IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re: GRACEWAY PHARMACEUTICALS, LLC, *et al.*,[1] Debtors.	Chapter 11 Case No. 11-13036 (PJW) Jointly Administered
KIP HORTON, Liquidating Trustee of the Graceway Liquidating Trust Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant.	Adv. Proc. No. _____

COMPLAINT FOR TURNOVER OF PROPERTY AND FOR PAYMENT OF MONEY OWED TO THE LIQUIDATING TRUST

Plaintiff Kip Horton, in his capacity as the liquidating trustee (the "**Liquidating Trustee**" or "**Plaintiff**") of the Graceway Liquidating Trust (the "**Liquidating Trust**"), by and through his undersigned counsel, pursuant to 11 U.S.C. § 542, hereby files this *Complaint for Turnover of Property and for Payment of Money Owed to the Liquidating Trust* (the "**Complaint**"), against the United States Food and Drug Administration ("**Defendant**" or "**FDA**") and avers in support thereof, the following:

[1] The Debtors in these cases, along with the last four digits of each Debtor's federal tax identification number, are: Graceway Pharma Holding Corp., a Delaware corporation (9175), Case No. 11-13037 (PJW); Graceway Holdings, LLC, a Delaware limited liability company (2502), Case No. 11-13038 (PJW); Graceway Pharmaceuticals, LLC, a Delaware limited liability company (5385), Case No. 11-13036 (PJW); Chester Valley Holdings, LLC, a Delaware limited liability company (9457), Case No. 11-13039 (PJW); Chester Valley Pharmaceuticals, LLC, a Delaware limited liability company (3713), Case No. 11-13041 (PJW); Graceway Canada Holdings, Inc., a Delaware corporation (6663), Case No. 11-13042 (PJW); and Graceway International, Inc., a Delaware corporation (2399), Case No. 11-13043 (PJW). The mailing address for Graceway Pharmaceuticals, LLC is 340 Martin Luther King Jr. Blvd., Suite 500, Bristol, TN 37620 (Attn: John Bellamy). On October 4, 2011, Graceway Canada Company filed an application in the Ontario Superior Court of Justice (Commercial List) pursuant to the *Courts of Justice Act*, R.S.O. 1990, c. C. 43.

JURISDICTION AND VENUE

1. This is an adversary proceeding brought by Plaintiff for turnover of property of the estate under section 542 of title 11 of the United States Code (the "**Bankruptcy Code**").

2. This Court has subject matter jurisdiction over this adversary proceeding, pursuant to 28 U.S.C. §§ 157 and 1334(b) and the *Amended Standing Order of Reference* for the United States District of Delaware, dated February 29, 2012.

3. This adversary proceeding is a core proceeding pursuant to 28 U.S.C. § 157(b)(1) and (2) and this Court may enter a final order consistent with these statutes and Article III of the United States Constitution.

4. Venue is proper in the Bankruptcy Court for the District of Delaware (the "**Court**"), pursuant to 28 U.S.C. § 1409.

5. In accordance with Rule 7008-1 of the Local Rules of Bankruptcy Practice and Procedure of the United States Bankruptcy Court for the District of Delaware, the Plaintiff hereby states that it consents to the entry of final orders or judgments by this Court if it is determined that the Court, absent the consent of the parties, cannot enter final orders or judgments consistent with Article III of the United States Constitution.

PARTIES

6. Plaintiff is the Trustee of the Liquidating Trust established pursuant to the Plan and the Liquidating Trust Agreement, as defined below.

7. Defendant, the United States Food and Drug Administration, is an agency of the United States Government within the Department of Health and Human Services. *See* 21 U.S.C. § 393(a).

BACKGROUND

A. The Debtors' Bankruptcy Cases

8. On September 27, 2011 (the "**Petition Date**") the above-captioned Debtors ("**Graceway**" or the "**Debtors**") each filed voluntary petitions for relief under chapter 11 of the Bankruptcy Code.

9. On April 20, 2012, the Court entered the *Findings of Fact, Conclusions of Law and Order Confirming the Debtors' First Amended Joint Plan of Liquidation* [D.I. 722], confirming the Debtors' proposed plan of reorganization [D.I. 551] (the "**Plan**").

10. The Effective Date of the Plan was May 4, 2012 [D.I. 740] and pursuant to the Plan, the Debtors and the Liquidating Trustee executed that certain Liquidating Trust Agreement, dated May 4, 2012 (the "**Liquidating Trust Agreement**"), which established the Liquidating Trust for the purpose of liquidating the Debtors' assets and distributing the proceeds thereof.

