
Boiler #2 (16.329 MMBtu/hr)	0.715	0.715	0.715	5.006	2.575	0.122	0.286	0.132
Boiler #3 (32.659 MMBtu/hr)	1.430	1.430	1.430	10.013	5.150	0.243	0.572	0.265
Water Heater a (2 MMBtu/hr)	0.065	0.065	0.065	0.859	0.721	0.005	0.047	0.016
Water Heater b (2 MMBtu/hr)	0.065	0.065	0.065	0.859	0.721	0.005	0.047	0.016
Water Heater c (2 MMBtu/hr)	0.065	0.065	0.065	0.859	0.721	0.005	0.047	0.016
Water Heater d (2 MMBtu/hr)	0.065	0.065	0.065	0.859	0.721	0.005	0.047	0.016
EGEN 1 (1500kW, ~2169bhp)	0.2025	0.2025	0.203	8.15	1.80	0.1875	0.485	0.014
EGEN 2 (2000kW, 2937bhp)	0.0425	0.0425	0.043	8.73	0.475	0.2475	0.1725	0.018
EGEN 3 (500 kW, 757bhp)	0.42	0.42	0.42	5.87	1.26	0.39	0.48	0.005
Firepump (110 bhp)	0.061	0.061	0.061	0.85	0.18	0.056	0.069	0.0007
2,000 gal Diesel Tank							0.00048	0.0005
6,000 gal Diesel Tank							0.00099	0.001
10,030 gal Waste Solvent Tank							0.13	0.121
40 R&D/QC Fume Hoods[1]							0.30	0.30
Manufacturing Process Bldg 5[2]							2.13	2.11
Manufacturing Process Bldg 12[2]							2.75	2.70
Total	***3.847***	***3.847***	***3.847***	***47.061***	***16.899***	***1.388***	***7.45***	***5.86***

1. Emission factor = 15 lb/yr/hood in accordance with the Research & Development Council of New Jersey guidelines, as submitted by the applicant. (modified 12/2010). Applicant states there are a total of 70 fume hoods at the plant. Emissions from 30 manufacturing operations fume hoods are accounted for in the Manufacturing Process Buildings emissions. Emissios from the remaining 40 fume hoods are accounted for here.
2. Emissions provided by applicant, calculated with Emission Master software (modified 12/2010). Note that the emissions inventory table in MAQP#4460-00 did not include itemized VOC and HAP emissions from Bldgs 5 and 12. Based on the information available at the time, these emissions were combined with estimates of emissions from other sources at the site. MAQP#4460-01 includes the emissions from both manufacturing buildings (Bldg. 5 and 12) and has been updated, to represent the current information submitted by the applicant.

The complete emission inventory is on file with the Department.

V. Existing Air Quality

The GSK facility located in Ravalli County near Hamilton, Montana, is classified as attainment/not classified for all pollutants.

VI. Ambient Air Impact Analysis

The Department determined that the impacts from this permitting action will be minor. The Department believes it will not cause or contribute to a violation of any ambient air quality standard.

VII. Taking or Damaging Implication Analysis

As required by 2-10-105, MCA, the Department conducted the following private property taking and damaging assessment.

YES	NO	
X		1. Does the action pertain to land or water management or environmental regulation affecting private real property or water rights?
	X	2. Does the action result in either a permanent or indefinite physical occupation of private property?
	X	3. Does the action deny a fundamental attribute of ownership? (ex.: right to exclude others, disposal of property)
	X	4. Does the action deprive the owner of all economically viable uses of the property?
	X	5. Does the action require a property owner to dedicate a portion of property or to grant an easement? [If no, go to (6)].
		5a. Is there a reasonable, specific connection between the government requirement and legitimate state interests?
		5b. Is the government requirement roughly proportional to the impact of the proposed use of the property?
	X	6. Does the action have a severe impact on the value of the property? (consider economic impact, investment-backed expectations, character of government action)
	X	7. Does the action damage the property by causing some physical disturbance with respect to the property in excess of that sustained by the public generally?
	X	7a. Is the impact of government action direct, peculiar, and significant?
	X	7b. Has government action resulted in the property becoming practically inaccessible, waterlogged or flooded?
	X	7c. Has government action lowered property values by more than 30% and necessitated the physical taking of adjacent property or property across a public way from the property in question?
	X	Takings or damaging implications? (Taking or damaging implications exist if YES is checked in response to question 1 and also to any one or more of the following questions: 2, 3, 4, 6, 7a, 7b, 7c; or if NO is checked in response to questions 5a or 5b; the shaded areas)

