UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 2

In the Matter of Pharmaceutical Innovations, Inc. Respondent Proceeding Under the Federal Insecticide, Fungicide and Rodenticide Act, as amended.

CONSENT AGREEMENT AND FINAL ORDER

Docket No. FIFRA-02-2017-5101

PRELIMINARY STATEMENT

This administrative proceeding for the assessment of a civil penalty is initiated pursuant to Section 14(a) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 U.S.C. § 1361(a) (hereinafter referred to as "FIFRA" or the "Act"), and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, 40 C.F.R. Part 22 (hereinafter "CROP").

Complainant in this proceeding is the Director of the Division of Enforcement and Compliance Assistance, United States Environmental Protection Agency, Region 2 ("EPA"). Pursuant to Section 22.13(b) of the CROP, where the parties agree to settlement of one or more causes of action before the filing of an Administrative Complaint, a proceeding may be simultaneously commenced and concluded by issuance of a Consent Agreement and Final Order ("CA/FO") pursuant to 40 C.F.R. §§ 22.18(b)(2) and 22.18(b)(3). Complainant and Respondent agree that settling this matter by entering into this CA/FO pursuant to 40 C.F.R. §§ 22.13(b),

22.18(b)(2) and 22.18(b)(3) of the CROP, is an appropriate means of resolving this matter without litigation.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Respondent is Pharmaceutical Innovations, Inc., a New Jersey corporation (hereinafter "Respondent" or "PI").

2. Respondent is a "person" as that term is defined in FIFRA § 2(s), 7 U.S.C. § 136(s), and is subject to FIFRA and the regulations promulgated thereunder.

3. Since at least 1991, Respondent maintained and/or operated an "establishment" as defined in Section 2(dd) of FIFRA, 7 U.S.C. § 136(dd), located at 897 Frelinghuysen Avenue, Newark, New Jersey 07114 ("Respondent's Facility" or "the Facility"). EPA assigned the establishment number 65071-NJ-001.

4. At the Facility, from at least October 1, 2014 to October 1, 2015, Respondent produced and distributed or sold "PI Spray" and "PI Spray II," antibacterial cleaners produced and distributed or sold for the purpose of cleaning ultrasound probes, transducers, mammography compressor plates, cassettes and other inanimate hard surfaces in healthcare facilities.

5. Respondent is a "producer" within the meaning of Section 2(w) of FIFRA, 7 U.S.C. § 136(w).

6. Respondent is a "distributor or seller" within the meaning of Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg).

7. "To distribute or sell" is defined by Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), as "to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver."

8. Respondent is a "wholesaler," "dealer," "retailer," or "other distributor" within the meaning of Section 14(a)(1) of FIFRA, 7 U.S.C. § 136l(a)(1).

9. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines a "pest" as any insect, rodent, nematode, fungus, weed, or any form of terrestrial or aquatic plant or animal life or virus, bacteria or other micro-organism.

10. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines the term "pesticide" as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.

11. Section 2(mm) of FIFRA, 7 U.S.C. § 136(mm) defines the term "antimicrobial pesticide" as, among other things "a pesticide that (A) is intended to (i) disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms."

12. Title 40 C.F.R. § 152.15(a)(1) states, in part, that a substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if "(a) [t]he person who distributes or sells the substance claims, states or implies (by labeling or otherwise): (1) [t]hat the substance (either by itself or in combination with any other substance) can or should be used as pesticide. . ."

13. Title 40 C.F.R. § 152.15(c) states that a substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if . . . "[t]he person who distributes or sells the substance has actual or constructive knowledge that the substance will be used or is intended to be used, for a pesticidal purpose."

14. Pursuant to Section 3 of FIFRA, 7 U.S.C. § 136a, all pesticides distributed or sold must be registered with EPA.

15. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), states that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide that is not registered with EPA.

16. Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines "label" as the written, printed or graphic matter on, or attached to, the pesticide or any of its containers or wrappers.

17. Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines "labeling" as all labels or other written, printed or graphic matter (a) accompanying the pesticide or (b) to which reference is made in literature accompanying the pesticide.

18. Section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A) states that a pesticide is misbranded if its labeling bears any statement, design or graphic representation relative thereto or to its ingredients which is false and misleading in any particular.

