NOTICE OF PROPOSED GENERAL PLAN APPROVAL FOR PHARMACEUTICAL AND SPECIALTY CHEMICAL PRODUCTION (BAQ-GPA-24)

The Department of Environmental Protection (Department) proposes to issue the following General Plan Approval for Pharmaceutical and Specialty Chemical production (Pharm/Chem General Plan Approval) which contains pre-determined Best Available Technology (BAT) and other regulatory requirements: BAQ-GPA-24 (Pharmaceutical and Specialty Chemical Production)

This Pharm/Chem General Plan Approval is designed to be used as a plan approval for regulated facilities that construct sources or modify sources to produce and/or handle pharmaceutical and/or specialty chemical products that result in an increase in emissions of Volatile Organic Compounds (VOCs) and/or Hazardous Air Pollutants (HAPs), the emission of a HAP not previously emitted or a change in HAP emission release characteristics. This Pharm/Chem General Plan Approval does not allow the installation of new air pollution control devices, except for vent condensers. Use of this Pharm/Chem General Plan Approval is limited to Title V permitted facilities that produce or handle pharmaceutical or specialty chemical products and which have a previously established Plantwide Applicability Limit (PAL) for VOC emissions.

Pharmaceutical and Specialty Chemical Processes, for the purpose of this Pharm/Chem General Plan Approval, are limited to those processes classified under SIC codes 2833 through 2844 and 2879.

The proposed Pharm/Chem General Plan Approval contains conditions that prescribe applicability, emissions, compliance, notification, monitoring, record keeping and reporting, and administrative requirements.

Prior to initiating construction or modification using this Pharm/Chem General Plan Approval, the owner or operator of a pharmaceutical and/or specialty chemical production facility must submit an application form provided by the Department.

Title V facilities may use this Pharm/Chem General Plan Approval as a plan approval only when new source review (25 *Pa. Code* Chapter 127, Subchapter E) and prevention of significant deterioration review requirements (25 *Pa. Code* Chapter 127, Subchapter D) are not applicable. This Pharm/Chem General Plan Approval cannot be used for a plan approval that will cause a Title V facility to exceed its established VOC PAL under the Title V permit.

The proposed Pharm/Chem General Plan Approval establishes the following restrictions for pharmaceutical and/or specialty chemical production facilities:

The Best Available Technology (BAT) requirement under primary operating scenarios would be the use of an existing appropriately designed combustion control device such as a Thermal Oxidizing Unit (TOU) for control of combustible VOCs and HAPS that would be followed by an existing appropriately designed scrubber for control of acid gases. The combustion control device must achieve 99.9% destruction and removal efficiency (DRE) for VOCs and HAPs and 99.99% for methylene chloride. Scrubbers associated with a combustion control device must meet an overall halogen and hydrogen halide removal efficiency of at least 99%.

Under secondary operating scenarios like during unplanned combustion control device outages and/or scrubber malfunctions, an alternative operating scenario using a vent condenser meeting 25 *Pa. Code* §129.68 may be employed to complete the processing of batches or material currently in process to the next stable process hold point. However, no new batches may be charged, or processing initiated without using a properly operating combustion control device and scrubber.

In addition to meeting the standards for national emission standards for hazardous air pollutants (NESHAP), namely, 40 CFR Part 63, Subpart GGG, MMM, PPP and FFFF, we are proposing special risk assessment requirements in this Pharm/Chem General Plan Approval that would require the permittee to assess and limit risk and hazards associated with HAP emissions towards human health each time a process change is initiated.

Under special risk assessment requirements the permittee shall submit a list of hazardous air pollutants (HAPs) to be permitted under this Pharm/Chem General Plan Approval detailing the maximum annual mass quantity of each new HAP and/or increase in existing HAPs to be used along with a human health risk assessment. The risk assessment must include an air impact modeling analysis of each HAP. The air impact modeling analysis provides estimates of maximum short-term and long-term ambient air concentrations used to determine the potential for adverse human health effects from inhalation. An air dispersion modeling protocol that describes the selection of the air dispersion model, the actual site conditions and source parameters, and the proposed methods for modeling must be submitted for review and approval by the Department prior to use of this General Plan Approval for the permitting of a new or increased HAP. The approval will remain in effect as long as the parameters of the protocol remain unchanged. The risk assessment for approval of new HAP compounds will make use of the acute and chronic endpoint criterion described in the GP. The results of the approved risk assessment shall be submitted to the Department with the General Plan Approval application.

Each time new construction or a process change is made such that the quantity of existing HAPs released increases above the previously submitted maximum annual mass quantity or a new HAP is emitted, a new ambient air impact analysis must be performed on each HAP, and submitted to the Department along with the General Plan Approval application and fee to demonstrate that the ambient air concentrations do not exceed the appropriate endpoint criterion.

Within 180 days of receiving Department approval to use this Pharm/Chem General Plan Approval, performance testing of the combustion control device and associated scrubber shall be performed when a process change causes an increase in emission loading to the existing air pollution control device(s). Stack testing shall be performed to verify that the new or increased VOC and/or HAP loading to the existing control system will result in the destruction or removal efficiency required. Also, parameters such as oxidizer temperature, scrubber flow rate and pH shall be verified to be adequate at the new or increased VOC and/or HAP loading.

The authorization to use the Pharm/Chem General Plan Approval will be valid for a period of 18 months after the issue date. If the construction, modification or installation is not commenced within 18 months of the issuance of authorization, or if there is more than an 18-month lapse in construction, modification or installation, a new Pharm/Chem General Plan Approval Application and fee shall be submitted.

This Pharm/Chem General Plan Approval establishes the following fees:

a. Plan approval application fee:

One Thousand Dollars ($1,000)

A new authorization and permit fee as indicated above is required each time the permittee makes a process change that requires construction or modification of sources or use of new HAPs or a change in HAP emissions release characteristics that would affect the ambient air impact analysis required in condition 13.

b. Plan approval extension fee:

Three Hundred Dollars ($300)

Interested parties are encouraged to obtain and review a complete copy of this proposed Pharm/Chem General Plan Approval by contacting Jeanette Van Skike, Division of Permits, Bureau of Air Quality, 12th Floor Rachel Carson State Office Building, P.O. Box 8468, Harrisburg, PA 17105-8468, telephone (717) 787-4325. TDD users may telephone the Department through the AT&T Relay Service, 1-800-654-5984. Internet users can access a copy of the Pharm/Chem General Plan Approval at http://www.depweb.state.pa.us (DEP Keyword: "Air Quality Home").

The Department invites written comments on the proposed Pharm/Chem General Plan Approval. Notice and opportunity for comment will also be provided to the U.S. Environmental Protection Agency and the States of Delaware, Maryland, New Jersey, New York, Ohio, Virginia and West Virginia. Interested persons may submit written comments, suggestions, or objections to Virendra Trivedi, Environmental Engineer Manager, New Source Review Section, Division of Permits, Bureau of Air Quality, 12th Floor Rachel Carson State Office Building, P.O. Box 8468, Harrisburg, PA 17105-8468. The Department will also consider written requests that a public hearing be held concerning this proposed Pharm/Chem General Plan Approval. Written public comments must be submitted to the Department by December 26, 2007. Comments received by facsimile will not be accepted.

KATHLEEN A. MCGINTY
Secretary