

**ENVIRONMENTAL APPEALS BOARD
 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
 WASHINGTON, D.C.**

In re:)	
)	
Novartis Pharmaceuticals Corp.)	RCRA Appeal No. 20-01
)	
)	

**ORDER DIRECTING CLARIFICATION
 OF SERVICE OR NEW SERVICE AND
 DIRECTING RESPONSE TO PETITION**

On August 14, 2020, the Environmental Appeals Board (“Board”) received a petition for review of a permit renewal issued to Novartis Pharmaceuticals Corporation (“Novartis”) on July 15, 2020, for operations at its East Hanover, New Jersey, facility. The petition consists of a three-page letter and attachments; a copy of the petition is attached to this Order as Attachment A. The petition includes a “cc:” or copy list of six persons, of which three are U.S. Environmental Protection Agency (“EPA”) employees: (1) Peter Lopez, EPA Region 2 Regional Administrator; (2) Judy-Ann Mitchell, Deputy Director, EPA Region 2 Land, Chemical, and Redevelopment Division; and (3) Sam Abdellatif, EPA Region 2 Case Manager.

The Board did not receive a response from EPA Region 2 on or around September 14, 2020, when, under the 40 C.F.R. part 124 procedural rules, a response brief would have been due to the Board.

As a result of a telephone call placed by the Clerk of the Board to Sam Abdellatif, and a later e-mail to the Clerk from Bruce Aber, EPA Region 2 Assistant Regional Counsel (copy


attached as Attachment B), it has come to the Board's attention that none of the three EPA Region 2 personnel purportedly copied on the petition appear to have received the petition.¹

In light of these events, the Board hereby DIRECTS Novartis to confirm the date as well as the methods and addresses or other contact information it used to serve the six parties copied on the petition. If Novartis cannot provide such information regarding past service, the Board directs Novartis to serve EPA Region 2 and the other parties with the August 14, 2020 petition for the first time. Novartis's response to this Order, whether confirmation of past service or provision of new, first-time service, must be filed with the Board and served on the parties on or before **Wednesday, September 30, 2020**. EPA Region 2 will then have until **Friday, October 30, 2020**, to file a response to the petition.

So ordered.

ENVIRONMENTAL APPEALS BOARD

Dated: **Sep 17 2020**

By: 
Kathie A. Stein
Environmental Appeals Judge

¹ The part 124 procedural rules set forth the following requirement regarding proof of service:

A certificate of service must be appended to each document filed stating the names of persons served, the date and manner of service, as well as the electronic, mailing, or hand delivery address, or facsimile number, as appropriate.

40 C.F.R. § 124.19(i)(4).

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing **Order Directing Clarification of Service or New Service and Directing Response to Petition** in the matter of *Novartis Pharmaceutical Corporation*, RCRA Appeal No. 20-01, were sent to the following persons in the manner indicated:

By Electronic Mail:

Eugene Gabay
Principal Consultant
Environmental Resources Management Inc.
105 Maxess Road, Suite 316
Melville, New York 11747
(631) 756-8900
eugene.gabay@erm.com

Bruce Aber
Assistant Regional Counsel
Office of Regional Counsel
U.S. Environmental Protection Agency, Region 2
290 Broadway, 16th Floor
New York, New York 10007-1866
(212) 637-3224
aber.bruce@epa.gov

Date: **Sep 17 2020**



Eurika Durr
Clerk of the Board

ERM

105 Maxess Road, Suite 316
Melville, NY
11747

Telephone: +1 631-756-8900
Fax: +1 631-756-8901
www.erm.com



13 August 2020

Clerk of Environmental Appeals Board
U.S. Environmental Protection Agency
Ariel Rios Building (MC-1103M)
1200 Pennsylvania Avenue, NW
Washington D.C. 20460-0001

Re: Petition for Review in Respect to EPA's July 15, 2020 Notice of Issuance of Final HSWA Permit Renewal
Novartis Pharmaceuticals Corporation
EPA Identification No.: NJD002147023

On behalf of Novartis Pharmaceuticals Corporation (Novartis), Environmental Resources Management Inc. (ERM) is submitting this petition for review in accordance with 40 Code of Federal Register (C.F.R.) § 124.19. This petition for review is in respect to the HSWA Permit Renewal issued on July 15, 2020, by the United States Environmental Protection Agency ("EPA") for the Novartis East Hanover, New Jersey facility (EPA Identification No.: NJD002147023).