19. Section 2(q)(1)(G), 7 U.S.C. § 136(q)(1)(G) states that a pesticide is misbranded if the label does not contain a warning or caution statement which is adequate to protect health and the environment.

20. Section 2(q)(2)(C)(iii) & (iv), 7 U.S.C. §§ 136(q)(2)(C)(iii) & (iv) states that a pesticide is misbranded if the label does not contain the net weight or measure of the content and the registration number assigned to the pesticide, and the use classification.

21. 40 C.F.R. §§ 156.10(a)(5)(i) through (x) states that a pesticide is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Such claims may include false and misleading statements as to the efficacy (40 C.F.R. § 156.10(a)(5)(ii)) or safety (40 C.F.R. § 156.10(a)(5)(ix)) of the product or its ingredients.

22. 40 C.F.R. § 156.10(g) states that the label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients."

23. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), states that it shall be unlawful for any person in any state to distribute or sell to any person any pesticide that is misbranded.

24. On or about November 4, 2015, pursuant to Sections 8 and 9 of FIFRA, 7 U.S.C. §§ 136f and 136g, an authorized inspector from EPA Region 2 conducted an inspection ("the Inspection") at the Respondent's Facility.

25. At the Inspection, EPA's inspector learned that the Respondent produces, distributes and sells the PI Spray and PI Spray 2 products for use as antibacterial cleaners of ultrasound and other medical equipment.

26. At the Inspection, EPA's inspector collected physical samples of the PI Spray and PI Spray 2 products.

27. At the Inspection, EPA's inspector obtained documentary evidence of the distribution and sale of the PI Spray and PI Spray 2 products.

28. The label and/or labeling for the PI Spray product had the following claims: "Ultrasound Antibacterial Solution," "Bactericidal Activity," "Tuberculocidal activity."

29. The label and/or labeling for the PI Spray 2 product had the following claims: "Antibacterial Solution for Ultrasound and Mammography," "PI-Spray 2 Antibacterial Solution is a hospital use bactericide," and "Bactericidal activity."

30. Respondent's website advertised the PI Spray and PI Spray 2 products as being "[t]he Antibacterial cleaner designed for between patient use." The Material Safety Data Sheet (MSDS) for the PI Spray and PI Spray 2 products included the following statement: "Antibacterial solution".

31. The PI Spray and the PI Spray 2 products were intended for preventing, destroying, repelling or mitigating viruses, bacteria, and/or other microorganisms, which are "pests."

32. The PI Spray and PI Spray 2 products were required to be registered with EPA prior to their sale and distribution by Respondent.

33. From October 1, 2014 to October 1, 2015, Respondent sold or distributed PI Spray on at least 225 occasions.

34. From October 1, 2014 to October 1, 2015, Respondent sold or distributed PI Spray 2 on at least 275 occasions.

35. The PI Spray and PI Spray 2 products were not registered with EPA prior to their sale and distribution by Respondent.

36. Each of Respondent's sales or distributions of the unregistered pesticides PI Spray and PI Spray 2, as described in Paragraphs 33 and 34, above, constitutes an unlawful act pursuant to Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).

37. The labels and/or labeling on or accompanying each container of PI Spray and PI Spray 2 sold by the Respondent as described in Paragraphs 33 and 34, above, displayed false and misleading claims within the meaning of 40 C.F.R. §§ 156.10(a)(5)(ii) & (ix), including the following: "Efficacy Tests Have Demonstrated That PI-Spray is an Effective Antibacterial," "Efficacy Tests Have Demonstrated that P-Spray Transducer Solution is an Effective Bactericide," "Safe for Probes and Transducers," and "Contained for Safety."

38. The labels for the PI Spray and PI Spray 2 products sold by the Respondent as described in Paragraphs 33 and 34, above, did not display an EPA producer establishment number, as required by 40 C.F.R. § 156.10(a)(1)(v).

39. The labels for the PI Spray and PI Spray 2 products sold by the Respondent as described in Paragraphs 33 and 34, above, did not bear the terms "active ingredients" and "inert ingredients" and did not include the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients, as required by 40 C.F.R. § 156.10(g).

40. The label for the PI Spray 2 product sold by the Respondent as described in Paragraph 34, above, did not display a warning that was adequate to protect health and the environment, as required by Section 2(q)(1)(G), 7 U.S.C § 136(q)(1)(G).

