

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

In the Matter of:)	
)	
Novartis Pharmaceuticals Corporation)	
)	
Permittee)	Appeal No.: RCRA 20-01
)	
Final RCRA Permit)	
EPA Identification No. NJD 002147023)	
)	

**JOINT STATUS REPORT, UNOPPOSED MOTION FOR VOLUNTARY REMAND, AND
JOINT MOTION TO DISMISS WITHOUT PREJUDICE IF VOLUNTARY REMAND IS
GRANTED**

I. JOINT STATUS REPORT

This is in response to the Environmental Appeals Board’s October 21, 2020 Order (“Order”) Granting the United States Environmental Agency Region 2’s (“EPA”) October 20, 2020 Motion to Stay Appeal. The Order directed the parties to file a Status Report no later than Friday, November 20, 2020.

On October 27, 2020, counsel for EPA sent representatives of Novartis Pharmaceuticals Corporation (“Novartis”) and its technical consultant Environmental Resources Management Inc. (“ERM”) proposed minor revisions to the permit language for 2 RCRA permit documents (Module 2 and Module 3 of the permit), and minor revisions to the Statement of Basis.

On October 29, 2020, representatives of Novartis and ERM informed EPA that they had reviewed the changes that are proposed to be made to the 2 permit documents (as well as to the Statement of Basis) and were in agreement on the revisions.

II. UNOPPOSED MOTION FOR VOLUNTARY REMAND

The United States Environmental Protection Agency Region 2 (“EPA”) and Environmental Resources Management Inc. (“ERM”), acting on behalf of Novartis Pharmaceuticals Corporation (“Novartis”) (EPA and Novartis shall hereinafter be referred to collectively as “the Parties”) respectfully provide the Environmental Appeals Board (“EAB”) with this Unopposed Motion for Voluntary Remand.

A. BACKGROUND

1. On September 12, 2019, EPA issued a draft RCRA HSWA Permit (“draft Permit”) renewal to Novartis for operations at its East Hanover, New Jersey facility. The draft Permit provided a 45 day opportunity for public comment. A public meeting was held on October 7, 2019. Novartis was the only entity to attend the public meeting and it was the only entity to provide public comments. No private persons/citizens attended. EPA responded to the public comments and issued the final RCRA HSWA Permit (“final Permit” or “Permit”) renewal to Novartis on July 15, 2020. The effective and expiration dates of the EPA’s final Permit were August 15, 2020 and August 14, 2030, respectively.
2. On August 14, 2020, prior to the effective date, ERM, on behalf of Novartis, filed a petition letter, dated August 13, 2020 (hereinafter “the Petition”) to the Environmental Appeals Board (EAB) seeking a review of the Permit. The Petition did not seek review of the selected final remedies for corrective action, but only of six relatively minor technical issues that would require minor modifications to the text of the permit documents.
3. On September 16, 2020, the clerk of the EAB contacted an EPA technical staff member and the undersigned EPA attorney to inquire as to the status of EPA’s response to the Petition. At that time, the undersigned attorney informed the EAB clerk by phone, followed by email notification on same date, that EPA was unaware that a Petition had been filed, as none of the EPA Region 2

personnel copied on the Petition appeared to have received it. Moreover, no certificate of service accompanied the Petition which was electronically filed with the EAB. Subsequently, by Order of September 17, 2020, the EAB allowed EPA until Friday October 30, 2020 to file a response to the Petition.

4. As a result of EPA's consideration of positions asserted in the Petition, EPA has determined that revision of the contested Permit provisions consistent with the Petition (with one exception to which Novartis has consented) is appropriate.
5. On October 15, 2020, EPA and representatives of Novartis including ERM held a conference call to discuss the Petition. At that time, the Parties reached a tentative agreement in principle, subject to written memorialization and review and ratification by the Parties, on revisions to the language of the permit documents in order to address the technical issues raised in the Petition.
6. On October 20, 2020, EPA filed a Motion for Stay of the Permit Appeal for thirty (30) days to allow the Parties to conclude settlement discussions.
7. On October 21, 2020, the EAB issued an Order granting a stay until November 30, 2020, but requiring that a Joint Status Report be submitted by November 20, 2020.
8. On October 27, 2020, counsel for EPA sent representatives of Novartis, including ERM, proposed changes to the language for 2 permit documents (Module 2 and Module 3 of the permit) and to the Statement of Basis.
9. On October 29, 2020, representatives of Novartis informed EPA that they had reviewed the changes that were proposed to be made to the 2 permit documents and to the Statement of Basis and they were in agreement with the revisions.

