

Enclosure 1

Notification of Discharge Requirements

Pharmaceutical Manufacturing Point Source Category and the General Pretreatment Regulations

MT-PF00103

Industrial User:	Corixa Corporation dba GlaxoSmithKline Vaccines GSK-Hamilton 553 Old Corvallis Road Hamilton, MT 59840
Publicly Owned Treatment Works (POTW):	City of Hamilton Publicly Owned Treatment Works, NPDES #MT-0020028
Regulated Process Wastewater:	Wastewaters generated from the MPL and QS-21 adjuvant manufacturing processes. These process wastestreams are regulated by the Pharmaceutical Manufacturing Point Source Category (40 CFR Part 439).
Applicable Pretreatment Standards:	40 CFR § 439.27, Pretreatment Standards for New Sources (PSNS) 40 CFR § 403, General Pretreatment Regulations

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PART I – Facility Information

A General Facility Information

The GSK-Hamilton facility (facility) is a campus with buildings that support pharmaceutical manufacturing of MPL and QS-21 adjuvants. These adjuvants are shipped offsite to other GSK locations for vaccine formulation. The GSK-Hamilton facility is owned by Corixa Corporation dba GlaxoSmithKline Vaccines and is located at 553 Old Corvallis Road, Hamilton MT 59840.

B Outfalls

No regulated process wastewater shall be discharged to the City of Hamilton POTW except at Outfalls 001 and 002, designated below. The outfalls designated below shall not be changed without notification to the EPA.

Table 1 - Outfall Descriptions

Outfall Number	Description of Discharge Point
001	Discharge of the treated MPL process wastewater from the pH neutralization skid in Building 11 to a 6-inch sewer line.
002	Discharge of the treated QS-21 process wastewater from the pH neutralization skid in Building 16 to an 8-inch sewer line.

PART II – Effluent Limitations and Monitoring Requirements

A Dilution Prohibition (40 CFR § 403.6(d))

Dilution is prohibited as a substitute for treatment. The facility shall not increase the use of process water, or in any other way attempt to dilute the discharge as a partial or complete substitute for adequate treatment to achieve compliance.

B Specific Effluent Limitations, Monitoring Requirements (40 CFR § 403.12(g)(1-6); 40 CFR § 403.6(e); 40 CFR § 439.27)

1 Specific Effluent Limitations and Monitoring Requirements

All regulated process wastewater discharged through Outfalls 001 and 002 shall meet the limits identified in the Table 1. The limits in Table 1 are based on the Pharmaceutical Manufacturing, Subpart B Pretreatment Standards for New Sources (PSNS) at 40 CFR §439.27.

Compliance with these limits shall be demonstrated by collecting samples or measurements at the minimum frequency and using the sample types listed in Table 1. The monitoring results shall be submitted to the EPA in accordance with the Periodic Compliance Report required by Part III.B of this

Notification of Discharge Requirements. Samples and measurements taken at Outfalls 001 and 002 shall be representative of the volume and nature of the discharge of the production day. Monitoring shall be conducted by sampling after treatment processes and prior to the introduction of sanitary flows.

Table 2 – Pharmaceutical Manufacturing Point Source Category PSNS, 40 CFR §439.27 - Discharges to Outfalls 001 and 002

ICIS Code	Parameter	Units	Daily Maximum	Monthly Average	Instantaneous	Sample Type ⁽¹⁾	Frequency of Analysis ⁽²⁾
50050	Flow	gpd	Report	Report	---	Continuous	Continuous
00400	pH	S.U.	---	---	≥5.0	Continuous	Continuous
81552	Acetone	mg/L	20.7	8.2	---	(3)(4)	Quarterly
51002	n-Amyl acetate	mg/L	20.7	8.2	---	(3)(4)	Quarterly
81585	Ethyl acetate	mg/L	20.7	8.2	---	(3)(4)	Quarterly
45013	Isopropyl acetate	mg/L	20.7	8.2	---	(3)(4)	Quarterly
34423	Methylene Chloride	mg/L	3.0	0.7	---	(3)(4)	Quarterly