Based on this analysis, the Department determined there are no taking or damaging implications associated with this permit action.

VIII. Environmental Assessment

An environmental assessment, required by the Montana Environmental Policy Act, was completed for this project. A copy is attached.

DEPARTMENT OF ENVIRONMENTAL QUALITY
Permitting and Compliance Division
Air Resources Management Bureau
P.O. Box 200901, Helena, Montana 59620
(406) 444-3490

FINAL ENVIRONMENTAL ASSESSMENT (EA)

Issued To: Corixa Corporation d/b/a GlaxoSmithKline Biologicals, NA

Montana Air Quality Permit Number #: 4460-01

Preliminary Determination Issued: 01/26/2011
Department Decision Issued: 02/15/2011
Permit Final: 03/03/2011

1. *Legal Description of Site*: S ½ of Section 7, Township 6 North Range 20 West, Ravalli County, Montana

2. *Description of Project*: On October 19, 2010, the Department received a complete application for a modification to MAQP #4460-00 to include the following changes:

   - GSK would change the process for producing product in Building 12 from the High Density process to the Low Density process.

   - GSK determined that the cooling water temperature supplied to the condensation emission control systems in Building 5 is slightly higher than presented in the original permit application. Also the chilled water temperature supplied to the condensation emission control systems in Building 12 is higher than presented in the original permit application. These changes in water temperature increase the volatile organic compounds (VOC) and hazardous air pollutants (HAP) emissions from both buildings slightly, and should be noted in the permit.

   - GSK proposed to change the method of monitoring the operation of the condensation emission control systems in both Building 5 and Building 12. Instead of measuring the exhaust gas temperature from each condenser, as outlined in Section II.A. of the permit, the inlet cooling water and inlet chilled water temperatures would be measured.

   - Lastly, GSK noted that the there was a misrepresentation of the number of laboratory hoods included as point sources in the emissions inventory in the previous permit. This modification would correct the emissions inventory calculations.

3. *Objectives of Project*: The objective of this permitting action is to identify the change in the type of manufacturing process in Building 12 (from High Density to Low Density), modify the inlet water temperature and means of monitoring the cooling temperature at the condensers in Buildings 5 and 12, and to correct the number of vent hoods included in the emissions inventory.

4. *Alternatives Considered*: In addition to the proposed action, the Department also considered the "no-action" alternative. The "no-action" alternative would deny issuance of the air quality preconstruction permit to the proposed facility. However, the Department does not consider the "no-action" alternative to be appropriate because GSK demonstrated compliance with all applicable rules and regulations as required for permit issuance. Therefore, the "no-action" alternative was eliminated from further consideration.

5. *A Listing of Mitigation, Stipulations, and Other Controls*: A list of enforceable conditions, including a BACT analysis, would be included in MAQP #4460-01.

6. *Regulatory Effects on Private Property*: The Department considered alternatives to the conditions imposed in this permit as part of the permit development. The Department determined that the permit conditions are reasonably necessary to ensure compliance with applicable requirements and demonstrate compliance with those requirements and do not unduly restrict private property rights.

7. The following table summarizes the potential physical and biological effects of the proposed project on the human environment. The "no-action" alternative was discussed previously.