10. Based on the agreed upon changes that are planned to be made to the 2 permit documents and to the Statement of Basis, the issues raised in the Petition have been addressed and the Parties agree that the Petition is now able to be withdrawn through the proposed Voluntary Remand and Joint Motion to Dismiss without Prejudice, as described further below.

B. VOLUNTARY REMAND

11. The Board has the inherent discretionary authority to grant voluntary motions for remand in permit appeal proceedings. In re Peabody Western Coal Company, 14 E.A.D. 712, 2010 WL 3258142, *5 (Aug 13, 2020). “The Board will typically grant a motion for voluntary remand in a case where the permit issuer “shows good cause for its request and/or granting the motion makes sense from an administrative or judicial efficiency standpoint.” Id.
12. The Board also has the authority to grant remand of a Petition to a Region so that the agreed-upon revisions can be incorporated into the Final Permit. In re Rohm & Haas Company (RCRA Appeal No. 98-2) (Oct. 5, 2000).
13. As a result of EPA’s consideration of the issues raised in Petitioner’s August 13, 2020 Petition, EPA has determined that revision of the contested provisions is appropriate.
14. Therefore, EPA believes that voluntary remand of the Permit is the best course of action for the purpose of revising only the minor technical issues raised in the Petition for which the Parties have agreed upon a resolution. Following the voluntary remand and withdrawal of the Petition as a result of the Joint Motion to Dismiss, as set forth in the section below, the Petitioner has agreed to request a class 1 modification of the Permit to incorporate the agreed upon changes. EPA

would then approve a class 1 permit modification (and the Permittee shall send public notice of the modification as per 40 C.F.R. Section 270.42(a)(1)(ii)) in accordance with the procedural requirements of 40 C.F.R. Section 124.5 and 40 C.F.R. Sections 270.41 and 270.42(a)(1)(ii).

15. A remand is in the best interests of administrative efficiency as it is expected to allow for the resolution of this appeal.

16. As per 40 C.F.R. Section 124.9(f)(2), counsel for EPA has conferred with representatives of Novartis and its consultant, ERM, and Novartis has advised that it supports the request for a voluntary remand being made in this motion.

III. JOINT MOTION TO DISMISS WITHOUT PREJUDICE IF VOLUNTARY REMAND IS GRANTED

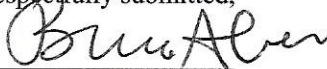
17. If the Board grants the Unopposed Motion for Voluntary Remand as set forth above, the Parties jointly move the Board for voluntary dismissal of the Petition without prejudice to the Petitioner refiling the Petition being dismissed if the Petitioner should conclude that that the agreed upon changes are unexpectedly not implemented. Upon remand and withdrawal of the Petition as a result of the Joint Motion to Dismiss, the Permittee will request a class 1 permit modification in accordance with 40 C.F.R. Section 270.42(a)(1) to incorporate the changes that have been agreed to, and EPA would approve the class 1 permit modifications (and the Permittee shall send public notice of the modification as per 40 C.F. R. Section 270.42(a)(1)(ii)) in accordance with the procedural requirements of 40 C.F.R. Section 124.5 and 40 C.F.R. Sections 270.41 and 270.42(a)(1)(ii).

18. Wherefore, based on the facts and law set forth above, the Parties move the Board to (1) grant the Unopposed Motion for Remand, and (2) if the Unopposed Motion for Remand is granted, grant the Parties' Joint Motion to Dismiss the Petition for Review without Prejudice.

19. The undersigned counsel for EPA hereby certifies that the above Status Report and above two motions complies with the word limit of 40 CFR Section 124.19(f)(5) because this motion contains 1705 words.

Dates: November 18, 2020

Respectfully submitted,



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In the Matter of Novartis Pharmaceuticals Corporation, Appeal No RCRA-20-01.

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing Joint Status Report, Unopposed Motion for Voluntary Remand, and Joint Motion to Dismiss Without Prejudice if Voluntary Remand is Granted, In the Matter of Novartis Pharmaceuticals Corporation, RCRA Appeal No. 20-01, were sent to the following persons in the manner indicated.

By Electronic Email

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CLERK OF THE ENVIRONMENTAL APPEALS BOARD

U.S. Environmental Protection Agency

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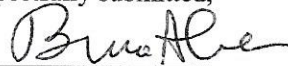
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Respectfully submitted,



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