

PRETREATMENT PERMIT MODIFICATION

issued to

SHEFFIELD PHARMACEUTICALS, LLC
170 Broad Street
New London, CT 06320

Location Address:

170 Broad Street
New London, CT

Permit ID: SP0002442

Permit Expires: September 12, 2015

SECTION 1: GENERAL PROVISIONS

- (A) This permit modification is issued in accordance with section 22a-430 of Chapter 446k, Connecticut General Statutes ("CGS"), and Regulations of Connecticut State Agencies ("RCSA") adopted thereunder, as amended, and a modified Memorandum of Agreement dated June 3, 1981, by the Administrator of the United States Environmental Protection Agency which authorizes the State of Connecticut to administer a Pretreatment Program pursuant to 40 CFR Part 403 (Title 40 of the Code of Federal Regulations, Part 403).
- (B) SHEFFIELD PHARMACEUTICALS, LLC, ("Permittee"), shall comply with all conditions of this permit including the following sections of the RCSA which have been adopted pursuant to section 22a-430 of the CGS and are hereby incorporated into this permit. Your attention is especially drawn to the notification requirements of subsections (i)(2), (i)(3), (j)(1), (j)(6), (j)(8), (j)(9)(C), (j)(11)(C), (D), (E), and (F), (k)(3) and (4) and (l)(2) of section 22a-430-3.

Section 22a-430-3 General Conditions

- (a) Definitions
- (b) General
- (c) Inspection and Entry
- (d) Effect of a Permit
- (e) Duty
- (f) Proper Operation and Maintenance
- (g) Sludge Disposal
- (h) Duty to Mitigate
- (i) Facility Modifications; Notification
- (j) Monitoring, Records and Reporting Requirements
- (k) Bypass
- (l) Conditions Applicable to POTWs
- (m) Effluent Limitation Violations (Upsets)
- (n) Enforcement
- (o) Resource Conservation
- (p) Spill Prevention and Control
- (q) Instrumentation, Alarms, Flow Recorders
- (r) Equalization

Section 22a-430-4 Procedures and Criteria

- (a) Duty to Apply
- (b) Duty to Reapply
- (c) Application Requirements
- (d) Preliminary Review
- (e) Tentative Determination
- (f) Draft Permits, Fact Sheets
- (g) Public Notice, Notice of Hearing
- (h) Public Comments

- (i) Final Determination
 - (j) Public Hearings
 - (k) Submission of Plans and Specifications. Approval.
 - (l) Establishing Effluent Limitations and Conditions
 - (m) Case by Case Determinations
 - (n) Permit issuance or renewal
 - (o) Permit Transfer
 - (p) Permit revocation, denial or modification
 - (q) Variances
 - (r) Secondary Treatment Requirements
 - (s) Treatment Requirements for Metals and Cyanide
 - (t) Discharges to POTWs - Prohibitions
- (C) Violations of any of the terms, conditions, or limitations contained in this permit may subject the Permittee to enforcement action, including but not limited to, penalties, injunctions and/or forfeitures pursuant to applicable sections of the CGS and RCSA. Specifically, civil penalties of up to twenty-five thousand dollars (\$25,000) may be assessed per violation per day.
- (D) Any false statement in any information submitted pursuant to this permit may be punishable as a criminal offense under section 22a-438 or 22a-131a of the CGS or in accordance with section 22a-6, under section 53a-157b of the CGS.
- (E) The authorization to discharge under this permit may not be transferred without prior written approval of the Commissioner of Energy and Environmental Protection ("the Commissioner"). To request such approval, the Permittee and proposed transferee shall register such proposed transfer with the Commissioner at least thirty (30) days prior to the transferee becoming legally responsible for creating or maintaining any discharge which is the subject of the permit transfer. Failure by the transferee to obtain the Commissioner's approval prior to commencing such discharge(s) may subject the transferee to enforcement action for discharging without a permit pursuant to applicable sections of the CGS and RCSA.
- (F) Nothing in this permit shall relieve the Permittee of other obligations under applicable federal, state and local law.
- (G) An annual fee shall be paid for each year this permit is in effect as set forth in section 22a-430-7 of the RCSA.
- (H) This permitted discharge is consistent with the applicable goals and policies of the Connecticut Coastal Management Act (section 22a-92 of the CGS).

SECTION 2: DEFINITIONS

- (A) The definitions of the terms used in this permit shall be the same as the definitions contained in section 22a-423 of the CGS and sections 22a-430-3(a) and 22a-430-6 of the RCSA.
- (B) In addition to the above, the following definitions shall apply to this permit:

"----" in the limits column on the monitoring table means a limit is not specified but a value must be reported on the discharge monitoring report ("DMR").

"Average Monthly Limit" means the maximum allowable "Average Monthly Concentration" as defined in section 22a-430-3(a) of the RCSA when expressed as a concentration (e.g. mg/l). Otherwise, it means "Average Monthly Discharge Limitation" as defined in section 22a-430-3(a) of the RCSA.

"Daily Concentration" means the concentration of a substance as measured in a daily composite sample, or the arithmetic average of all grab sample results defining a grab sample average.

"Daily Composite" means (1) a composite sample taken over a full operating day consisting of grab samples collected at equal intervals of no more than sixty (60) minutes and combined proportionally to flow, or (2) a composite sample continuously collected over a full operating day proportionally to flow. Upon submission of documentation by the applicant satisfactory to the Commissioner that a discharge is of consistent effluent quality, the Commissioner may allow equal sampling intervals of up to four (4) hours for a daily composite sample.

"Daily Quantity" means the quantity of waste generated during an operating day.

"gpd" means gallons per day.

"Grab Sample Average" (or "GSA") means the arithmetic average of all grab sample analyses. Grab samples shall be collected at least once every four (4) hours over a full operating day for as long as a discharge exists on that day (minimum of two (2) grab samples per day).

"Instantaneous Limit" means the highest allowable concentration of a substance as measured by a grab sample, or the highest allowable measurement of a parameter as obtained through instantaneous monitoring.

"Maximum Daily Limit" means the maximum allowable "Daily Concentration" (defined above) when expressed as a concentration (e.g. mg/l). Otherwise, it means the maximum allowable "Daily Quantity" as defined above unless it is expressed as a flow quantity. If expressed as a flow quantity it means "Maximum Daily Flow" as defined in section 22a-430-3(a) of the RCSA.

"mg/l" means milligrams per liter.