During review of the Responsiveness Summary and HSWA permit and associated attachments, Novartis has identified the following items and based on the related comments, respectfully requests the HSWA Permit be modified to address those comments.

Novartis's comments as they pertain to each of the individual documents is provided below.

Items from the Final HSWA Permit Renewal Responsiveness Summary

1. **Item 8, Pages 7 and 8 of 11:** EPA correctly applied the update described in item 8 to the HSWA Permit Module III.B.2 and to page 2 in the Statement of Basis (SOB) to clarify that 1,1,1-trichloroethane (TCA) originated from an off-site source. Novartis requests that EPA also apply a similar language to the second sentence of the paragraph titled "AOC, Groundwater" on page 16 of the SOB to read "*However, TCE, PCE, 1,1-DCE and TCA appear to be coming from upgradient offsite sources attributable to the East Hanover Regional Contaminant Area.*"

Novartis Permit Modification Statement of Basis

2. **Section II, page 5 of 22:** The second sentence in the third paragraph identifies the building number of the parking garage as "Building 433"; the current building number is 317. Therefore, Novartis requests that EPA revise this sentence to read "*In this location, Novartis constructed office Buildings 310 and 315, which are used for administrative purposes and Building 317 that is an above ground parking garage.*"

Items from HSWA Permit Module II

3. **Section D Groundwater, page 3 of 6:** The first paragraph indicates the existence of 20 groundwater monitoring wells. This number of wells noted is no longer reflective of the current number of groundwater monitoring wells due to the closure of two groundwater monitoring wells. In an email dated May 30, 2018, the NJDEP approved the removal of monitoring wells S101L and S101U, which were subsequently closed/abandoned on June 28, 2018. (see Attachment A). Therefore, Novartis request that the beginning of the first sentence in Section D be revised to read "*Novartis currently has 18 groundwater monitoring wells.*"
4. **Section G Final HSWA Permit, page 6 of 6, Item 8:** Item 8 reads, "*Provide annual reports of the above-mentioned monitoring and sampling to NJDEP and EPA.*" This sentence should be modified to clarify that only the vapor intrusion reports need to be submitted annually. This modification would then put the 1,4 dioxane sampling on the same schedule as noted in the HSWA Permit in Module II Section G, Item 2 and Module III.B.3 that requires the groundwater sampling results be submitted in accordance with the reporting requirements as described in the NJDEP Chloroform GRAP, which is biennially.
5. **Section G Final HSWA Permit, page 5 of 6, Item 4** requires reporting of 1,4-dioxane results on an annual basis. However, Module II Section G, Item 2 requires "groundwater" sampling be reported as described in the NJDEP Chloroform GRAP. Novartis request that the reporting requirement for 1,4-dioxane in Section G Final HSWA Permit, page 5 of 6, Item 4 be changed to biennially which would put the groundwater reporting requirements for 1,4-dioxane on the same reporting schedule that is required in the NJDEP Chloroform GRAP. Further comment on this topic is provide in Item 6 below.

Items from HSWA Permit Module III

6. **Section B.2:** On page 4 of 12, the first sentence of the last paragraph reads "*Novartis shall, as a precautionary measure, also conduct annual groundwater sampling of 1,4-dioxane and will submit an annual report to EPA and NJDEP of the results of such sampling.*" As a precautionary measure, Novartis agrees to conduct groundwater sampling of 1,4-dioxane starting with the November 2020 sampling event. However, Novartis believes annual reporting for 1,4-dioxane is not necessary and requests that EPA revise the sentence to reflect the requirement for biennial reporting schedule specified in the August 23, 2018 NJDEP Chloroform GRAP. Novartis also request that language in the last paragraph on page 4 of 12 be added to state that whenever the onsite potable wells are closed and the site goes to a 100% public water supply, 1,4-dioxane testing will no longer be required.

It should be noted, 1,4-dioxane was used as a stabilizer for chlorinated solvents, particularly TCA, and is a common contaminant associated with chlorinated solvent sites (EPA 2013a; Mohr 2001). For this reason Novartis continues to maintain its position that the presence of 1,4-dioxane in groundwater is related to the upgradient offsite sources of CVOCs attributable to the East Hanover Regional Contaminant Area.

We appreciate this opportunity to provide a petition for review of the HSWA Permit Renewal. Please contact me at (516) 250-6155 or Eugene.Gabay@erm.com if you have any questions.