- ¹ See the definitions of composite and grab samples in Parts IV.H.2 and IV.H.4 of this Notification of Discharge Requirements.
- ² The quarterly monitoring frequencies are based on calendar quarters.
- ³ Grab samples taken at 4-hour or equally timed intervals to generate four grab samples for the discharge throughout the production day.
- ⁴ The grab samples taken throughout the daily discharge may be combined into a single sample for analysis using lab-compositing techniques. Otherwise, the separate results from all grab samples taken throughout the day may be averaged into a single daily average.

The facility may submit a request to the EPA to forego sampling of a regulated pollutant listed above if it has demonstrated through sampling and other technical factors that the pollutant is neither present nor expected to be present in the discharge or is present only at background levels from intake water and without any increase in the pollutant due to activities of the facility. The approval by the EPA of such a request is subject to the conditions listed in 40 CFR § 403.12(e)(2).

C Sampling and Analysis Methods (40 CFR § 403.12(g)(3) and (5))

All sampling and analytical data must be representative of conditions occurring during the reporting period. All sampling and analyses shall be performed in accordance with procedures contained in 40 CFR Part 136 and amendments thereto or with any other test procedures approved by the EPA (*see* 40

CFR §§136.4 and 136.5). Where 40 CFR Part 136 does not include sampling or analytical techniques for the pollutants in question, or where the EPA determines that Part 136 sampling and analytical techniques are inappropriate for the pollutant in question, sampling and analyses shall be performed using validated analytical methods or any other sampling and analytical procedures, including procedures suggested by EPA.

D Record-Keeping Requirements (40 CFR § 403.12(o))

The facility shall maintain records of all information resulting from any monitoring activities required by the Pretreatment Regulations, including documentation associated with Best Management Practices (BMPs) (e.g., inspections of spill control BMPs) for a minimum of three years. Refer to Part IV.B of this enclosure for additional information about Retention of Records. Such records shall include for all samples:

1. The date, exact place, method, and time of sampling and the names of the person or persons taking the samples;
2. The dates analyses were performed;
3. Who performed the analyses;
4. The analytical techniques/methods used; and
5. The results of such analyses.

E Slug Discharge (40 CFR § 403.8(f)(2)(vi))

A slug discharge is any discharge of a non-routine, episodic nature, including but not limited to an accidental spill or a non-customary batch discharge, which has a reasonable potential to cause Interference or Pass Through (see Part IV.G for definitions) or in any other way violate the POTW's regulations or local limits. The facility shall take steps to prevent slug discharges and ensure it maintains and implements a current slug discharge control plan that adequately addresses current conditions. Reporting requirements for any slug discharges are found in Part III.C of this Notification of Discharge Requirements.

The slug discharge control plan shall contain, at a minimum, the following elements:

1. Description of discharge practices, including non-routine batch discharges;
2. Description of stored chemicals;
3. Procedures for immediately notifying the POTW of Slug Discharges, including any discharge that would violate a general or specific prohibition listed in Part II.F, with procedures for follow-up written notification within five days;
4. If necessary, procedures to prevent adverse impact from accidental spills, including inspection and maintenance of storage areas, handling and transfer of materials, loading and unloading operations, control of plant site run-off, worker training, building of containment structures or equipment, measures for containing toxic organic pollutants (including solvents), and/or measures and equipment for emergency response.

F General and Specific Discharge Prohibitions

The following pollutants shall not be introduced into a POTW:

1 General Prohibitions (40 CFR § 403.5(a))

The facility may not introduce into the POTW any pollutant(s) which cause Pass Through or Interference.