"NA" as a Monitoring Table abbreviation means "not applicable".

"NR" as a Monitoring Table abbreviation means "not required".

"Quarterly", in the context of a sampling frequency, means sampling is required in the months of March, June, September, and December. In the event that the discharge does not occur in any of these sampling months, the Permittee shall sample during the next discharge event.

"Range During Sampling" or "RDS", as a sample type, means the maximum and minimum of all values recorded as a result of analyzing each grab sample of; 1) a Composite Sample, or 2) a Grab Sample Average. For those permittees with continuous monitoring and recording pH meters, Range During Sampling shall mean the maximum and minimum readings recorded with the continuous monitoring device during the Composite or Grab Sample Average sample collection.

"Range During Month" or "RDM", as a sample type, means the lowest and the highest values of all of the monitoring data for the reporting month.

"Semi-Annual" in the context of a sampling frequency, means the sample must be collected in the months of June and December.

"S.U." means Standard Units.

"Twice per Month" when used as a sample frequency shall mean two samples per calendar month collected no less than twelve (12) days apart.

"ug/l" means micrograms per liter.

SECTION 3: COMMISSIONER'S FINAL DETERMINATION

- (A) The Commissioner has made a final determination and found that the continuance of the existing system to treat the discharge will protect the waters of the state from pollution. The Commissioner's final determination is based on Application No. 201406890 for permit modification received on June 3, 2014 and the administrative record established in the processing of that application.
- (B) The Commissioner hereby authorizes the Permittee to discharge in accordance with the provisions of this permit, the above referenced application, and all approvals issued by the Commissioner or the Commissioner's authorized agent for the discharges and/or activities authorized by, or associated with, this permit as follows:
- (1) From the issuance of this permit through and including [LAST DAY OF MONTH, MONTH OF PERMIT MODIFICATION], the Commissioner hereby authorizes the Permittee to discharge in accordance with the terms and conditions of Permit No. SP0002442, issued by the Commissioner to the Permittee on September 13, 2013, the previous application submitted by the Permittee on May 27, 2011, and all modifications and approvals issued by the Commissioner or the Commissioner's authorized agent for the discharge and/or activities authorized by, or associated with, Permit No. SP0002442, issued by the Commissioner to the Permittee on September 13, 2013.
 - (2) From [FIRST DAY OF MONTH, MONTH FOLLOWING PERMIT MODIFICATION] until this permit expires or is modified or revoked, the Commissioner hereby authorizes the Permittee to discharge in accordance with the terms and conditions of Permit No. SP0002442, issued by the Commissioner to the Permittee on [DATE OF PERMIT ISSUANCE], Application No. 201406890 received by the Department on June 3, 2014, and all

modifications and approvals issued by the Commissioner or the Commissioner's authorized agent for the discharge and/or activities authorized by, or associated with, Permit No. SP0002442, issued by the Commissioner to the Permittee on [DATE OF PERMIT MODIFICATION ISSUANCE].

- (C) The Commissioner reserves the right to make appropriate revisions to the permit in order to establish any appropriate effluent limitations, schedules of compliance, or other provisions that may be authorized under the Federal Clean Water Act or the CGS or regulations adopted thereunder, as amended. The permit as modified or renewed under this paragraph may also contain any other requirements of the Federal Clean Water Act or CGS or regulations adopted thereunder which are then applicable.

SECTION 4: EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS

- (A) The discharge shall not exceed and shall otherwise conform to the specific terms and conditions listed below. The discharge is restricted by, and shall be monitored in accordance with, the table below.

Table A

Discharge Serial Number: 201-1 **Monitoring Location: 1**
Wastewater Description: Treated wastewaters from cleaning operations associated with the formulation and packaging of gels, toothpastes, creams, ointments, denture adhesives, lip care, nasal care and iodine ointments, vacuum pump condensate, air compressor condensate, mop water from the cleaning of warehouse floors, production floor scrubber wastewater and mop water and wastewater from the cleaning of laboratory glassware and equipment.
Monitoring Location Description: At the sample valve after the final centrifugal pump (C1)
Discharge is to: The City of New London Publicly Owned Treatment Works

PARAMETER	UNITS	FLOW/TIME BASED MONITORING				INSTANTANEOUS MONITORING		
		Average Monthly Limit	Maximum Daily Limit	Sample/Reporting Frequency ²	Sample Type or Measurement to be reported	Instantaneous limit or required range	Sample/ Reporting Frequency ²	Sample Type or measurement to be reported
Acetone	mg/l	1.0	2.0	Quarterly	GSA	3.0	NR	Grab
Copper, Total	mg/l	---	---	Twice Per Month	Daily Composite	NA	NR	Grab
Ethyl acetate	mg/l	0.25	0.5	Semi-Annual	GSA	0.5	NR	Grab
Flow (Day of Sampling)	gpd	NA	16,000	Twice Per Month	Total Flow	NA	NR	NA
Flow, Maximum During 24 hr Period ¹	gpd	NA	16,000	Daily	Total Flow	NA	NR	NA
Fluoride, Total	mg/l	20.0	30.0	Monthly	Daily Composite	30.0	NR	Grab
Isopropyl acetate	mg/l	0.25	0.5	Semi-Annual	GSA	0.5	NR	Grab
Methylene chloride	mg/l	0.25	0.5	Semi-Annual	GSA	0.5	NR	Grab
n-Amyl acetate	mg/l	0.25	0.5	Semi-Annual	GSA	0.5	NR	Grab
Oil Petroleum, Total Recoverable	mg/l	100.0	150.0	Monthly	GSA	150.0	NR	Grab
pH (Day of Sample)	S.U.	NA	NA	Twice Per Month	NA	6.0-10.0	NR	RDS
pH, Maximum	S.U.	NA	NA	NR	NA	10.0	Continuous	Continuous
pH, Minimum	S.U.	NA	NA	NR	NA	6.0	Continuous	Continuous
Phenol	mg/l	----	10.0	Monthly	Grab	10.0	NR	Grab
Phosphorus, Total As P	mg/l	NA	---	Monthly	Daily Composite	NA	NR	Grab
Surfactants (MBAS)	mg/l	NA	---	Quarterly	Daily Composite	NA	NR	Grab
Titanium, Total	mg/l	NA	---	Quarterly	Daily Composite	NA	NR	Grab
Total Suspended Solids	mg/l	NA	---	Monthly	Daily Composite	NA	NR	Grab
Zinc, Total	mg/l	---	---	Twice Per Month	Daily Composite	NA	NR	Grab

Table A Footnotes:

¹ For this parameter, the Permittee shall maintain at the facility a record of the Total Daily Flow for each day of discharge and shall report the Maximum Daily Flow for each month.

