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

PRELIMINARY DETERMINATION
ON PERMIT APPLICATION

Date of Mailing: December 23, 2009

Name of Applicant: Corixa Corporation d/b/a GlaxoSmithKline Biologicals, NA

Source: Pharmaceutical Preparations Manufacturing Facility

Proposed Action: The Department of Environmental Quality (Department) proposes to issue a permit, with conditions, to the above-named applicant. The application was assigned Permit Application Number 4460-00.

Proposed Conditions: See attached.

Public Comment: Any member of the public desiring to comment must submit such comments in writing to the Air Resources Management Bureau (Bureau) of the Department at the above address. Comments may address the Department's analysis and determination, or the information submitted in the application. In order to be considered, comments on this Preliminary Determination are due by January 7, 2009. Copies of the application and the Department's analysis may be inspected at the Bureau's office in Helena. For more information, you may contact the Department.

Departmental Action: The Department intends to make a decision on the application after expiration of the Public Comment period described above. A copy of the decision may be obtained at the above address. The permit shall become final on the date stated in the Department's Decision on this permit, unless an appeal is filed with the Board of Environmental Review (Board).

Procedures for Appeal: Any person jointly or severally adversely affected by the final action may request a hearing before the Board. Any appeal must be filed by the date stated in the Department's Decision on this permit. The request for a hearing shall contain an affidavit setting forth the grounds for the request. Any hearing will be held under the provisions of the Montana Administrative Procedures Act. Submit requests for a hearing in triplicate to: Chairman, Board of Environmental Review, P.O. Box 200901, Helena, MT 59620.

For the Department,

Vickie Walsh
Air Permitting Program Supervisor
Air Resources Management Bureau
(406) 444-3490

Debbie Skibicki
Lead Environmental Engineer
Air Resources Management Bureau
(406) 444-1472

VW:PS
Enclosures

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

DRAFT ENVIRONMENTAL ASSESSMENT (EA)

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

Montana Air Quality Permit Number: 4460-00

Preliminary Determination Issued: December 23, 2009
Department Decision Issued:
Permit Final:

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

2. *Description of Project*: GSK operates a stationary pharmaceutical preparations facility. 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.

3. *Objectives of Project*: This project objective is to assign an MAQP to GSK for the pharmaceutical preparations facility which would bring the facility into compliance with the state of Montana's permitting requirements. Further, continued operation of the facility would result in business and revenue for GSK.

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 #4460-00.

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

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. Therefore, only minor effects on terrestrial and aquatic life and habitats, water quality, quantity and distribution, geology and soil quality, stability, and moisture, and vegetation cover, quantity, and quality would be expected as a result of this 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 the facility would be minor because MAQP #4460-00 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.

As 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.

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. 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 #4460-00, 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 getting 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. As already mentioned, this permitting action would permit an existing facility that should have previously obtained an air quality permit. 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 #4460-00. 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.

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

If an EIS is not required, explain why the EA is an appropriate level of analysis: The current permitting action is for the construction and operation of a pharmaceutical preparations facility. MAQP #4460-00 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: Debbie Skibicki
Date: December 18, 2009