Yours sincerely,



Eugene Gabay
Principal Consultant

CC
Peter Lopez
Regional Administrator, EPA Region 2

Judy-Ann Mitchell
Deputy Director, USEPA Region 2
Land, Chemical, and Redevelopment Division

Sam Abdellatif
USEPA Case Manager, Region 2

Robb Truedinger
Head Liabilities & Remediation
Novartis Real Estate & Facility Services

Lawrence Kunz
Head HSE & BCM
Novartis Pharmaceuticals Corporation

Michael Draikiwicz
Vice President
ESI

Attachment A



ENVIRO-SCIENCES (OF DELAWARE), INC.

781 ROUTE 15 SOUTH / 2ND FLOOR
LAKE HOPATCONG, NJ 07849
(973) 398-8183 • Fax (973) 398-8037

September 11, 2018

Mr. Lawrence Kunz, PE
Head HSE&BCM-East Hanover
Novartis Business Services
One Health Plaza 434-235
East Hanover, NJ 07936-1080

**Re: Well Abandonment Records
Wells S101L and S101U
East Hanover Campus**

Dear Mr. Kunz:

On June 28, 2018, wells S101L and S101U were abandoned from the Novartis East Hanover Campus as approved by the NJDEP Case Manager in an email correspondence dated May 30, 2018. The wells were abandoned by a licensed driller in accordance with the New Jersey Department of Environmental Protection (NJDEP) Requirements and Procedures for the Decommissioning of Wells, Subchapter 7:9D-3.1. A copy of the Well Decommissioning Reports for each well is included with this letter.

If you have any questions or comments, please do not hesitate to contact me at (973) 398-8183, Ext. 221 or by email at lclifford@enviro-sciences.com.

Sincerely,

ENVIRO-SCIENCES (OF DELAWARE), INC.

Laura Clifford
Manager, Hydrogeology

cc: Michael Draikiwicz

WELL DECOMMISSIONING REPORT

PROPERTY OWNER: N/A NOVARTIS PHARMACEUTICALS CORP

Company/Organization: NOVARTIS PHARMACEUTICALS CORP

Address: 13155 NOEL RD #100 LB73 DALLAS, Texas 75240

WELL LOCATION: Novartis

Address: 59 RT 10

County: Morris Municipality: East Hanover Twp Lot: 12 Block: 99

Easting (X): 522439 Northing (Y): 717827
Coordinate System: NJ State Plane (NAD83) - USFEET

**DATE WELL
DECOMMISSIONED:** June 28, 2018

WELL USE: MONITORING

Other Use(s): _____

Local ID: S-101L

Reason for Decommissioning: No longer in use

Finished Well Depth (ft.): 118

Was a New Well Drilled? N

Formation Type: Unconsolidated

New Well Permit Number: _____

WELL DECOMMISSIONING INFORMATION

	Depth to Top (ft.)	Depth to Bottom (ft.)	Diameter (inches)	Material	Wgt/Rating/Screen # Used (lbs/ch no.)
Borehole					
Casing	0	6	8	Steel	sch 40
Casing	0	95	4	PVC	sch 40
Screen	95	118	4	PVC	.020

MATERIALS USED

	Depth to Top (ft.)	Depth to Bottom (ft.)	Outer Diameter (in.)	Inner Diameter (in.)	Material		
					Bentonite (lbs.)	Neat Cement (lbs.)	Water (gal.)
Grout	0	118	4	0	846	54	
Sand/Gravel							

ADDITIONAL INFORMATION

Obstructions: No

Authorization Official: Mark Ortega

Obstruction Type: _____

Authorization Number: A1806076

Alternative Decomm. Method? No

Authorization Date: June 18, 2018

Method Used _____

ATTACHMENTS: _____

WELL DECOMMISSIONING REPORT

PROPERTY OWNER: N/A NOVARTIS PHARMACEUTICALS CORP

Company/Organization: NOVARTIS PHARMACEUTICALS CORP

Address: 13155 NOEL RD #100 LB73 DALLAS, Texas 75240

WELL LOCATION: Novartis

Address: 59 RT 10

County: Morris Municipality: East Hanover Twp Lot: 12 Block: 99

Easting (X): 522442 Northing (Y): 717837
Coordinate System: NJ State Plane (NAD83) - USFEET