² The first entry in this column is the 'Sample Frequency'. If this entry is not followed by a 'Reporting Frequency' and the 'Sample Frequency' is more frequent than monthly, then the 'Reporting Frequency' is monthly. If the 'Sample Frequency' is specified as monthly, or less frequently, then the 'Reporting Frequency' is the same as the 'Sample Frequency'.

- (B) All samples shall be comprised of only those wastewaters described in this schedule. Therefore, samples shall be taken prior to combination with wastewaters of any other type and after all approved treatment units, if applicable. All samples taken shall be representative of the discharge during standard operating conditions.
- (C) In cases where limits and sample type are specified but sampling is not required, the limits specified shall apply to all samples which may be collected and analyzed by the Department of Energy and Environmental Protection personnel, the Permittee, or other parties.
- (D) Although n-amyl acetate, ethyl acetate, isopropyl acetate, and methylene chloride are chemicals regulated under the Federal categorical pretreatment standard applicable to this facility (40 CFR 439, Subpart D), the Permittee is authorized to forego sampling for these parameters in accordance with section 40 CFR 403.12(e)(2) of the federal regulations. Consistent with this section of the regulations, the Permittee shall include a statement on each Discharge Monitoring Report (“DMR”), on a form provided (Attachment A of this permit), certifying there has been no increase in the levels of n-amyl acetate, ethyl acetate, isopropyl acetate, and methylene chloride due to the activities at the facility since filing of the last DMR. Additionally, in the event that any of these chemical parameters are found to be present or are expected to be present based on changes that occur in the Permittee’s operations, the Permittee shall notify the Department and must immediately comply with the monitoring requirements provided in the table above.
- (E) The Permittee shall collect all wastewater generated from the cleaning of tanks used in the manufacturing of formulations containing zinc oxide and non-conforming materials as described in Appendix I of the Operation and Maintenance Plan and dispose of these materials through a licensed hauler in a manner acceptable to the Commissioner.

SECTION 5: SAMPLE COLLECTION, HANDLING AND ANALYTICAL TECHNIQUES AND REPORTING REQUIREMENTS

- (A) Chemical analyses to determine compliance with effluent limits and conditions established in this permit shall be performed using the methods approved by the Environmental Protection Agency pursuant to 40 CFR 136 unless an alternative method has been approved in writing in accordance with 40 CFR 136.4 or as provided in section 22a-430-3(j)(7) of the RCSA. Chemicals which do not have methods of analysis defined in 40 CFR 136 shall be analyzed in accordance with methods specified in this permit.
- (B) All metals analyses identified in this permit shall refer to analyses for total recoverable metal as defined in 40 CFR 136 unless otherwise specified.
- (C) The results of chemical analysis required above shall be entered on the DMR, provided by this office, and reported to the Water Permitting and Enforcement Division at the address below. Except for continuous monitoring, any monitoring required more frequently than monthly shall be reported on an attachment to the DMR, and any additional monitoring conducted in accordance with 40 CFR 136 or other methods approved by the Commissioner shall also be included on the DMR, or as an attachment, if necessary. The report shall also include a detailed explanation of any violations of the limitations specified. The DMR shall be received at this address by the last day of the month following the month in which samples are taken.

Water Permitting and Enforcement Division (Attn: DMR Processing)
Bureau of Materials Management and Compliance Assurance
Connecticut Department of Energy and Environmental Protection
79 Elm Street
Hartford, CT 06106-5127

- (D) If this permit requires monitoring of a discharge on a calendar basis (e.g. monthly, quarterly) but a discharge has not occurred within the frequency of sampling specified in the permit, the Permittee must submit the DMR as scheduled, indicating "NO DISCHARGE". For those permittees whose required monitoring is discharge dependent (e.g. per batch), the minimum reporting frequency is monthly. Therefore, if there is no discharge during a calendar month for a batch discharge, a DMR must be submitted indicating such by the end of the following month.
- (E) NetDMR Reporting Requirements
 1. Prior to one-hundred and eighty (180) days after the issuance of this permit, the Permittee may either submit monitoring data and other reports to the Department in hard copy form or electronically using NetDMR, a web-based tool that allows Permittees to electronically submit discharge monitoring reports (DMRs) and other required

reports through a secure internet connection. Unless otherwise approved in writing by the Commissioner, no later than one-hundred and eighty (180) days after the issuance of this permit the Permittee shall begin reporting electronically using NetDMR. Specific requirements regarding subscription to NetDMR and submittal of data and reports in hard copy form and for submittal using NetDMR are described below:

a. *Submittal of NetDMR Subscriber Agreement*

On or before fifteen (15) days after the issuance of this permit, the Permittee and/or the person authorized to sign the Permittee's DMRs ("Signatory Authority") as described in section 22a-430-3(b)(2) of the RCSA shall contact the Department at deep.netdmr@ct.gov and initiate the NetDMR subscription process for electronic submission of DMR information. Information on NetDMR is available on the Department's website at www.ct.gov/deep/netdmr. On or before ninety (90) days after issuance of this permit the Permittee shall submit a signed and notarized copy of the *Connecticut DEEP NetDMR Subscriber Agreement* to the Department.

b. *Submittal of Reports Using NetDMR*

Unless otherwise approved by the Commissioner, on or before one-hundred and eighty (180) days after issuance of this permit, the Permittee and/or the Signatory Authority shall electronically submit DMRs and reports required under this permit to the Department using NetDMR in satisfaction of the DMR submission requirement of Section 5(C) of this permit.

