STATE DISPOSAL SYSTEM (SDS) PERMIT MNP069337

Public Comment Period Begins: January 13, 2014
Public Comment Period Ends: February 12, 2014
Current Permit Issued: March 18, 2009
Current Permit Expiration Date: February 28, 2014

Name and Address of Permittee:
ANI Pharmaceuticals Inc.
1302 Concourse Drive, Suite 101
Linthicum, Maryland 21090

Facility Name and Location:
ANI Pharmaceuticals - Baudette
County Road 1 S
T160N, R31W, Section 10,
Baudette, Lake of the Woods County,
Minnesota

Description of Permitted Facility
The ANI Pharmaceuticals - Baudette facility (Facility) is located at NE 1/4 of NE 1/4 of Section 10, Township 160 North, Range 31 West, Baudette, Lake of the Woods County, Minnesota.

ANI Pharmaceuticals, Inc., Hormone Manufacturing Facility, manufactures and packages pharmaceutical solid dose products. The pharmaceutical processes are batch operations that flow from blending to tableting, then coating, imprinting and packaging. Operations differ weekly according to production schedules. There are multiple sources of wastewater on site. Process wastewater is generated from the cleaning and rinsing of equipment and rooms used during manufacturing. Reverse osmosis (RO) wastewater is a continuous operation, which increases with water use in production. Caustic wastewaters are generated from cleaning coating operations and from carbon bed sanitation in the RO Mechanical Room. This wastewater is treated by a neutralization tank that monitors pH prior to discharge.

All waste streams are combined prior to the discharge to the Baudette publicly owned treatment works. Wastewater is discharged at average and maximum rates of 0.012 million gallons per day (mgd) and 0.020 mgd, respectively.
The discharge from this facility is subject to the categorical pretreatment standards for existing pharmaceutical manufacturers, as specified in 40 CFR pt. 439, subp. D (Mixing/Compounding and Formulation).

Sugar waste produced at the facility is hauled to Western Lakes Sanitary Sewer District.

The location of the Facility is shown on the attached map.

**Preliminary Determination on the Draft Permit**
The Minnesota Pollution Control Agency (MPCA) Commissioner has made a preliminary determination to reissue this SDS permit for a term of approximately five years.

A draft permit is available for review at the MPCA office at the St. Paul address listed below, at the Detroit Lakes regional office and on-line at http://www.pca.state.mn.us/news/data/index.cfm?PN=1.

A copy of the draft permit will be mailed to you if the MPCA receives your written or oral request at this office. If you have questions about this draft permit or the Commissioner’s preliminary determination, please contact Emily Schnick at 651-757-2699.

**Written Comments**
You may submit written comments on the conditions of the draft permit or on the Commissioner’s preliminary determination.

Written comments must include the following:

1. A statement of your interest in the permit application or the draft permit.
2. A statement of the action you wish the MPCA to take, including specific references to sections of the draft permit that you believe should be changed.
3. The reasons supporting your position, stated with sufficient specificity as to allow the Commissioner to investigate the merits of your position.

**Petition for Public Informational Meeting**
You also may request that the MPCA Commissioner hold a public informational meeting. A public informational meeting is an informal meeting that the MPCA may hold to solicit public comment and statements on matters before the MPCA, and to help clarify and resolve issues.

A petition requesting a public informational meeting must include the following information:

1. A statement identifying the matter of concern.
2. The information required under items 1 through 3 of “Written Comments,” identified above.
3. A statement of the reasons the MPCA should hold a public informational meeting.
4. The issues that you would like the MPCA to address at the public informational meeting.

**Petition for Contested Case Hearing**
You also may submit a petition for a contested case hearing. A contested case hearing is a formal evidentiary hearing before an administrative law judge. In accordance with Minn. R. 7000.1900, the MPCA will grant a petition to hold a contested case hearing if it finds that: (1) there is a material issue of fact in dispute concerning the application or draft permit; (2) the MPCA has the jurisdiction to make a determination on the disputed material issue of fact; and (3) there is a reasonable basis underlying the disputed material issue of fact or facts such that the
holding of the contested case hearing would allow the introduction of information that would aid the MPCA in resolving the disputed facts in making a final decision on the draft permit. A material issue of fact means a fact question, as distinguished from a policy question, whose resolution could have a direct bearing on a final MPCA decision.

A petition for a contested case hearing must include the following information:

1. A statement of reasons or proposed findings supporting the MPCA decision to hold a contested case hearing according to the criteria in Minn. R. 7000.1900, as discussed above.
2. A statement of the issues proposed to be addressed by a contested case hearing and the specific relief requested or resolution of the matter.

In addition and to the extent known, a petition for a contested case hearing should also include the following information:

1. A proposed list of prospective witnesses to be called, including experts, with a brief description of proposed testimony or summary of evidence to be presented at a contested case hearing.
2. A proposed list of publications, references, or studies to be introduced and relied upon at a contested case hearing.
3. An estimate of time required for you to present the matter at a contested case hearing.

**MPCA Decision**

You may submit a petition to the Commissioner requesting that the MPCA Citizens’ Board (Board) consider the permit issuance. To be considered timely, the petition must be received by the MPCA by 4:30 p.m. on the date the public comment period ends, identified on page 1 of this notice. Under the provisions of Minn. Stat. § 116.02, subd. 6(4), the decision whether to issue the permit and, if so, under what terms will be presented to the Board for decision if: (1) the Commissioner grants the petition requesting the matter be presented to the Board; (2) one or more Board members request to hear the matter before the time the Commissioner makes a final decision on the permit; or (3) a timely request for a contested case hearing is pending. You may participate in the activities of the Board as provided in Minn. R. 7000.0650.

The written comments, requests, and petitions submitted on or before the last day of the public comment period will be considered in the final decision on this permit. If the MPCA does not receive written comments, requests, or petitions during the public comment period, MPCA staff as authorized by the Board, will make the final decision on the draft permit.

Comments, petitions, and/or requests must be submitted in writing on or before the end date of the public comment period identified on page 1 of this notice to:

Emily Schnick 5th Floor  
Minnesota Pollution Control Agency  
520 Lafayette Road North  
St. Paul, MN 55155-4194
Topographic Map of Permitted Facility

MNP069337, ANI Pharmaceuticals, Inc.
T160N, R31W, Section 10
Baudette, Lake of the Woods County, Minnesota

Map produced by: MPCA Staff, 1/22/2009
Source: USGS Quad
Scale: 1:20,000

WS 001: Total discharge to Baudette POTW