2 Specific Prohibitions (40 CFR § 403.5(b))

- a) Pollutants which create a fire or explosion hazard in the POTW, including, but not limited to, wastestreams with a closed cup flashpoint of less than 140 degrees Fahrenheit or 60 degrees Centigrade using the test methods specified in 40 CFR § 261.21;
- b) Pollutants which will cause corrosive structural damage to the POTW, but in no case discharges with pH lower than 5.0, unless the works is specifically designed to accommodate such discharges;
- c) Solid or viscous pollutants in amounts which will cause obstruction to the flow in the POTW resulting in Interference;
- d) Any pollutant, including oxygen demanding pollutants (biochemical oxygen demand, etc.) released in a discharge at a flow rate and/or pollutant concentration which will cause Interference with the POTW;
- e) Heat in amounts that will inhibit biological activity in the POTW resulting in Interference, but in no case heat in such quantities that the temperature at the POTW Treatment Plant exceeds 40 °C (104 °F) unless the EPA, upon request of the POTW, approves alternate temperature limits;
- f) Petroleum oil, nonbiodegradable cutting oil, or products of mineral oil origin in amounts that will cause interference or pass through;
- g) Pollutants that result in the presence of toxic gases, vapors, or fumes within the POTW in a quantity that may cause acute worker health and safety problems; or
- h) Any trucked or hauled pollutants, except at discharge points designated by the POTW.

PART III – Reporting and Notification Requirements

A Baseline Report and 90-day Compliance Report (40 CFR § 403.12(b) and (d))

The facility has fulfilled the Baseline Monitoring and 90-day Compliance reporting requirements for the QS-21 manufacturing scheduled to begin in Building 16 in 2021. The 90-day compliance report for the QS-21 manufacturing will be due 90 days after the commencement of this manufacturing process.

B Periodic Compliance Reports (40 CFR § 403.12(e); 40 CFR § 403.12(g)(6); 40 CFR § 403.12(l))

The facility shall submit Periodic Compliance Reports to the EPA and the POTW (see Part III.I for address) as follows:

1 Due Dates

Periodic Compliance Reports are due by the dates listed below and shall not be submitted until the compliance monitoring period is complete. The report shall contain information from the associated compliance monitoring period.

Table 3 - Periodic Compliance Reporting Frequency

Compliance Monitoring Period	Due Date
January through June	July 31
July through December	January 31

2 Discharge Monitoring Report

Periodic Compliance Reports shall include discharge monitoring reports (DMR) containing the results from sampling from outfalls 001 and 002 conducted in accordance with the effluent limitations and monitoring requirements in Part II.B of this Notification of Discharge Requirements.

The DMR shall be fully completed using all applicable information during the compliance monitoring period. In the event no discharge occurs during the compliance monitoring period, this may be indicated with the No Data Indicator (NODI) Code of C - “NO DISCHARGE” on the DMR.

3 Monitoring Activity/Sampling Records (40 CFR § 403.12)

A copy of the laboratory analysis report and other supporting information shall be included for any reportable data submitted in the compliance report as an attachment either in the hard copy report or submitted to NetDMR. The laboratory analysis report and other supporting information shall include the information listed in Part II.D.

4 Flow Data

Submit a record on the DMR of the measured average and maximum daily flows from Outfalls 001 and 002 for each month in the reporting period.

5 pH Data

Submit a record on the DMR of the measured minimum and maximum pH from Outfalls 001 and 002 for each month in the reporting period.

6 Additional Monitoring (40 CFR § 403.12(g)(6))

If the facility monitors any regulated pollutant listed in Part II.B.1 of this Notification of Discharge Requirements at Outfalls 001 and 002 more frequently than required using the procedures required by Part II.C of this Notification of Discharge Requirements, the results of this monitoring shall be included in the Periodic Compliance Report.

7 Certification Statement

Include the certification statement required by 40 CFR § 403.12(l) and referenced in Part III.J of this Notification of Discharge Requirements. The certification statement shall be signed by the appropriate signatory official as stated in Part III.J of this Notification of Discharge Requirements.