11. Pursuant to the Section 8.1 of the Plan, the Liquidating Trustee has the right and standing to enforce "any and all Causes of Action against any Entity and rights of the Debtors that arose before or after the Petition Date, including, but not limited to, the rights and powers of a trustee or debtor-in-possession…."

12. Under the terms of the Liquidating Trust Agreement, the Liquidating Trustee is, among other things, authorized to investigate, prosecute and compromise Causes of Action on behalf of the Trust for the benefit of the creditors of the Debtors.

B. Graceway's PDUFA Refund Demand

13. Prior to the Petition Date, Graceway was engaged in the manufacture, marketing and sale of pharmaceutical products throughout the United States. Specifically relevant to this

Complaint, Graceway was the sponsor of two formulations of imiquimod, marketed under the trade names of "Aldara" and "Zyclara," respectively.

14. Aldara was initially approved on February 27, 1997 for the treatment of external genital warts/condyloma acuminate ("**EGW**") and, in 2004, was further approved for the treatment of actinic keratosis ("**AK**") superficial basal cell carcinoma.

15. On December 16, 2008 Graceway submitted NDA 22-483 to the FDA for approval of Zyclara for the treatment of AK.

16. On October 16, 2009, the Division of Dermatology and Dental Products (the "**Division**") issued a response naming one deficiency in Graceway's application. Graceway submitted a formal appeal of this decision and, on January 15, 2010 Graceway's appeal was granted.

17. On January 29, 2010, Graceway resubmitted NDA 22-483 for review.

18. While NDA 22-483 was pending, Graceway was also preparing to submit an application for approval of Zyclara for the treatment of EGW, and on February 8, 2010 Graceway submitted NDA 201-153 seeking approval of Zyclara for the treatment of EGW.

19. Following FDA guidance, Graceway paid the full fee, $1,405,500.00, associated with the filing of an original application in connection with its submission of NDA 201-153.

20. On March 25, 2010, the FDA issued final approval of NDA 22-483 for the use Zyclara for the treatment of AK.

21. On April 23, 2010, the FDA informed Graceway that NDA 201-153 was accepted for filing.

22. On May 21, 2010, the FDA requested that Graceway amend NDA 201-153 by submitting draft labeling that combines the EGW usage with the recently-approved AK usage.

23. At the same time, the FDA also requested that Graceway submit a corresponding supplement to NDA 22-483, so that upon approval of the two NDAs, they would be merged under NDA 22-483.

24. Under 21 U.S.C. § 379h(a)(1)(A)(ii), the application fee for a supplement is half the amount for a fee for an original application.

25. A "supplement" is defined as "a request to the Secretary to approve a change in a human drug application which has been approved." *See* 21 U.S.C. § 379g(2).

26. If an application or supplement is withdrawn after the application or supplement is filed, the FDA "may refund the fee or a portion of the fee if no substantial work was performed on the application or supplement after the application or supplement was filed." *See* 21 U.S.C. § 379h(a)(1)(G).

27. Following approval of the NDA 22-483 for Zyclara to treat AK, NDA 201-153 was in the nature of a supplement to NDA 22-483, rather than an original application in its own right.

28. The FDA acknowledged this change in the nature of NDA 201-153, when it requested that Graceway file a corresponding supplement to NDA 22-483 and when it indicated that if NDA 201-153 were to be approved, it would be merged with NDA 22-483.

29. Accordingly, while Graceway paid the full application fee for an original application when it filed NDA 201-153, following the approval of NDA 22-483 and the FDA's indication that it was treating NDA 201-153 as a supplement, the applicable fee for NDA 201-153 was that required for a supplement, rather than a full application.

30. At the time Graceway filed NDA 201-153, the applicable fee for an application was $1,405,500.00 while the applicable fee for a supplement was $702,750.00. *See Prescription Drug User Fee Rates for Fiscal Year 2010*, 74 Fed. Reg. 38451-01, 38455 (Aug. 3, 2009).

31. If a sponsor believes that it is entitled to a refund or adjustment of a fee paid under 21 U.S.C § 379h, it may file a request for such consideration, as long as that request is submitted within 180 days after the fee was due. *See* 21 U.S.C. § 379h(i).

32. On July 29, 2010, by letter from then Senior Vice President of Regulatory Affairs Sean Brennan, Graceway submitted a written request for adjustment to the fee paid for NDA 201-153.

33. Specifically, Graceway requested that the FDA refund the difference between the full application fee paid, and the fee that would be applicable if NDA 201-153 were treated as a supplement (the "**PDUFA Refund**" or the "**PDUFA Refund Amount**").

