
North Coast Regional Water Quality Control Board

May 27, 2020

Ketan C. Mehta, CEO and Founder
Nina Mehta, President
NeilMed Pharmaceuticals Inc.
601 Aviation Blvd.
Santa Rosa, CA 95403
Ketan@neilmed.com

Dear Mr. Mehta and Ms. Mehta:

Subject: **Notice of Violation for NeilMed Pharmaceuticals, Inc.**

File: Storm Water, Industrial, Sonoma County, NeilMed Pharmaceuticals, Inc.

This Letter is to notify NeilMed Pharmaceuticals, Inc., (hereinafter “Operator” or “you”) of violations of the requirements listed below, associated with your continued failure to obtain coverage under and comply with the requirements of the National Pollutant Discharge Elimination System (NPDES) General Permit for Storm Water Discharges Associated with Industrial Activities, Order No. 2014-0057- DWQ NPDES NO. CAS000001 (Industrial General Permit or Permit). NeilMed, Pharmaceuticals, Inc. is in violation of the following provisions of law:

- California Water Code (Water Code) sections 13260, 13264, and 13376
- Clean Water Act section 301

The Industrial General Permit requires manufacturing facilities, including those that manufacture medicinal chemicals and botanical products (Standard Industrial Classification (SIC) Code 2833) and pharmaceutical preparations (SIC Code 2834) to enroll and comply with its requirements.¹ The North Coast Regional Water Quality

¹ The Industrial General Permit is available at the State Water Resources Control Board website at:

https://www.waterboards.ca.gov/water_issues/programs/stormwater/docs/industrial/2014indgenpermit/wqo2014_0057_dwq_revmar2015.pdf

Control Board (Regional Water Board) has determined, and previously notified you several times, that based on the nature of the industrial activities associated with the your facility, you must obtain coverage under the Industrial General Permit.

BACKGROUND

On November 1 and November 27, 2018, Regional Water Board staff observed exterior industrial activities at your facility, located at 601 Aviation Blvd, Santa Rosa, Sonoma County (Facility), that have potential to impact waters of the state. Runoff from the Facility flows into a municipal storm drain system and discharges directly to an unnamed tributary to Windsor Creek and thence Mark West Creek, a water of the United States.

On January 8, January 20, and January 23, 2019, Regional Water Board staff directed you via email to enroll your Facility for coverage under the Industrial General Permit. On February 12, 2019, the Regional Water Board sent you a Notice of Non-Compliance (NNC) due to your failure to obtain coverage under the Industrial General Permit. You failed to act as directed in the NNC, and did not file a Notice of Intent (NOI), No Exposure Certification (NEC), or Notice of Non-Applicability (NONA) including a No-Discharge Technical Report via SMARTS. On March 15, 2019, Regional Water Board staff sent you a second NNC, stating that “you must file a Notice of Intent (NOI) or a No Exposure Certification (NEC) electronically through the Stormwater Multiple Application and Report Tracking System (SMARTS) by March 05, 2019.” The second NNC also stated that “failing to submit the required documents by April 15, 2019, 60 days from the date of the initial Notice of Non-Compliance (February 12, 2019), is a violation of section 13399.30 of the Water Code.”

On May 16, 2019, you emailed to the Regional Water Board a copy of a partially completed NONA form that you stated you had submitted to the Los Angeles Regional Water Quality Control Board. Note that pursuant to the Permit, and as stated in the NNC letters, a NONA must be filed via SMARTS, and accompanied by a No-Discharge Technical Report signed by a California licensed professional engineer. You did not file your NONA via SMARTS, you did not submit the form you filled to the correct Regional Water Board, and you did not submit a No-Discharge Technical Report signed by a California licensed engineer. Therefore, you did not take acceptable steps to comply with the NNC and you continued to operate without appropriate permit coverage.

On June 11, 2019, Regional Water Board staff discussed this matter with you by telephone, and you agreed to submit the required documents by June 14, 2019. On June 13, 2019, staff sent you a reminder email. However, you again failed to file for Permit coverage or take other appropriate steps. Accordingly, on July 10, 2019, the Regional Water Board Assistant Executive Officer issued to you a settlement offer Order No. R1- 2019-0035, proposing liability assessment for failure to obtain coverage under the Permit. The settlement offer proposed a \$5,000 Mandatory Minimum Penalty (MMP), pursuant to Water Code section 13399.33 subdivision (a)(1), plus \$2,180.80 in staff costs, in accordance with Water Code section 13399.33 subdivision (d).