C Potential Problem and Slug Reporting (40 CFR § 403.12(f))

The facility shall notify the EPA and the POTW immediately of all discharges that could cause problems to the POTW, including any slug loadings. A slug discharge is any discharge of a non-routine, episodic nature, including but not limited to an accidental spill or a non-customary batch discharge, which has a reasonable potential to cause Interference or Pass Through, or in any other way violate the effluent limits outlined in this Notification of Discharge Requirements or the POTW's regulations.

D Effluent Violation Reporting (40 CFR § 403.12(g)(2))

If sampling indicates a violation, the facility shall notify the EPA and the POTW within 24 hours of becoming aware of the violation. The facility shall also repeat the sampling and analysis and submit the results of the repeat analysis to the EPA within thirty (30) days after becoming aware of the violation. Resampling is not required if:

1. The EPA performs sampling of the facility's discharge at a frequency of at least once per month; or
2. The EPA performs sampling of the facility's discharge between the time when the initial sampling was conducted and the time when the facility receives the results of this sampling.

E Notification of Changed Discharge (40 CFR § 403.12(j))

The facility shall promptly notify the EPA and the POTW in advance of any substantial change in the volume or character of pollutants in its discharge, including any of the listed or characteristic hazardous wastes referenced in Part III.F of this Notification of Discharge Requirements.

F Hazardous Waste Discharge Notification (40 CFR § 403.12(p))

1. The facility shall notify the POTW, the EPA Regional Waste Management Division Director, and State Hazardous Waste Authorities in writing of any discharge into the POTW of a substance, which, if otherwise disposed of, would be a hazardous waste under 40 CFR Part 261. Notifications to the EPA Regional Waste Management Division Director may be mailed to the same address listed in Part III.I for other EPA notifications. Such notification must include:
 - a) The name of the hazardous waste as set forth in 40 CFR Part 261;
 - b) The EPA hazardous waste number;
 - c) The type of discharge (continuous, batch, or other);
 - d) If the facility discharges more than 100 kilograms of such waste per calendar month to the POTW, the notification shall also contain the following information to the extent such information is known and readily available to the facility:

- i. An identification of the hazardous constituents contained in the wastes;
 - ii. An estimation of the mass and concentration of such constituents in the wastestream discharged during that calendar month; and
 - iii. An estimation of the mass of constituents in the wastestream expected to be discharged during the following twelve months.
2. The facility shall provide the notification no later than 180 days after the discharge of the listed or characteristic hazardous waste. Any notification need be submitted only once for each hazardous waste discharged. However, notifications of changed discharges must be submitted pursuant to Part III.E of this Notification of Discharge Requirements. This notification requirement does not apply to pollutants already reported in a Baseline Report, 90-day Compliance Report, or Periodic Compliance Report.
3. The facility is exempt from the notification requirement during a calendar month in which they discharge no more than fifteen kilograms of hazardous wastes, unless the wastes are acute hazardous wastes as specified in 40 CFR §§ 261.30(d) and 261.33(e). Discharge of more than fifteen kilograms of non-acute hazardous wastes in a calendar month, or of any quantity of acute hazardous wastes as specified in 40 CFR §§ 261.30(d) and 261.33(e), requires a one-time notification. Subsequent months during which the facility discharges more than these quantities of any hazardous waste do not require additional notification.
4. In the case of any new regulations under section 3001 of the Resource Conservation and Recovery Act (RCRA) identifying additional characteristics of hazardous waste or listing any additional substance as a hazardous waste, the facility must notify the POTW, the EPA Regional Waste Management Waste Division Director, and State hazardous waste authorities of the discharge of such substance within ninety (90) days of the effective date of such regulations.
5. In the case of any hazardous waste notification, the facility shall certify that it has a program in place to reduce the volume and toxicity of hazardous wastes generated to the degree it has determined to be economically practical.