41. Each of Respondent's sales or distributions of the PI Spray and PI Spray 2 products as described in Paragraphs 33-34 and 37-40, above is a sale or distribution of a misbranded pesticide.

42. Each of Respondent's sales or distributions of the PI Spray and PI Spray 2 products as described in Paragraphs 33-34 and 37-40, above constitutes an unlawful act pursuant to Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

43. In August 2017, Respondent submitted to EPA evidence that it had conducted a voluntary recall of the remaining PI Spray and PI Spray 2 products in possession of its customers in the United States.

44. In August 2017, Respondent provided to EPA evidence of its proper disposal of the PI Spray and PI Spray II product recalled as described in paragraph 43, above.

CONSENT AGREEMENT

Based upon the foregoing, and pursuant to Section 22.18 of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation or Suspension of Permits, 40 C.F.R. § 22.18, it is hereby agreed that:

1. Respondent shall hereinafter maintain compliance with the statutory provisions of FIFRA, as amended, 7 U.S.C. § 136 *et seq*., and its implementing regulations, including the requirements which prohibit the sale of unregistered and misbranded pesticides.

2. Respondent certifies that, as of the date of execution of this CA/FO, it is in compliance with the statutory provisions of Section 12 of FIFRA, 7 U.S.C. § 136j, and its implementing regulations.

3. Respondent further certifies that:

(i) As of September 8, 2016 Respondent stopped the production of the PI Spray product.

(ii) As of May 4, 2016, Respondent stopped the production of the PI Spray 2 product.

(iii) As of February 24, 2017, Respondent stopped the production of PI Spray 2 which contained a revised label that had removed the pesticidal claim on it.

(iv) As of April 13, 2017, Respondent is no longer producing, marketing, distributing or selling the PI Spray and PI Spray 2 products and presently retains no stock of either product; and

(v) Respondent's sale or distribution of: (1) products under the product name PI Spray or PI Spray 2 or (2) products that are pesticides, including products considered to be intended for a pesticidal purpose, as set forth at 40 C.F.R. Section 152.15, without first registering such products in accordance with FIFRA § 3, 7 U.S.C. § 136a, would constitute an unlawful act pursuant to Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).

4. Respondent shall pay, either by certified check or electronically by Fedwire, a civil penalty in the amount of **Two Hundred and Fifty Thousand Dollars ($250,000.00)**. Payment shall be received (if made by check) or effected (if implemented by Fedwire) on or before 30 days from the Regional Administrator's signature of the Final Order. If the payment is

made by check, then the check shall be made payable to the "Treasurer of the United States of America" and shall be mailed by one of the following two methods:

a. STANDARD DELIVERY

The check shall be mailed to:

United States Environmental Protection Agency
Fines & Penalties
Cincinnati Finance Center
P.O. Box 979077
St. Louis, Missouri 63197-9000

b. SIGNED RECEIPT CONIFRMATION DELIVERY (Fedex, DHL, UPS, USPS, Certified, Registered, etc.)

United States Environmental Protection Agency
Government Lockbox 979077
1005 Convention Plaza
SL-MO-C2-GL
St. Louis, MO 63101

The check shall be identified with a notation thereon listing the following: *In the Matter of Pharmaceutical Innovations, Inc.* and shall bear the Docket No. FIFRA-02-2017-5101.

If Respondent chooses to make payment electronically through Fedwire,

Respondent shall provide the following information to its remitter bank (Federal Reserve Bank of New York) when payment is made:

a. Amount of payment
b. SWIFT address: **FRNUS33, 33 Liberty Street, New York, NY 10045**
c. Account Code for Federal Reserve Bank of New York receiving payment: **68010727**
d. Federal Reserve Bank of New York ABA routing number: **021030004**
e. Field Tag 4200 of the Fedwire message should read: "**D 68010727 Environmental Protection Agency**"

f. Name of Respondent: **Pharmaceutical Innovations, Inc.**
g. Case Docket Number: **FIFRA-02-2017-5101**

5. Failure to pay the full amount of the penalty, according to the above provisions, will result in the referral of this matter to the United States Department of Justice and/or the United States Department of Treasury for collection and/or other appropriate action.