The settlement offer stated, in part, that “[t]his is a Conditional Offer subject to certain terms and conditions set forth below. If you choose this option you must sign and return to the Regional Water Board the enclosed Acceptance and Waiver form and submit a completed NOI, SWPPP, and facility site map electronically via SMARTS by August 2, 2019. This option is deemed complete only after payment of the mandatory minimum penalty amount and submission of the NOI, SWPP, and facility site map via SMARTS.” On September 11, 2019, you submitted the signed Acceptance and Waiver.

In summary, since January 8, 2019, Regional Water Board staff have informed you numerous times of the requirement to enroll your Facility for coverage under the Permit. In addition, you and/or your agents have advised the Regional Water Board numerous times by telephone or email, and you have agreed, in writing, that you will enroll the Facility for coverage under the Permit. However, to date, your Facility has not obtained appropriate regulatory coverage and continues to operate and conduct industrial activities.

RELEVANT REQUIREMENTS

Water Code section 13260 requires, in part, that a person discharging waste or proposing to discharge waste, within any region that could affect the quality of waters of the state, other than into a community sewer system shall file with the appropriate regional board a report of the discharge.

Water Code section 13264 states, in part that “[n]o person shall initiate any new discharge of waste or make any material changes in any discharge, or initiate a discharge to, make any material changes in a discharge to, or construct, an injection well, prior to the filing of the report required by Section 13260 and no person shall take any of these actions after filing the report but before whichever of the following occurs first:

- (1) The issuance of waste discharge requirements pursuant to Section 13263.
- (2) The expiration of 140 days after compliance with Section 13260 if the waste to be discharged does not create or threaten to create a condition of pollution or nuisance...

Water Code section 13376 states, in part, that: “[a] person who discharges pollutants or proposes to discharge pollutants to the navigable waters of the United States within the jurisdiction of this state or a person who discharges dredged or fill material or proposes to discharge dredged or fill material into the navigable waters of the United States within the jurisdiction of this state shall file a report of the discharge in compliance with the procedures set forth in Section 13260.”

Clean Water Act section 301 provides that except in compliance with sections 301, 1342, and 1344 of the Clean Water Act, “the discharge of any pollutant by any person shall be unlawful.” Clean Water section 1342 allows for the discharge of pollutants pursuant only to National Pollutant Discharge Elimination System (NPDES) permits.

The Industrial General Permit is the relevant NPDES permit for discharges from facilities such as yours.

Water Code sections 13261, 13265, and 13385 provide for the assessment of administrative civil liability, of up to \$10,000 per day, for failure to comply with applicable provisions of Water Code sections 13260, 13264, and 13376, and Clean Water Act section 301.

STATUTORY LIABILITY

As of May 6, 2020, it has been 484 days since Regional Water Board staff first directed you to enroll your Facility for coverage under the Industrial General Permit. It has been 237 days since you signed the acceptance waiver associated with Order No. R1-2019-0035, agreeing, part, to “apply for coverage under the IGP by completing a Notice of Intent online via the SMARTS database, and uploading the facility’s storm water pollution prevention plan (SWPPP) and current site map into SMARTS...by August 2, 2019.” It has been 170 days since the Regional Water Board Executive signed and executed Order No. R1-2019-0035. Yet, to date, you have failed to enroll your facility for coverage under the Permit.

Pursuant to Water Code section 13385, you are liable for penalties of up to \$10,000 for each day you fail to enroll for coverage under the Permit.

We encourage you to enroll the Facility for coverage under the IGP **immediately**. Enforcement staff at the Regional Water Board will consider your timeliness in taking appropriate action in making our recommendation to the Regional Water Board regarding the imposition of additional administrative civil liability for your ongoing violation of the Water Code and Clean Water Act.

Please provide my staff with confirmation of your enrollment under the Permit by June 26, 2020. If you have any questions regarding this matter, please contact Diana Henriouille at (707)576 2350 /Diana.Henriouille@waterboards.ca.gov or Doreen Kiruja at (707) 576 2699 / Doreen.kiruja@waterboards.ca.gov.

Sincerely,

Charles Reed
Point Source and Groundwater Protection Division Manager

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cc: Heaven Moore, P.E., NPDES Unit
Catherine Hawe, Attorney, State Water Board – Office of Enforcement