DMRs shall be submitted electronically to the Department no later than the thirtieth (30th) day of the month following the completed reporting period. All reports required under the permit, including any monitoring conducted more frequently than monthly or any additional monitoring conducted in accordance with 40 CFR 136, shall be submitted to the Department as an electronic attachment to the DMR in NetDMR. Once a Permittee begins submitting reports using NetDMR, it will no longer be required to submit hard copies of DMRs or other reports to the Department. The Permittee shall also electronically file any written report of non-compliance described in Section 6 of this permit as an attachment in NetDMR. NetDMR is accessed from: <http://www.epa.gov/netdmr>.

c. *Submittal of NetDMR Opt-Out Requests*

If the Permittee is able to demonstrate a reasonable basis, such as technical or administrative infeasibility, that precludes the use of NetDMR for electronically submitting DMRs and reports, the Commissioner may approve the submission of DMRs and other required reports in hard copy form ("opt-out request"). Opt-out requests must be submitted in writing to the Department for written approval on or before fifteen (15) days prior to the date the Permittee would be required under this permit to begin filing DMRs and other reports using NetDMR. This demonstration shall be valid for twelve (12) months from the date of the Department's approval and shall thereupon expire. At such time, DMRs and reports shall be submitted electronically to the Department using NetDMR unless the Permittee submits a renewed opt-out request and such request is approved by the Department.

All opt-out requests and requests for the NetDMR subscriber form should be sent to the following address or by email at deep.netdmr@ct.gov:

Attn: NetDMR Coordinator
Connecticut Department of Energy and Environmental Protection
79 Elm Street
Hartford, CT 06106-5127

(F) Copies of all DMRs shall be submitted concurrently to the New London Publicly Owned Treatment Works ("POTW").

SECTION 6: RECORDING AND REPORTING OF VIOLATIONS, ADDITIONAL TESTING REQUIREMENTS

(A) If any sample analysis indicates that an effluent limitation specified in Section 4 of this permit has been exceeded, a second sample of the effluent shall be collected and analyzed for the parameter(s) in question and the results reported to the Water Permitting and Enforcement Division (Attn: DMR Processing) within thirty (30) days of the exceedance.

- (B) The Permittee shall immediately notify the Water Permitting and Enforcement Division and the New London POTW of all discharges that could cause problems to the POTW, including but not limited to slug loadings of pollutants which may cause a violation of the POTW's NPDES permit, or which may inhibit or disrupt the POTW, its treatment processes or operations, or its sludge processes, use or disposal.
- (C) In addition to the notification requirements specified in Section 1B of this permit, if any sampling and analysis of the discharge performed by the Permittee indicates a violation of limits specified in Section 4 of this permit, the Permittee shall notify the Water Permitting and Enforcement within twenty-four (24) hours of becoming aware of the violation.

SECTION 7: COMPLIANCE SCHEDULE

- (A) On or before one hundred and fifty (**150**) days after the date of issuance of this permit, the Permittee shall submit for the Commissioner's review and written approval a scope of study for an investigation to reduce the flow of DSN 201-1 or eliminate the discharge. The scope of study shall include a substantive plan and schedule, for the Commissioner's review and written approval, for conducting the investigation, reporting to the Commissioner on the results of such investigation, including an evaluation of which alternatives are prudent and feasible, and implementation of the preferred alternative. Note: the Scope of Study to Reduce or Eliminate Wastewater Discharge, dated February 4, 2014, was approved on April 2, 2014.
- (B) On or before three hundred and sixty-five (**365**) days after the date of issuance of this permit, the Permittee shall submit for the Commissioner's review and written approval a comprehensive and thorough report that describes and evaluates alternative actions which may be taken by the Permittee to accomplish reduction of the discharge flow or elimination of the discharge. Such report shall:
 - (a) evaluate alternative actions to accomplish reduction of the discharge flow or elimination of the discharge including, but not limited to, pollutant source reduction, process changes/innovations, chemical substitutions, recycle and zero-discharge systems, water conservation measures, and other internal and/or end-of-pipe treatment technologies;
 - (b) state in detail the most expeditious schedule for performing each alternative;
 - (c) list all permits and approvals required for each alternative, including but not limited to any permits required under sections 22a-32, 22a-42a, 22a-342, 22a-361, 22a-368, 22a-430, or 22a-430b of the CGS;
 - (d) propose a preferred alternative or combination of alternatives with supporting justification; and
 - (e) propose a detailed program and schedule to perform all actions required in conjunction with the preferred alternative including but not limited to a schedule for submission of engineering plans and specifications for any internal and/or end of pipe treatment facilities, start and completion of any construction activities related to any treatment facilities, and applying for and obtaining all permits and approvals required for such actions.

Note: the Comprehensive Wastewater Reduction Study Report, dated September 9, 2014, along with supplemental documentation dated March 16, 2015, was approved on May 15, 2015.

- (C) The Permittee shall perform the approved actions in accordance with the approved schedule. Within fifteen (15) days after completing such actions, the Permittee shall certify to the Commissioner in writing that the actions have been completed as approved.
- (D) The Permittee shall use best efforts to submit to the Commissioner all documents required by this section of the permit in a complete and approvable form. If the Commissioner notifies the Permittee that any document or other action is deficient, and does not approve it with conditions or modifications, it is deemed disapproved, and the Permittee shall correct the deficiencies and resubmit it within the time specified by the Commissioner or, if no time is specified by the Commissioner, within thirty (30) days of the Commissioner's notice of deficiencies. In approving any document or other action under this Compliance Schedule, the Commissioner may approve the document or other action as submitted or performed or with such conditions or modifications as the Commissioner deems necessary to carry out the purposes of this section of the permit. Nothing in this paragraph shall excuse noncompliance or delay.
- (E) Dates. The date of submission to the Commissioner of any document required by this section of the permit shall be the date such document is received by the Commissioner. The date of any notice by the Commissioner under this permit, including but not limited to notice of approval or disapproval of any document or other action, shall be the date such

notice is personally delivered or the date three (3) days after it is mailed by the Commissioner, whichever is earlier. Except as otherwise specified in this permit, the word "day" as used in this section of the permit means calendar day. Any document or action which is required by this section of the permit to be submitted, or performed, by a date which falls on, Saturday, Sunday, or a Connecticut or federal holiday, shall be submitted or performed on or before the next day which is not a Saturday, Sunday, or Connecticut or federal holiday.