G Upset Effect, Notification, and Reporting (40 CFR § 403.16)

1. Effect of an Upset. An Upset shall constitute an affirmative defense to an action brought for noncompliance with categorical Pretreatment Standards if the requirements of (2), below, are met.
2. Conditions necessary for a demonstration of upset. If the facility wishes to establish the affirmative defense of Upset shall demonstrate, through properly signed, contemporaneous operating logs, or other relevant evidence that:
 - a) An Upset occurred, and the facility can identify the cause(s) of the Upset;
 - b) The facility was at the time being operated in a prudent and workman-like manner and in compliance with applicable operation and maintenance procedures;
 - c) The facility has submitted the following information to the POTW and the EPA within 24 hours of becoming aware of the Upset. If this information is provided orally, a written submission must be provided within five days:
 - i. A description of the Indirect Discharge and cause of noncompliance;

- ii. The period of noncompliance, including exact dates and times or, if not corrected, the anticipated time the noncompliance is expected to continue;
 - iii. Steps being taken and/or planned to reduce, eliminate and prevent recurrence of the noncompliance.
- 3. Burden of proof. In any enforcement proceeding the facility seeking to establish the occurrence of an Upset shall have the burden of proof.
- 4. Reviewability of agency consideration of claims of upset. In the usual exercise of prosecutorial discretion, EPA enforcement personnel should review any claims that non-compliance was caused by an Upset. No determinations made in the course of the review constitute final EPA action subject to judicial review. Industrial Users will have the opportunity for a judicial determination on any claim of Upset only in an enforcement action brought for noncompliance with categorical Pretreatment Standards.
- 5. User responsibility in case of upset. The facility shall control production or all discharges to the extent necessary to maintain compliance with categorical Pretreatment Standards upon reduction, loss, or failure of its treatment facility until the facility is restored or an alternative method of treatment is provided. This requirement applies in the situation where, among other things, the primary source of power to the treatment facility is reduced, lost or fails.

H Bypass Requirements Notification (40 CFR § 403.17)

- 1. For purposes of this section:
 - a) Bypass means the intentional diversion of wastewater from any portion of the facility's treatment works.
 - b) Severe property damage means substantial physical damage to property, damage to the treatment facilities which causes them to become inoperable, or substantial and permanent loss of natural resources which can reasonably be expected to occur in the absence of a bypass. Severe property damage does not mean economic loss caused by delays in production.
- 2. Allowable Bypass

An allowable bypass is one not violating applicable Pretreatment Standards or Requirements. The facility may allow any bypass to occur which does not cause a violation of Pretreatment Standards or Requirements, but only if it is also for essential maintenance to assure efficient operation. These bypasses are not subject to the provisions of (3) and (4), below.

- 3. Prohibition of Bypass
 - a) Unanticipated bypass. Bypass is prohibited, and the EPA may take enforcement action against the facility for a bypass, unless:
 - i. Bypass was unavoidable to prevent loss of life, personal injury, or severe property damage;
 - ii. There were no feasible alternatives to the bypass, such as the use of auxiliary treatment facilities, retention of untreated wastes, or maintenance during normal periods of

equipment downtime. This condition is not satisfied if adequate back-up equipment should have been installed in the exercise of reasonable engineering judgment to prevent a bypass which occurred during normal periods of equipment downtime or preventative maintenance; and

- iii. The facility submitted notices as required under (4), below.
 - b) Anticipated bypass. The EPA may approve an anticipated bypass, after considering its adverse effects, if the EPA determines that it will meet the three conditions listed in (3)(a), above.
4. Notification of Bypass
- a) Anticipated bypass. If the facility knows in advance of the need for a bypass, it shall submit prior notice to the EPA, if possible at least ten days before the date of the bypass.
 - b) Unanticipated bypass. The facility shall submit oral notice of an unanticipated bypass that exceeds applicable Pretreatment Standards to the EPA within 24 hours from the time the facility becomes aware of the bypass. A written submission shall also be provided within five days of the time the facility becomes aware of the bypass and must follow the notification and signatory requirements of Parts III.I and III.J. The written submission shall contain a description of the bypass and its cause; the duration of the bypass, including exact dates and times, and, if the bypass has not been corrected, the anticipated time it is expected to continue; and steps taken or planned to reduce, eliminate, and prevent reoccurrence of the bypass. EPA may waive the written report on a case-by-case basis if the oral report has been received within 24 hours.