6. If timely payment is not received on or before the due date, then Respondent shall also pay the following amounts:

a. Interest. If Respondent fails to make payment on or before the due date, interest for said payment shall be assessed at the annual rate established by the Secretary of the Treasury pursuant to 31 U.S.C. Section 3717 and 26 U.S.C. Section 6621 from the date said payment was required to have been made through the date said payment has been received ,

b. Handling Charges. Pursuant to 31 U.S.C. Section 3717(e)(1), a monthly handling charge of fifteen dollars ($15.00) shall be assessed for each thirty (30) day calendar day period or any portion thereof, following the date the payment was to have been made, in which payment of the amount remains in arrears.

c. Attorney Fees, Collection Costs, Nonpayment of Penalty. If Respondent fails to pay the amount of the assessed penalty on time, pursuant to 42 U.S.C. Section 7413(d)(5), in addition to such assessed penalty and interest and handling assessments, Respondent shall also pay the United States' enforcement expenses, including but not limited

to attorney fees and costs incurred by the United States for collection proceedings, and a quarterly nonpayment penalty for each calendar quarter during which such a failure to pay persists. Such nonpayment penalty shall be ten percent (10%) of the aggregate amount of Respondent's outstanding penalties and nonpayment penalties accrued from the beginning of such quarter.

7. If in the future, EPA believes that the information which Respondent certified to, pursuant to paragraph 3 above, was inaccurately or falsely certified, and EPA relied upon such information for purposes of settlement, EPA will so advise Respondent of its belief and basis, and will afford the Respondent thirty (30) days to submit comments to EPA. After review of any comments submitted, EPA shall provide a written statement of its decision to the Respondent, which decision shall be final and binding upon Respondent. Respondent agrees that false certification shall constitute a violation of this CA/FO and Respondent shall be liable to EPA for a lump stipulated penalty of $50,000 for such false certification.

8. Nothing in this document is intended or shall be construed to waive, prejudice or otherwise affect the right of EPA, or the United States, from pursuing any appropriate remedy, sanction or penalty prescribed by law against Respondent, if Respondent makes any material misrepresentations or provides materially false information herein or in any document submitted pursuant to this Consent Agreement.

9. Unless Respondent provides EPA with a written explanation in accordance with paragraph 10 below, all stipulated penalties are due and payable within thirty (30) calendar days of the Respondent's receipt from EPA of a written demand for payment of the penalties.

Respondent agrees that such demand may be mailed to the addressee identified in Paragraph 14, below. All stipulated penalty payments shall be made in accordance with the payment instructions in paragraph 4 of this Consent Agreement. Penalties shall accrue as provided above regardless of whether EPA has notified the Respondent of the violation or made a demand for payment, but need only be paid upon demand. Any payment of stipulated penalties shall be in addition to any other payments required under any other paragraph of this Consent Agreement. Nothing in this Consent Agreement, including payment of penalties identified in this Consent Agreement, shall preclude EPA from initiating a separate criminal investigation pursuant to 18 U.S.C. § 1001 *et seq.* or any other applicable laws. Failure to pay any stipulated penalty in full will result in referral of this matter to the United States Department of Justice or the United States Department of Treasury for collection and/or other appropriate action.

10. After receipt of a demand from EPA for stipulated penalties pursuant to paragraph 9 above, Respondent shall have thirty (30) calendar days in which to provide Complainant with a written explanation of why it believes a stipulated penalty is not appropriate for the cited violation(s) of the Consent Agreement (including any technical, financial or other information that Respondent deems relevant). Pursuant to paragraph 11 below, EPA shall evaluate the written explanation provided by Respondent.

11. The Complainant may, in her sole discretion, reduce or eliminate any stipulated penalty due under the CA/FO if Respondent has, in writing, demonstrated to EPA's satisfaction good cause for such action by EPA. If, after review of Respondent's submission, if any, pursuant to the preceding paragraph, Complainant determines that Respondent has failed to comply with the provisions of this Consent Agreement, and Complainant does not, in her sole

discretion, eliminate the stipulated penalties demanded by EPA, Complainant will notify Respondent, in writing, that either the full stipulated penalty or a reduced stipulated penalty must be paid by Respondent. Respondent shall pay the stipulated penalty amount indicated in EPA's notice within thirty (30) calendar days of its receipt of such written notice from EPA. Failure of the Respondent to pay any stipulated penalty demanded by EPA pursuant to this Consent Agreement will result in the referral of this matter to the United States Department of Justice or the United States Department of Treasury for collection and/or other appropriate action.