- (F) Notification of noncompliance. In the event that the Permittee becomes aware that it did not or may not comply, or did not or may not comply on time, with any requirement of this section of the permit or of any document required hereunder, the Permittee shall immediately notify the Commissioner and shall take all reasonable steps to ensure that any noncompliance or delay is avoided or, if unavoidable, minimized to the greatest extent possible. In so notifying the Commissioner, the Permittee shall state in writing the reasons for the noncompliance or delay and propose, for the review and written approval of the Commissioner, dates by which compliance will be achieved, and the Permittee shall comply with any dates, which may be approved in writing by the Commissioner. Notification by the Permittee shall not excuse noncompliance or delay, and the Commissioner's approval of any compliance dates proposed shall not excuse noncompliance or delay unless specifically so stated by the Commissioner in writing.
- (G) Notice to Commissioner of changes. Within fifteen (15) days of the date the Permittee becomes aware of a change in any information submitted to the Commissioner under this section of the permit, or that any such information was inaccurate or misleading or that any relevant information was omitted, the permittee shall submit the correct or omitted information to the Commissioner.
- (H) Submission of documents. Any document, other than a discharge monitoring report, required to be submitted to the Commissioner under this section of the permit shall, unless otherwise specified in writing by the Commissioner, be directed to:

Ewa Wozniak, Sanitary Engineer
Water Permitting and Enforcement Division
Bureau of Materials Management and Compliance Assurance
Department of Energy and Environmental Protection
79 Elm Street
Hartford, CT 06106-5127

SECTION 8: COMPLIANCE CONDITIONS

In accordance with 40 CFR 403.8(f)(2)(viii), the Commissioner may provide public notification, in a newspaper of general circulation in the area of the respective POTW, of permittees that at any time in the previous twelve (12) months were in significant noncompliance with the provisions of this permit. For the purposes of this provision, a permittee that is a Significant Industrial User is in significant noncompliance if its violation(s) meet(s) one or more of the following criteria:

- **Chronic violations:** Those in which sixty-six percent (66%) or more of all measurements taken for the same pollutant parameter during a six (6) month period exceed (by any magnitude) the Average Monthly, Maximum Daily, or Maximum Instantaneous Limit(s).
- **Technical Review Criteria violations:** Those in which thirty-three percent (33%) or more of all of the measurements taken for the same pollutant parameter during a six (6) month period equal or exceed the Average Monthly, Maximum Daily, or Maximum Instantaneous Limit(s) multiplied by 1.4 for biochemical oxygen demand, total suspended solids, fats, and oil and grease, or 1.2 for all other pollutants except pH.
- **Monitoring Reports:** Failure to provide, within forty-five (45) days after the due date, required reports such as DMRs.
- **Compliance Schedule:** Failure to meet within ninety (90) days after the schedule date, a compliance schedule milestone contained in or linked to a respective permit for starting construction, completing construction or attaining final compliance.
- **Noncompliance Reporting:** Failure to accurately report noncompliance in accordance with provisions identified in Section 6 of this permit.
- **Discretionary:** Any other violation of an effluent limit that the Department determines has caused, alone or in combination with other discharges, a violation of the POTW's NPDES permit, inhibition or disruption of the POTW, its treatment processes or operations, or its sludge processes, use or disposal.

- **Imminent Endangerment:** Any discharge of a pollutant that has caused imminent endangerment to human health, welfare or to the environment, or has resulted in the Department's exercise of its emergency authority under 40 CFR 403.8(f)(1)(vi)(B) to halt or prevent such a discharge.
- **Best Management Practices ("BMPs"):** Any other violation or group of violations, which may include failure to implement or follow BMPs, which the Department determines will adversely affect the operation or implementation of the pretreatment program.

This permit modification is hereby issued on

DRAFT
Michael Sullivan
Deputy Commissioner
Department of Energy and Environmental Protection

MM/EMW

cc: New London POTW

Certification: Waiver of Monitoring

Attachment A

“Based on my inquiry of the person or persons directly responsible for managing compliance with the Pretreatment Standard for Existing Sources 40 CFR 439.46 Pharmaceutical Manufacturing Category. I certify that, to the best of my knowledge and belief, there has been no increase in the level of **n-amyl acetate, ethyl acetate, isopropyl acetate, and methylene chloride** in the wastewaters due to the activities at the facility since filing of the last Discharge Monitoring Report.”

Authorized Official : _____ *Title:* _____

Signature: _____ *Date:* _____

DATA TRACKING AND TECHNICAL FACT SHEET

Permittee: SHEFFIELD PHARMACEUTICALS, LLC*

* previously known as Faria Limited LLC, d/b/a Sheffield Pharmaceuticals

PERMIT, ADDRESS, AND FACILITY DATA

PERMIT#: SP0002442

APPLICATION #: 201406890

<u>Mailing Address:</u>					<u>Location Address:</u>				
Street:	170 Broad Street				Street:	170 Broad Street			
City:	New London	ST:	CT	Zip: 06320	City:	New London	ST:	CT	Zip: 06320
Contact Name:	Jeffrey Davis				DMR Contact	Jeffrey Davis			
Phone No.:	(860) 442-4451				Phone No.:	(860) 442-4451			
Contact E-mail:	jeff.davis@sheffield-pharmaceuticals.com				DMR Contact E-mail:	jeff.davis@sheffield-pharmaceuticals.com			

PERMIT INFORMATION

DURATION 2 YEAR X 10 YEAR 30 YEAR

Note: The current permit was issued on September 13, 2013 and will expire on September 12, 2015. An application for permit renewal was submitted on March 16, 2015.

TYPE New Reissuance Modification X

CATEGORIZATION POINT (X) NON-POINT () GIS #

NPDES () PRETREAT (X) GROUND WATER(UIC) () GROUND WATER (OTHER) ()

NPDES MAJOR(MA)
 NPDES SIGNIFICANT or PRETREAT SIU (SI) X
 NPDES or PRETREATMENT (MI)

PRETREAT SIGNIFICANT INDUS USER(SIU) X
 PRETREAT CATEGORICAL (CIU) X

POLLUTION PREVENTION MANDATE ENVIRONMENTAL EQUITY ISSUE

SIC CODE: 2833, 2834, 2844

COMPLIANCE SCHEDULE YES X NO

POLLUTION PREVENTION TREATMENT REQUIREMENT WATER CONSERVATION X

WATER QUALITY REQUIREMENT REMEDIATION OTHER

OWNERSHIP CODE

Private X Federal State Municipal (town only) Other public

IS THE PERMITTEE SUBJECT TO A PENDING ENFORCEMENT ACTION? NO ___ YES X (See Other Comments)

DEEP STAFF ENGINEER: Ewa Wozniak

PERMIT FEES

Discharge Code	DSN Number	Annual Fee
501047Y	201-1	\$4,337.50

FOR SEWER DISCHARGES

Discharge to the City of New London Water Pollution Control Facility via its collection system. The facility ID. of the POTW is 095-001.