I Reporting and Notification Contacts

1. Submission of Reports Electronically or by Hard Copy Submission:

Until the effective date of the NPDES Electronic Reporting Rule, the facility may either submit Period Compliance Reports electronically, as described below, or submit hard copies to the address below. Other written reports and notifications required to be submitted to the EPA shall be sent to the following address:

NPDES and Wetlands Enforcement Section (8ENF-W-NW)
US EPA Region 8
1595 Wynkoop Street
Denver, CO 80202
Attention: Pretreatment

2. Establishment of NetDMR Account, if Submitting Reports Electronically:

- a) As of the date of this Notification of Discharge Requirements, the deadline for the electronic reporting of Periodic Compliance Reports is December 21, 2020 (40 CFR §127.16). On September 23, 2020, EPA signed the final "Phase 2 Extension Rule," which provides states and EPA additional time to implement electronic reporting for certain Clean Water Act discharge permitting requirements. In this final rule, EPA is extending the compliance

deadline for implementation of Phase 2 of the Electronic Reporting Rule by five years from December 21, 2020, to December 21, 2025.

- b) Upon the effective date of the NPDES Electronic Reporting Rule, the facility is required to establish a NetDMR account to electronically submit DMRs and notifications and must sign and certify all electronic submissions in accordance with the Signatory requirements of the Notification of Discharge Requirements. NetDMR is accessed from the internet at <https://netdmr.zendesk.com/home>. Additionally, the facility can contact the EPA via our R8NetDMR@epa.gov mailbox for any individual assistance or one-on-one training and support.
 - c) Effluent monitoring results shall be summarized for each month (flow and pH), quarterly for other pollutants of concern and recorded on a DMR to be submitted via NetDMR to the EPA on a **semi-annual** basis. If no discharge occurs during a month, it shall be stated as such on the DMR.
3. Written reports and notifications required to be submitted to the POTW shall be sent to the following addresses:

Donny Ramer, Public Works Director
920 New York Avenue
Hamilton, MT 59840

4. Verbal notifications required to be submitted to the EPA shall be made by calling either number below and asking to speak with NPDES Enforcement, Pretreatment Contact.

303-312-6312 or 800-227-8917

5. Verbal notifications required to be submitted to the POTW shall be made by calling the numbers below.

406-363-6716

J Report Signatory Requirements (40 CFR § 403.12(I))

The Baseline Report, 90-day Compliance Report, and Periodic Compliance Reports (Parts III.A and B) shall include the following certification statement as set forth in 40 CFR § 403.6(a)(2)(ii):

I certify under penalty of law that this document and all enclosures were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

The certification statement shall be signed as follows:

1. By a responsible corporate officer, if the facility is a corporation. For the purpose of this paragraph, a responsible corporate officer means:
 - a) A president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy- or decision-making functions for the corporation, or
 - b) The manager of one or more manufacturing, production, or operating facilities, provided, the manager is authorized to make management decisions which govern the operation of the regulated facility including having the explicit or implicit duty of making major capital investment recommendations, and initiate and direct other comprehensive measures to assure long-term environmental compliance with environmental laws and regulations; can ensure that the necessary systems are established or actions taken to gather complete and accurate information for control mechanism requirements; and where authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures.
2. By a general partner or proprietor if the facility is a partnership, or sole proprietorship respectively.
3. By a duly authorized representative of the individual designated in (1) or (2) of this section if:
 - a) The authorization is made in writing by the individual described in paragraph (1) or (2);
 - b) The authorization specifies either an individual or a position having responsibility for the overall operation of the facility from which the Industrial Discharge originates, such as the position of plant manager, operator of a well, or well field superintendent, or a position of equivalent responsibility, or having overall responsibility for environmental matters for the company; and
 - c) The written authorization is submitted to the EPA.
4. If an authorization under (3) of this section is no longer accurate because a different individual or position has responsibility for the overall operation of the facility, or overall responsibility for environmental matters for the company, a new authorization satisfying the requirements of (3) of this section must be submitted to EPA prior to or together with any reports to be signed by an authorized representative.