		Major	Moderate	Minor	None	Unknown	Comments Included
A	Terrestrial and Aquatic Life and Habitats			X			Yes
B	Water Quality, Quantity, and Distribution			X			Yes
C	Geology and Soil Quality, Stability and Moisture			X			Yes
D	Vegetation Cover, Quantity, and Quality			X			Yes
E	Aesthetics				X		Yes
F	Air Quality			X			Yes
G	Unique Endangered, Fragile, or Limited Environmental Resources			X			Yes
H	Demands on Environmental Resource of Water, Air and Energy			X			Yes
I	Historical and Archaeological Sites			X			Yes
J	Cumulative and Secondary Impacts			X			Yes

SUMMARY OF COMMENTS ON POTENTIAL PHYSICAL AND BIOLOGICAL EFFECTS: The following comments have been prepared by the Department.

A. Terrestrial and Aquatic Life and Habitats

B. Water Quality, Quantity and Distribution

C. Geology and Soil Quality, Stability and Moisture

D. Vegetation Cover, Quantity, and Quality

Previous MEPA analysis for the permitted pharmaceutical preparations facility determined that GSK is an existing site with existing emitting units and would be considered a minor source of emissions. No additional land disturbance is included in this proposed action and only minor increases in pollutant emissions are expected. Therefore, only minor impacts, if any, would be expected to vegetation cover, quantity, and quality as a result of this permitting action.

E. Aesthetics

As this facility has existed in some form for more than a decade, this permitting action (permitting units that have already been installed) would have no effect on aesthetics.

F. Air Quality

The air quality impacts from this permitting action would be minor because MAQP #4460-01 would include conditions limiting emissions of regulated pollutants. The permitting action would require specific operation of the installed emitting units for the protection of air quality. In addition, the facility would be considered a minor source of air pollution by industrial standards and would be located in an area where good air dispersion would occur. Therefore, air quality impacts would be minor.

G. Unique Endangered, Fragile, or Limited Environmental Resources

The Department, in an effort to assess any potential impacts to any unique endangered, fragile, or limited environmental resources in the area of operation, contacted the Montana Natural Heritage Program (MNHP). Search results of databases indicated 6 species occurrence reports for 6 species of concern: the gray wolf, fisher, Canada lynx, marten, wolverine, and grizzly bear.

The GSK pharmaceutical preparations facility is an existing site with existing emitting units. The 35-acre industrial site has existed in some form for more than a decade. As these species of concern generally avoid areas of human activity, this permitting action would have a minor impact on their habitats and life.

H. Demands on Environmental Resource of Water, Air and Energy

The GSK pharmaceutical preparations facility is an existing site with existing emitting units. As previously mentioned, it is the intent of this action to appropriately permit the facility. GSK would be considered a minor source of air emissions. No additional water or energy resources would be expended as a result of this permitting action, therefore overall impact on the environmental resources of water, air, and energy would be minor.

I. Historical and Archaeological Sites

The Department contacted the Montana Historical Society for a cultural resource file search for the area of the proposed project location. According to their records there are no previously recorded sites in the area of the GSK facility. The location is a currently active manufacturing site and no new historical or archaeological sites are expected to be found within the GSK facility area.

J. Cumulative and Secondary Impacts

Potential physical and biological effects of any individual considerations above would be expected to be minor. Collectively, the potential cumulative and secondary impacts would be expected to be minor because the facility is an existing facility and the current permit action will result in relatively small increases in pollutant emissions.

8. The following table summarizes the potential economic and social effects of the proposed project on the human environment. The "no-action" alternative was discussed previously.

		Major	Moderate	Minor	None	Unknown	Comments Included
A	Social Structures and Mores			X			Yes
B	Cultural Uniqueness and Diversity			X			Yes
C	Local and State Tax Base and Tax Revenue			X			Yes
D	Agricultural or Industrial Production			X			Yes
E	Human Health			X			Yes
F	Access to and Quality of Recreational and Wilderness Activities			X			Yes
G	Quantity and Distribution of Employment				X		Yes
H	Distribution of Population				X		Yes
I	Demands for Government Services			X			Yes
J	Industrial and Commercial Activity			X			Yes
K	Locally Adopted Environmental Plans and Goals			X			Yes
L	Cumulative and Secondary Impacts			X			Yes

SUMMARY OF COMMENTS ON POTENTIAL ECONOMIC AND SOCIAL EFFECTS: The following comments have been prepared by the Department.