NATURE OF BUSINESS GENERATING DISCHARGE

SHEFFIELD PHARMACEUTICALS, LLC conducts formulation and packaging of gels, toothpastes, creams, ointments, denture adhesives, lip care and iodine ointments.

PROCESS AND TREATMENT DESCRIPTION (by DSN)

DSN 201-1: The process wastewater is generated from the cleaning of mixing tanks and associated equipment used to formulate and package gels, toothpastes, creams, ointments, denture adhesives, lip care, nasal care and iodine ointments, vacuum pump condensate, air compressor condensate, general mop water from warehouse floors, production floor scrubber, production floor mop water and the cleaning of laboratory glassware and equipment. Treatment system consists of solids settling, oil water separation, and pH adjustment.

RESOURCES USED TO DRAFT PERMIT

- X Federal Effluent Limitation Guideline 40 CFR 439 Subpart D
Pharmaceutical Manufacturing Point Source
- ___ Performance Standards
- X Federal Development Document Pharmaceutical Manufacturing Point Source
name of category
- ___ Treatability Manual
- X Department File Information
- ___ Connecticut Water Quality Standards
- ___ Anti-degradation Policy
- X Coastal Management Consistency Review Form
The Applicant filed the appropriate CMCR form and demonstrated consistency with applicable statutory goals and policies.
- X Other – Explain (See General Comments)

BASIS FOR LIMITATIONS, STANDARDS OR CONDITIONS

X Case-by-Case Determination and Best Professional Judgment

DSN 201-1: pH, copper, phosphorus, fluoride, titanium, and zinc, total recoverable oil petroleum, acetone, n-amyl acetate, ethyl acetate, isopropyl acetate, methylene chloride, and surfactants (MBAS).

COMMENTS RELATED TO THE PERMIT ISSUED ON September 13, 2013

The selection of parameters of concern was determined using best professional judgment on a case-by-case basis. Also, permit requirements are consistent with other permits issued to facilities with pharmaceutical operations by the Department.

Basis for Effluent Limitations and Monitoring Requirements

During the technical review of Faria Limited LLC's application, DEEP staff used effluent characterization information in the application to determine that limits were needed for **pH, total recoverable oil petroleum, acetone, n-amyl acetate, ethyl acetate, isopropyl acetate, methylene chloride and fluoride** to protect the City of New London WPCF from pass-through or interference.

DEEP staff recommended **pH** limits of (6.0 - 10.0) S.U., which were considered to be protective of sanitary sewer systems.

The effluent limitations proposed for **total recoverable oil petroleum**, which had been identified as oil and grease (hydrocarbon fraction) previously, were based on a report entitled "Treatability of Oil and Grease Discharged to Publicly Owned Treatment Works", USEPA, Effluent Guidelines Division, EPA/440/1-75-066 (April 1975).

Section 22a-430-4(s) of the Regulations of Connecticut State Agencies (RCSA) was used as a guideline in establishing limitations for **fluoride**. Based on a review of the discharge monitoring data and treatment to be provided, Faria Limited LLC would be able to meet these proposed effluent limitations.

Wastewater discharges from the production of pharmaceutical manufacturing are regulated under 40 CFR 439, Pharmaceutical Manufacturing Category. Faria Limited LLC initiated this discharge prior to May 2, 1995, the effective date of the Pretreatment Standards for New Sources. Therefore, the facility is an existing source, subject to the Pretreatment Standards for Existing Sources (PSES) in 40 CFR 439.46. The PSES identify the following parameters for regulation: **acetone, n-amyl acetate, ethyl acetate, isopropyl acetate, and methylene chloride**. DEEP staff proposed effluent limitations for these parameters that were more stringent than required under section 40 CFR 439.46 using the criteria of best professional judgment pursuant to section 22a-430-4(m) of the RCSA and 40 CFR 125.3(d), based on information that these pollutants were reportedly not used at the facility or expected to be present in the effluent.

EPA's General Pretreatment Streamlining Regulations for Existing and New Sources of Pollution, 40 CFR 403.8(f)(2)(v) and 403.12(e), authorize the Control Authority (CT DEEP) to waive permit monitoring requirements for pollutants that are not present and/or used anywhere in the Permittee's facility, but are included in the respective federal category. Faria Limited LLC analyzed representative untreated samples of its process wastewater for **n-amyl acetate, ethyl acetate, isopropyl acetate, and methylene chloride** using the most sensitive EPA approved methods. None of these four parameters were found in detectable levels in the samples. As a result, DEEP staff recommended that Faria Limited LLC be authorized to forego monitoring of the four pollutants. Consistent with 40 CFR 403.12(e)(2), the Permittee is required to include a statement, as an attachment, on each Discharge Monitoring Report (DMR), certifying there has been no increase in the levels of n-amyl acetate, ethyl acetate, isopropyl acetate, and methylene chloride due to the activities at the facility since the filing of the last DMR. Additionally, in the event that any of these chemical parameters is found to be present or is expected to be present based on changes that occur in the Permittee's operations, the Permittee shall immediately notify the Department and begin monitoring for the parameter(s) as required in Table A of the permit. The company also requested monitoring waiver for acetone. However, acetone was found to be present in the untreated samples. Therefore, acetone was not included in the waiver of monitoring.

DEEP staff recommended monitoring requirements for total titanium, copper and zinc, total recoverable oil petroleum, total phosphorus (as P), and surfactants (MBAS) due to the potential for these parameters to be present in the effluent. Faria Limited LLC, on rare occasions, manufactures formulations containing zinc oxide. The Permittee is required to collect all wastewater generated from the cleaning of tanks used in manufacturing those formulations and dispose of these materials through a licensed hauler in a manner acceptable to the Commissioner.

A field Notice of Violation (FNOVWRIN11301) was issued to the Faria Limited LLC on April 20, 2011 to address wastewater discharges that the Applicant had initiated or was maintaining into the City of New London POTW, without having obtained a discharge permit. Faria Limited LLC submitted, on May 27, 2011, for the Commissioner's review and approval wastewater discharge permit applications for all unpermitted pharmaceutical related wastewater discharges into the City of New London POTW. Faria Limited LLC registered a minor discharge of non-contact cooling water to the sanitary sewer (100 gpd) under the Minor Non-contact Cooling Water General Permit (GCW000256). Also, the company registered its stormwater discharges under the Stormwater Associated with Industrial Activities General Permit (GSI002328). The Permittee is also subject to the terms and conditions of the General Permit for the Discharge of Minor Boiler Blowdown (no registration required). Pretreatment permit no. SP0002442 was issued on September 13, 2013.