**DATE WELL
DECOMMISSIONED:** June 28, 2018

WELL USE: MONITORING

Other Use(s): _____

Local ID: S-101U

Reason for Decommissioning: No longer in use

Finished Well Depth (ft.): 93

Was a New Well Drilled? N

Formation Type: Unconsolidated

New Well Permit Number: _____

WELL DECOMMISSIONING INFORMATION

	Depth to Top (ft.)	Depth to Bottom (ft.)	Diameter (inches)	Material	Wgt/Rating/Screen # Used (lbs/ch no.)
Borehole					
Casing	0	68	4	PVC	sch 40
Casing	0	60	8	Steel	sch 40
Screen	68	93	4	PVC	.020

MATERIALS USED

	Depth to Top (ft.)	Depth to Bottom (ft.)	Outer Diameter (in.)	Inner Diameter (in.)	Material		
					Bentonite (lbs.)	Neat Cement (lbs.)	Water (gal.)
Grout	0	93	4	0	0	650	42
Sand/Gravel							

ADDITIONAL INFORMATION

Obstructions: No

Authorization Official: Mark Ortega

Obstruction Type: _____

Authorization Number: A1806075

Alternative Decomm. Method? No

Authorization Date: June 18, 2018

Method Used _____

ATTACHMENTS: _____

Eugene Gabay

From: Bergman, Erica <Erica.Bergman@dep.nj.gov>
Sent: Wednesday, May 30, 2018 11:22 AM
To: Laura Clifford
Cc: Abdellatif.Sameh@epa.gov; Michael Draikiwicz
Subject: RE: Novartis EH Campus: GW RAPAs modification request

Laura,

As discussed today, the request to remove wells S101L and S101U from groundwater gauging in RAR and RAP application was approved by the geologist. I contacted Chris Blake from permitting and he let me know that he can remove the wells from the GW RA permit prior to issuing, so no need for you to submit anything.

I plan to give the RAR a final review shortly and will let Chris Blake know so he can move forward with issuing the GW RA permit.

Erica Bergman
New Jersey Department of Environmental Protection
Site Remediation Program – Bureau of Case Management
401 E. State Street - Mail Code 401-05F
P.O. Box 420
Trenton, NJ 08625-0420
erica.bergman@dep.nj.gov
609-292-7406

From: Laura Clifford
Sent: Friday, May 18, 2018 11:05 AM
To: Bergman, Erica
Cc: Abdellatif.Sameh@epa.gov; Michael Draikiwicz
Subject: RE: Novartis EH Campus: GW RAPAs modification request

Erica –

Good morning. I did not hear back on the below so I reached out via a call earlier this week and still have not heard back. I am reaching out again because Novartis is planning on starting demolition in the area of wells S101L and S101U; Building 437, in the very near future (construction fencing is already up). They (their contractor) reached out to see if I had status on the abandonment request of these two wells.

If easier for you, I can contact Renee (GW Permitting) in regards to the request below. Let me know.

If I do not hear back from you by COB Wednesday 05/23, I will assume that it is easier for you and/or you have no issue with me reaching out to Renee in regards to Novartis GW RAPAs you said you had already forwarded to GW Permitting.

Thanks
Laura

From: Laura Clifford
Sent: Wednesday, May 09, 2018 10:17 AM
To: Bergman, Erica <Erica.Bergman@dep.nj.gov>
Cc: Abdellatif.Sameh@epa.gov; Michael Draikiwicz <MDraikiwicz@enviro-sciences.com>
Subject: RE: Novartis EH Campus: GW RAPAs modification request

Erica –

Good morning. We did not hear back on this so I am following up. Have you heard back from the permitting department and should I forward revised Groundwater Monitoring Tables and Figures to replace the ones in the packages submitted in February?

Thanks
Laura

From: Laura Clifford
Sent: Tuesday, April 24, 2018 4:14 PM
To: Bergman, Erica <Erica.Bergman@dep.nj.gov>
Cc: Abdellatif.Sameh@epa.gov; Michael Draikiwicz <MDraikiwicz@enviro-sciences.com>; Laura Clifford <LClifford@enviro-sciences.com>
Subject: Novartis EH Campus: GW RAPAs modification request

Erica –

ESI submitted on February 23, 2018, two GW RAPAs with groundwater monitoring plans for the Novartis East Hanover Site (SPR PI No. 009506); one for Chloroform and one for Sodium & Chloride. Novartis is requesting to remove two wells from each of the RAPAs/GW Monitoring Plans due to the upcoming demolition of Building 437. The wells are S101L and S101U which are located 50 – 100 feet southeast of Building 437 (see below). In each plan these wells were only included for DTW measurements, no sampling for analytical analysis. If the Applications are not under review yet, can Novartis just submit updated Groundwater Monitoring Plans and Figures depicting Sampling Location Maps as replacement pages to the previously submitted GW RAPAs?