A. Social Structures and Mores

B. Cultural Uniqueness and Diversity

C. Local and State Tax Base and Tax Revenue

D. Agricultural or Industrial Production

The GSK pharmaceutical preparations facility is an existing site with existing emitting units. As previously mentioned, it is the intent of this action to appropriately permit the facility. GSK would be considered a minor source of emissions. The 35-acre industrial site has existed in some form for more than a decade; emitting units added in the last several years pushed the facility potential emissions over the permitting threshold. The facility would be small by industrial standards and would have a relatively small amount of pollutants emitted as a result of the operations. The proposed modifications include changes to existing equipment, and minor increases in pollutant emissions. Therefore, the facility would have minor impacts on social structures and mores, cultural uniqueness and diversity, local and state tax base and tax revenue, and agricultural or industrial production.

E. Human Health

The proposed project would result in minor impacts to human health because of the air emissions discharged from the facility. The project, permitted by MAQP #4460-01, would comply with all applicable air quality rules, regulations, and standards. These rules, regulations, and standards are designed to be protective of human health.

F. Access to and Quality of Recreational and Wilderness Activities

The Department is not aware of any direct access to recreational or wilderness activities which this project would affect. The facility currently exists, the permitting action addresses changes to the manufacturing operations within existing buildings, minor emissions increases, and brings the facility into compliance with air quality regulations. Any impacts to the access and quality of recreational and wilderness activities would be expected to be minor.

G. Quantity and Distribution of Employment

No new employees would be added as a result of this permitting action, therefore, the quantity and distribution of employment would remain unchanged.

H. Distribution of Population

The distribution of population around the GSK Hamilton facility is expected to remain unchanged. No new employees would be added as a result of this permitting action, therefore no workers would be moving into the area on the basis of this project.

I. Demands for Government Services

It would be expected that there would be demand for government services associated with compliance activities and acquiring the proper permits related to this project. However, overall demands for government services would be minor due to the size/classification of this facility.

J. Industrial and Commercial Activity

The current level of industrial and commercial activity would be maintained with the appropriate permitting of the GSK Hamilton facility. Therefore, there would be no impact on industrial and commercial activity for this action.

K. Locally Adopted Environmental Plans and Goals

The Department is not aware of any locally adopted environmental plans and goals affected by issuing MAQP #4460-01. The MAQP would contain limits for protecting air quality and keeping facility emissions in compliance with any applicable air quality standards.

L. Cumulative and Secondary Impacts

Potential economic and social effects of any individual considerations above would be expected to be minor. The Department has determined that collectively, the potential cumulative and secondary impacts would be expected to be minor because the facility is an existing facility and the current permit action will result in relatively small increases in pollutant emissions.

Recommendation: No Environmental Impact Statement (EIS) is required.

The current permitting action is for identifying the change in the type of manufacturing process in Building 12 (from High Density to Low Density), modifying the inlet water temperature and means of monitoring the cooling temperature at the condensers in Buildings 5 and 12, and correcting the number of vent hoods included as point sources in the emissions inventory. MAQP #4460-01 includes conditions and limitations to ensure the facility will operate in compliance with all applicable rules and regulations. In addition, there are no significant impacts associated with this proposal.

Other groups or agencies contacted or which may have overlapping jurisdiction: Montana Historical Society – State Historic Preservation Office, Natural Resource Information System – Montana Natural Heritage Program

Individuals or groups contributing to this EA: Department of Environmental Quality – Air Resources Management Bureau, Montana Historical Society – State Historic Preservation Office, Natural Resource Information System – Montana Natural Heritage Program

EA prepared by: Deanne Fischer
Date: December 29, 2010