The permit contains a compliance schedule, which requires SHEFFIELD PHARMACEUTICALS, LLC to investigate and implement actions to reduce the flow of or eliminate the discharge. SHEFFIELD PHARMACEUTICALS, LLC submitted a report entitled Comprehensive Wastewater Reduction Study Report, dated September 9, 2014, along with supplemental documentation dated March 16, 2015. This report was approved on May 15, 2015.

A special condition is included in Section 4 of this permit that reads "The Permittee shall collect all wastewater generated from the cleaning of tanks used in the manufacturing of formulations containing zinc oxide and non-conforming materials as described in Appendix I of the Operation and Maintenance Plan and dispose of these materials through a licensed hauler in a manner acceptable to the Commissioner."

COMMENTS RELATED TO THE 2015 PERMIT MODIFICATION

On June 3, 2014, SHEFFIELD PHARMACEUTICALS, LLC submitted to the Department an application to modify its existing Permit No. SP0002442. Specifically, SHEFFIELD PHARMACEUTICALS, LLC requested approval to have wastewater associated with the manufacturing and packaging of lip care products and nasal care products discharged to the company's wastewater treatment system. The Department evaluated SHEFFIELD PHARMACEUTICALS, LLC's request and determined that the inclusion of the lip care and nasal care wastewater will not adversely impact the New London POTW. As a result of the inclusion of this wastewater, the Department is requiring that SHEFFIELD PHARMACEUTICALS, LLC monitor for phenol on a monthly basis and comply with the maximum daily limit of 10 mg/l. The Department also set the maximum instantaneous limit to 10 mg/l using the criteria of best professional judgment. The phenol limit of 10 mg/l was derived using best professional judgment and is consistent with the maximum instantaneous limit in the General Permit for Miscellaneous Discharges of Sewer Compatible (MISC) Wastewater. In addition, maximum daily flow of 16,000 gallons per day does not have to be increased as the inclusion of the lip care wastewater will not increase the flow beyond the permitted limit.

Effluent Violations

MONTH/YEAR	DSN	PARAMETER	TYPE OF LIMIT	PERMITTED LIMIT	EXCEEDENCE
January 2014	201-1	Oil petroleum, total recoverable	Maximum, Daily	100.0 mg/l	200.0 mg/l
REASON: <input type="checkbox"/> Equipment Related <input type="checkbox"/> Operator Error <input type="checkbox"/> Unknown <input checked="" type="checkbox"/> None provided <input type="checkbox"/> Other					
REASON: None provided.					

MONTH/YEAR	DSN	PARAMETER	TYPE OF LIMIT	PERMITTED LIMIT	EXCEEDENCE
April 2014	201-1	Oil petroleum, total recoverable	Maximum, Daily	100.0 mg/l	260.0 mg/l
REASON: <input type="checkbox"/> Equipment Related <input type="checkbox"/> Operator Error <input type="checkbox"/> Unknown <input checked="" type="checkbox"/> None provided <input type="checkbox"/> Other					
REASON: None provided.					

MONTH/YEAR	DSN	PARAMETER	TYPE OF LIMIT	PERMITTED LIMIT	EXCEEDENCE
May 2014	201-1	pH	Maximum Instantaneous	10.0 S.U.	10.21 S.U.
REASON: <input type="checkbox"/> Equipment Related <input type="checkbox"/> Operator Error <input type="checkbox"/> Unknown <input type="checkbox"/> None provided <input checked="" type="checkbox"/> Other					
REASON: The high pH discharge consisted of a single gallon of water that was residual in the pipe as the effluent valve switched position.					

MONTH/YEAR	DSN	PARAMETER	TYPE OF LIMIT	PERMITTED LIMIT	EXCEEDENCE
June 2014	201-1	Acetone	Maximum, Daily	2.0 mg/l	2.4275 mg/l
REASON: <input type="checkbox"/> Equipment Related <input checked="" type="checkbox"/> Operator Error <input type="checkbox"/> Unknown <input type="checkbox"/> None provided <input type="checkbox"/> Other					
REASON: Quality Control Laboratory performed a qualification on HPLC equipment and a quantity of acetone used to clean the equipment was released down the drain to the waste water treatment system.					

MONTH/YEAR	DSN	PARAMETER	TYPE OF LIMIT	PERMITTED LIMIT	EXCEEDENCE
June 2014	201-1	Acetone	Average Monthly	1.0 mg/l	2.4275 mg/l
REASON: <input type="checkbox"/> Equipment Related <input checked="" type="checkbox"/> Operator Error <input type="checkbox"/> Unknown <input type="checkbox"/> None provided <input type="checkbox"/> Other					
REASON: Quality Control Laboratory performed a qualification on HPLC equipment and a quantity of acetone used to clean the equipment was released down the drain to the waste water treatment system.					

MONTH/YEAR	DSN	PARAMETER	TYPE OF LIMIT	PERMITTED LIMIT	EXCEEDENCE
April 2015	201-1	pH	Maximum Instantaneous	10.0 S.U.	13.7 S.U.
REASON: <input type="checkbox"/> Equipment Related <input type="checkbox"/> Operator Error <input type="checkbox"/> Unknown <input type="checkbox"/> None provided <input checked="" type="checkbox"/> Other					
REASON: The high pH discharge is a result of a small delay when the pH went above the discharge limit mid-discharge. Once the high pH was detected, the effluent valve closed and re-circulation valve opened automatically as intended.					

MONTH/YEAR	DSN	PARAMETER	TYPE OF LIMIT	PERMITTED LIMIT	EXCEEDENCE
April 2015	201-1	pH	Minimum Instantaneous	6.0 S.U.	4.11 S.U.
REASON: <input type="checkbox"/> Equipment Related <input type="checkbox"/> Operator Error <input type="checkbox"/> Unknown <input type="checkbox"/> None provided <input checked="" type="checkbox"/> Other					
REASON: The low pH is a single second result in the middle of a 5 minute discharge, with an approx. pH of 8.8 one second earlier and 8.4 one second later. This is a fluke that has not repeated itself since.					