Please let me know how we should proceed.

Thanks
Laura

Laura Clifford
Manager, Hydrogeology

Enviro-Sciences (of Delaware), Inc.

781 Route 15 S, 2nd Floor
Lake Hopatcong, New Jersey 07849
O: 973-398-8183, ext. 221
C: 973-356-9507
lclifford@enviro-sciences.com

ATTACHMENT B

From: Aber, Bruce <Aber.Bruce@epa.gov>
Sent: Wednesday, September 16, 2020 6:12 PM
To: Durr, Eurika <Durr.Eurika@epa.gov>
Cc: Abdellatif, Sameh <Abdellatif.Sameh@epa.gov>
Subject: Novartis Petition for Review

Re: Novartis Pharmaceuticals Corp. HSWA Renewal Permit Petition to the EAB
EPA ID No. NJD 002147023

Dear Ms. Durr:

As per your request, this confirms our telephone conversation this afternoon. At that time I informed you that your phone call to Mr. Sam Abdellatif is the first that either he or I have heard about the petition of the Novartis Pharmaceuticals Corporation (Novartis) HSWA Renewal Permit, which was submitted by Novartis' environmental consultant, ERM. I am the staff attorney who helped prepare the Permit documents for EPA Region 2, and I worked on it with Mr. Abdellatif, who is the lead Region 2 contact person (project manager) for the Permit and for the Novartis Site.

As I indicated during our phone call, EPA Region 2 management and staff have been working remotely due to COVID-19. EPA senior management and staff who were identified as "CC"s on the petition (EPA Regional Administrator Pete Lopez, EPA Deputy Division Director Judy-Ann Mitchell, and Project Manager Sam Abdellatif) have not reported to have received a copy of the petition. There is no Certificate of Service accompanying the August 13, 2020 petition letter, so it is unclear exactly how the petition was delivered to the three EPA senior management and staff who were cc'd on the petition letter.

After our call this afternoon I checked EPA's Cover Letter (from EPA Deputy Director Judy-Ann Mitchell to Novartis Pharmaceuticals Corp Head Mr. Robert E. Ackerman, Jr.) that accompanied EPA's final Notice of Issuance for this Permit. The Cover Letter explicitly stated: **"Please send a copy of any such petition for review by the Environmental Appeals Board to the Regional Administrator, EPA Region 2, to the attention of the undersigned, at mitchell.judy-ann@epa.gov concurrently with its filing with the EAB."** I will need to check to see if any email was in fact sent to Mrs. Mitchell. I am sure that if an email had in fact actually been sent to Mrs. Mitchell, that she would have immediately alerted EPA management and staff, including Mr. Abdellatif and me, about this petition.

Further, EPA's mail room has a process for notifying EPA Region management and staff when hard-copy mail is received, but there has been no indication from the mail room that the Novartis petition was received by EPA Region 2. I will have to check to confirm.

In summary, based on the absence of prior receipt of this petition, EPA needs time now to assess the content of the petition and decide how to respond to it. I took a cursory look at the petition

letter and it appears that Novartis is asking for minor technical corrections to be made to some of the final permit documents. It is unclear if the petition demonstrates, as it is required to do under 40 C.F.R. Section 124.19(a), that the technical issues now being raised were raised by Novartis during the public comment period (September 12, 2019 to October 26, 2019). Novartis is not contesting EPA's selection of the remedy.

Given the end of fiscal year commitments that EPA staff and management are presently working on satisfying, can the EAB kindly allow a reasonable period of time after the 30th of this month, say until **October 30, 2020**, for EPA Region 2 to get back to the EAB with a Status Report concerning our response to the petition?

Thank you very much in advance for your consideration of this request.

Sincerely,

Bruce Aber
Assistant Regional Counsel
Office of Regional Counsel
U.S. Environmental Protection Agency, Region 2
290 Broadway, 16th Floor
New York, NY 10007-1866
(212) 637-3224 (phone)
Aber.bruce@epa.gov

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