34. The PDUFA Refund Amount is $702,750.00. *See* Paragraph 32, *supra*.

35. On February 19, 2014, the Liquidating Trustee, through its counsel, DLA Piper LLP (US), sent a letter to the Defendant requesting an update as to the status of the PDUFA Refund Amount and requesting that FDA promptly process the PDUFA Refund Amount to the Liquidating Trust.

36. The PDUFA Refund was not paid to the Debtors prior to the Effective Date, and has not been paid to the Liquidating Trust.

CLAIM FOR RELIEF

COUNT I: Turnover of Estate Property Pursuant to 11 U.S.C. § 542(a)

37. The allegations of paragraphs 1-36 are re-alleged and incorporated by reference as if more fully set forth herein.

38. Section 542(a) of the United States Bankruptcy Code provides, in pertinent part:

> [A]n entity, other than a custodian, in possession, custody, or control during the case, of property that the trustee may use, sell, or lease under section 363 of [the Bankruptcy Code],...shall deliver to the trustee, and account for, such property or the value of such property....
>
> 11 U.S.C. § 542(a).

39. Section 541 of the Bankruptcy Code provides that a debtor's estate is comprised of, subject to certain exceptions, "all legal or equitable interests of the debtor as of the commencement of the case." 11 U.S.C. § 541(a)(1). It further provides that a debtor's estate includes any "[p]roceeds, product, offspring, rents, or profits of or from property of the estate." 11 U.S.C. § 541(a)(6).

40. The PDUFA Refund is estate property that is in Defendant's possession and is to be turned over to the Liquidating Trust, as successor in interest to the Debtors.

41. Prior to the Effective Date, the PDUFA Refund, its proceeds, and the funds due and owing as a result of the PDUFA Refund Amount, constituted property of the Debtors' Estate pursuant to 11 U.S.C. § 541.

42. The PDUFA Refund became property of the Liquidating Trust on the Effective Date of the Plan.

43. The FDA has not processed the PDUFA Refund to the Debtors or the Liquidating Trust and, therefore, is currently in possession or control of the PDUFA Refund Amount, which is property of the estate.

44. The Liquidating Trustee is charged with the recovery of assets for the benefit of the Plans' Beneficiaries and the Liquidating Trustee would be entitled to use, sell, or lease the PDUFA Refund and the proceeds thereof, subject to the terms of the Plan.

45. Therefore, pursuant to 11 U.S.C. § 542(a), the Liquidating Trustee is entitled to the turnover of the PDUFA Refund Amount.

COUNT II: Judgment for Debt Owed to the Debtors Pursuant to 11 U.S.C. § 542(b)

46. The allegations of paragraphs 1-36, and 39 are re-alleged and incorporated by reference as if more fully set forth herein.

47. Section 542(b) of the Bankruptcy Code provides, in pertinent part:

> [A]n entity that owes a debt that is property of the estate and that is matured, payable on demand, or payable on order, shall pay such debt to, or on the order of, the trustee, except to the extent such debt may be offset under section 553 of [the Bankruptcy Code] against a claim against the debtor.
>
> 11 U.S.C. § 542(b).

48. The Defendant is obligated to pay to the Liquidating Trust the sum of $702,750.00, on account of the PDUFA Refund Amount.

49. The PDUFA Refund Amount is matured, payable on demand, and/or payable on order.

50. The Defendant has not paid the debt owed to the Liquidating Trust on account of the PDUFA Refund Amount.

51. Accordingly, the Liquidating Trustee is entitled to judgment (i) declaring that the FDA owes the Liquidating Trust $702,750.00, on account of the PDUFA Refund Amount and (ii) directing the FDA to make payment to the Liquidating Trust on account of such debt.

PRAYER FOR RELIEF:

WHEREFORE, Plaintiff requests that this Court grant him the following relief against Defendant as to Counts I and II of this Complaint, and that the Court enter judgment against Defendant:

A. Requiring Defendant to deliver to Liquidating Trustee, and account for, such property or the value of such property, or the proceeds thereof, the amount of $702,750.00 on account of the PDUFA Refund; or

B. Requiring Defendant to pay the debt or the proceeds thereof to, or on the order of, Liquidating Trustee, in the amount of $702,750.00, on account of the PDUFA Refund; and

C. Granting Plaintiff such other and further relief as the Court deems just and proper.

Dated: July 30, 2014
Wilmington, Delaware

Respectfully submitted,

/s/ Stuart M. Brown

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