MONTH/YEAR	DSN	PARAMETER	TYPE OF LIMIT	PERMITTED LIMIT	EXCEEDENCE
May 2015	201-1	pH	Maximum Instantaneous	10.0 S.U.	10.98 S.U.
REASON: <input type="checkbox"/> Equipment Related <input type="checkbox"/> Operator Error <input type="checkbox"/> Unknown <input type="checkbox"/> None provided <input checked="" type="checkbox"/> Other					
REASON: The high pH discharge is a result of a small delay when the pH went above the discharge limit mid-discharge. Once the high pH was detected, the effluent valve closed and re-circulation valve opened automatically as intended.					



**NOTICE OF TENTATIVE DECISION OF INTENT TO
MODIFY A STATE PERMIT FOR THE FOLLOWING DISCHARGE
INTO THE WATERS OF THE STATE OF CONNECTICUT**

TENTATIVE DECISION

The Commissioner of Energy and Environmental Protection (the "Commissioner") hereby gives notice of a tentative decision to issue a permit modification based on an application submitted by **SHEFFIELD PHARMACEUTICALS, LLC** ("the applicant") under section 22a-430 of the Connecticut General Statutes ("CGS") for a permit to discharge into the waters of the state.

In accordance with applicable federal and state law, the Commissioner has made a tentative decision that the continuance of the existing system to treat the discharge would protect the waters of the state from pollution and the Commissioner proposes to issue a permit modification for this discharge to the New London Water Pollution Control Facility ("WPCF").

The proposed permit modification, if issued by the Commissioner, will require that all wastewater be treated to meet the applicable effluent limitations and periodic monitoring to demonstrate that the discharges will not cause pollution.

APPLICANT'S PROPOSAL

SHEFFIELD PHARMACEUTICALS, LLC proposes to continue discharging up to a maximum of 16,000 gallons per day of treated wastewaters from cleaning operations associated with the formulation and packaging of gels, toothpastes, creams, ointments, denture adhesives and iodine ointments, vacuum pump condensate, air compressor condensate, mop water from the cleaning of warehouse floors, production floor scrubber wastewater and mop water and wastewater from the cleaning of laboratory glassware and equipment to the City of New London WPCF from the pharmaceutical manufacturing facility. The company is now proposing to discharge wastewater associated with the manufacture and packaging of lip care products and nasal care products.

The name and mailing address of the permit applicant are: SHEFFIELD PHARMACEUTICALS, LLC, 170 Broad Street, New London, CT, 06320.

The activity takes place at: 170 Broad Street, New London, CT, 06320.

The proposed activity is within the coastal area as defined in section 22a-94 of the CGS. Pursuant to section 22a-98 of the CGS, the applicant must demonstrate that the activities are consistent with all applicable goals and policies in section 22a-92 of the CGS, and that such activities incorporate all reasonable measures mitigating any adverse impacts on coastal resources and future water-dependent development activities.

REGULATORY CONDITIONS

Type of Treatment

DSN 201-1: Solids settling, oil water separation and neutralization.

Effluent Limitations

This permit contains effluent limitations consistent with a Case-by-Case Determination using the criteria of Best Professional Judgment and Pretreatment Standards for Existing Sources (PSES), and which will protect the waters of the state from pollution when all the conditions of this permit have been met.

In accordance with section 22a-430-4(l) of the Regulations of Connecticut State Agencies ("RCSA"), the permit contains effluent limitations for the following types of toxic substances: heavy metals and volatile organic compounds.

Compliance Schedule

This permit contains an enforceable compliance schedule, which requires the permittee to investigate and implement actions to reduce or eliminate the discharge.

COMMISSIONER'S AUTHORITY

The Commissioner is authorized to approve or deny such permits pursuant to section 22a-430 of the CGS and the Water Discharge Permit Regulations (sections 22a-430-3 and 4 of the RCSA).

INFORMATION REQUESTS

The application has been assigned the following numbers by the Department of Energy and Environmental Protection. Please use these numbers when corresponding with this office regarding this application.

APPLICATION NO. 201104540

PERMIT NO. SP0002442

Interested persons may obtain copies of the application from Jeffrey Davis, SHEFFIELD PHARMACEUTICALS, LLC, 170 Broad Street, New London, CT 06320, (860) 442-4451.

The application is available for inspection by contacting Ewa Wozniak at (860) 424-3018, at the Department of Energy and Environmental Protection, Bureau of Materials Management and Compliance Assurance, 79 Elm Street, Hartford, CT 06106-5127 from 8:30 - 4:30, Monday through Friday.

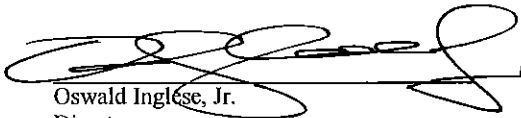
Any interested person may request in writing that his or her name be put on a mailing list to receive notice of intent to issue any permit to discharge to the surface waters of the state. Such request may be for the entire state or any geographic area of the state and shall clearly state in writing the name and mailing address of the interested person and the area for which notices are requested.

PUBLIC COMMENT

Prior to making a final determination to approve or deny any application, the Commissioner shall consider written comments on the application from interested persons that are received within thirty (30) days of this public notice. Written comments should be directed to Ewa Wozniak, Bureau of Materials Management and Compliance Assurance, Department of Energy and Environmental Protection, 79 Elm Street, Hartford, CT 06106-5127. The Commissioner may hold a public hearing prior to approving or denying an application if in the Commissioner's discretion the public interest will be best served thereby, and shall hold a hearing upon receipt of a petition signed by at least twenty-five (25) persons. Notice of any public hearing shall be published at least thirty (30) days prior to the hearing.

Petitions for a hearing should include the application number noted above and also identify a contact person to receive notifications. Petitions may also identify a person who is authorized to engage in discussions regarding the application and, if resolution is reached, withdraw the petition. Original petitions must be *mailed or delivered* to: Department of Energy and Environmental Protection Office of Adjudications, 79 Elm Street, 3rd floor, Hartford, CT 06106-5127. Petitions cannot be sent by fax or email. Additional information can be found at www.ct.gov/deep/adjudications.

The Connecticut Department of Energy and Environmental Protection is an Affirmative Action and Equal Opportunity Employer that is committed to complying with the Americans with Disabilities Act. To request an accommodation contact us at (860) 418-5910 or deep.accommodations@ct.gov.



Oswald Inglese, Jr.
Director
Water Permitting and Enforcement Division
Bureau of Materials Management and Compliance Assurance

Dated:

SEP 04 2015