PART IV – General Conditions

A Compliance with Pretreatment Standards and Requirements

Compliance with the conditions of this Notification of Discharge Requirements does not relieve the facility of its obligations regarding compliance with any and all applicable Local, State, and Federal Pretreatment Standards and Requirements including any such standards or requirements that may become effective during the term of this notification.

B Retention of Records (40 CFR § 403.12(o))

The facility is required to retain for a minimum of three (3) years any records of monitoring activities and results (whether or not such monitoring activities are required). This includes but is not limited to

any calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation, copies of all reports required by the Pretreatment Regulations, records of all data and laboratory reports, and records of Best Management Practices (BMPs). The facility shall make such records available for inspection and copying by the EPA. This period of retention shall be extended during the course of any unresolved litigation regarding the facility or when requested by the EPA.

C Confidentiality (40 CFR § 403.14)

In accordance with 40 CFR Part 2, any information submitted pursuant to this Notification of Discharge Requirements may be claimed as confidential by the submitter. Any such claim must be asserted at the time of submission in the manner prescribed on the application form or instructions, or, in the case of other submissions, by stamping the words ‘confidential business information’ on each page containing such information. If no claim is made at the time of submission, the EPA may make the information available to the public without further notice. Information and data provided to the EPA which is effluent data shall be available to the public without restriction.

D Transferability (40 CFR § 403.8(f)(1)(iii)(B)(2))

This Notification of Discharge Requirements is non-transferable without, at a minimum, prior notification of the EPA and POTW, and the facility shall provide of a copy of the existing Notification of Discharge Requirements to the new owner or operator.

E Civil and Criminal Liability

Nothing in this Notification of Discharge Requirements may be construed to relieve the industrial user from civil and/or criminal penalties for noncompliance. The Clean Water Act provides for specified civil and criminal monetary penalties for violations of its provisions. However, the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, requires the EPA to adjust the civil monetary penalties for inflation on a periodic basis. The civil and criminal penalties for Pretreatment violations may be found in 40 CFR Part 19 and CWA Section 1319.

F Right of Entry

Pursuant to section 308 of the Clean Water Act, the EPA or an EPA authorized representative (including an authorized contractor acting as a representative of the EPA), upon presentation of his or her credentials, shall have a right to:

1. Enter upon the premises where a regulated facility or activity is located or conducted, or where records must be kept;
2. Have access to and copy, at reasonable times, any records that must be kept;
3. Inspect at reasonable times any facilities, equipment (including monitoring and control equipment), practices, or regulated operations;
4. Sample or monitor, for the purposes of assuring compliance, any substances or parameters at any location; and

5. Inspect any production, manufacturing, fabricating, or storage area where regulated pollutants could originate, be stored, or be discharged to the POTW.

G Cause for Reissuance or Modification

The Notice of Discharge Requirements may be modified, revoked or reissued for cause: this includes the establishment of new or revised limitations to the Pharmaceutical Manufacturing Regulations, establishment of new or revised standard or requirements in the Pretreatment Regulations or substantial changes in operation or the volume or character of pollutants in the regulated wastewater discharge. The EPA may request information periodically to ensure the Notice of Discharge Requirements is representative of current conditions.

H Definitions

1. Best Management Practices (BMPs) - Schedules of activities, prohibitions of practices, maintenance procedures, and other management practices to implement the prohibitions listed in 40 CFR § 403.5(a)(1) and (b). BMPs also include treatment requirements, operating procedures, and practices to control plant site runoff, spillage or leaks, sludge or waste disposal, or drainage from raw materials storage.
2. Composite Sample - A flow proportional composite sample representative of the discharge for the production day. Operational data should be obtained through 24-hour flow proportional composite samples. Sampling may be done manually or automatically, and discretely or continuously. If discrete sampling is employed, at least 12 aliquots should be composited. Discrete sampling may be flow proportioned either by varying the time interval between each aliquot or the volume of each aliquot. All composites should be flow proportional to either the stream flow at the time of collection of the influent aliquot or to the total influent flow since the previous influent aliquot. Volatile pollutant aliquots must be combined in the laboratory immediately before analysis. (40 CFR § 403.12(g)(3) and Appendix E)
3. Daily Maximum - Daily Maximum Limit: The highest allowable daily discharge of a pollutant measured during a calendar day or any 24-hour period that reasonably represents the calendar day for the purposes of sampling. Where daily maximum limitations are expressed in units of mass, the daily discharge is the total mass discharged over the course of the day. Where daily maximum limitations are expressed in terms of a concentration, the daily discharge is the arithmetic average measurement of the pollutant concentration derived from all representative measurements taken that day.
4. Grab Sample - An individual sample collected over a period of time not exceeding 15 minutes. (40 CFR § 403 Appendix E)
5. Industrial User - The source of the introduction of pollutants into a POTW from any non-domestic source regulated under section 307(b), (c) or (d) of the Clean Water Act.
6. Interference - A discharge which, alone or in conjunction with a discharge or discharges from other sources, both:

- a) Inhibits or disrupts the POTW, its treatment processes or operations, or its sludge processes, use or disposal; and
 - b) Therefore is a cause of a violation of any requirement of the POTW's NPDES permit (including an increase in the magnitude or duration of a violation) or of the prevention of sewage sludge use or disposal in compliance with the following statutory provisions and regulations or permits issued thereunder (or more stringent State or local regulations):
Section 405 of the Clean Water Act, the Solid Waste Disposal Act (SWDA) (including title II, more commonly referred to as RCRA, and including State regulations contained in any State sludge management plan prepared pursuant to subtitle D of the SWDA), the Clean Air Act, the Toxic Substances Control Act, and the Marine Protection, Research and Sanctuaries Act.
7. Monthly Average - The highest allowable average of *daily maximum* measurements over a calendar month, calculated as the sum of all *daily maximum values* measured during a calendar month divided by the number of *daily discharges* measured during that month.
 8. Pass Through - A discharge which exits the POTW into waters of the United States in quantities or concentrations which, alone or in conjunction with a discharge or discharges from other sources, is a cause of a violation of any requirement of the POTW's NPDES permit (including an increase in the magnitude or duration of a violation).
 9. Publicly Owned Treatment Works (POTW) - A treatment works as defined by section 212 of the CWA, which is owned by a State or municipality (as defined by section 502(4) of the CWA). This definition includes any devices and systems used in the storage, treatment, recycling and reclamation of municipal sewage or industrial wastes of a liquid nature. It also includes sewers, pipes and other conveyances only if they convey wastewater to a POTW Treatment Plant. The term also means the municipality as defined in section 502(4) of the CWA, which has jurisdiction over the Indirect Discharges to and the discharges from such a treatment works.
 10. POTW Treatment Plant - That portion of the POTW which is designed to provide treatment (including recycling and reclamation) of municipal sewage and industrial waste.
 11. Severe property damage - Substantial physical damage to property, damage to the treatment facilities which causes them to become inoperable, or substantial and permanent loss of natural resources which can reasonably be expected to occur in the absence of a bypass. Severe property damage does not mean economic loss caused by delays in production.
 12. Upset - An exceptional incident in which there is unintentional and temporary noncompliance with categorical Pretreatment Standards because of factors beyond the reasonable control of the facility. An Upset does not include noncompliance to the extent caused by operational error, improperly designed treatment facilities, inadequate treatment facilities, lack of preventive maintenance, or careless or improper operation.