12. At any time prior to Respondent's payment of stipulated penalties, the Complainant, may, for good cause as independently determined by her, reduce or eliminate the stipulated penalty(ies). If the Complainant makes such determination, EPA shall notify Respondent in writing of any such action.

13. The civil penalty and any applicable stipulated penalties provided for herein are penalties within the meaning of Title 26, Section 162(f) of the United States Code, 26 U.S.C. § 162(f), and are not deductible expenditures for purposes of federal, state or local law.

14. Any responses, documentation, and other communication submitted in connection with this Consent Agreement shall be sent to:

Michael Kramer
Pesticides and Toxic Substances Branch – Pesticides Team
Division of Enforcement and Compliance Assistance
U.S. Environmental Protection Agency – Region 2
2890 Woodbridge Avenue, Building 205
Edison, NJ 08837

and

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

Unless the above-named EPA contacts are later advised otherwise in writing, EPA shall address any written future correspondence (including any correspondence related to payment of the penalty and any stipulated penalty) to Respondent at the following address:

Charles Buchalter, President
Pharmaceutical Innovations, Inc.
897 Frelinghuysen Avenue
Newark, NJ 07114

15. This Consent Agreement is being voluntarily and knowingly entered into by the Complainant and Respondent. Full payment of the penalty described in paragraph 4 above shall only resolve Respondent's liability for federal civil penalties for the violations and facts described in paragraphs 1 – 44 of the "Findings of Fact and Conclusions of Law" section in this Consent Agreement. Full payment of this penalty shall not in any case affect the right of EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law.

16. For the purpose of this proceeding and in the interest of an expeditious resolution of this matter, Respondent (a) admits that EPA has jurisdiction pursuant to Section 14 of FIFRA, 7 U.S.C. § 136l(a), to commence a civil administrative proceeding based on the Findings of Fact and Conclusions of Law section above; and (b) neither admits nor denies any determination in the Findings of Fact and Conclusions of Law contained herein.

17. Respondent has read the Consent Agreement, understands its terms, finds it to be reasonable and consents to the issuance and its terms. Respondent consents to the issuance of the accompanying Final Order. Respondent agrees that all terms of settlement are set forth herein.

18. Respondent explicitly and knowingly consents to the assessment of the civil penalty as set forth in this Consent Agreement and agrees to pay the civil penalty and any stipulated penalties that become due in accordance with the terms of this Consent Agreement.

19. Respondent explicitly and knowingly waives its right to request or to seek any Hearing on the Complaint, this Consent Agreement or on the Findings of Fact and Conclusions of Law herein, or on the accompanying Final Order.

20. The Respondent agrees not to contest the validity or any term of this CA/FO in any action brought: a) by the United States, including EPA, to enforce this CA/FO; or b) to enforce a judgment relating to this CA/FO. Any failure by Respondent to perform fully any requirement herein will be considered a violation of this CA/FO and may subject Respondent to a civil judicial action by the United States to enforce the provisions of this CA/FO.

21. Respondent waives any right it might have to appeal this Consent Agreement and the accompanying Final Order.

22. This Consent Agreement and any provision herein shall not be construed as an admission of liability in any criminal or civil action or other administrative proceeding, except in an action or proceeding to enforce or seek compliance with this Consent Agreement and its accompanying Final Order.

23. This Consent Agreement and Final Order does not relieve Respondent of its obligations to comply with all applicable provisions of federal, state or local law, nor shall it be construed to be a ruling on, or a determination of, any issue related to any federal, state or local permit. This Consent Agreement and Final Order does not waive, extinguish, or otherwise affect Respondent's obligation to comply with all applicable provisions of FIFRA and the regulations promulgated thereunder.

24. Nothing in this Consent Agreement and Final Order shall be construed as a release from any other action under any law and/or regulation administered by EPA.

25. Each undersigned signatory to this Consent Agreement certifies that: a) he or she is duly and fully authorized to enter into this Consent Agreement and all the terms, conditions and requirements set forth in this Consent Agreement and Final Order, and b) he or she is duly and fully authorized to bind the party on behalf of whom (which) he or she is entering this Consent Agreement to comply with and abide by all the terms, conditions and requirements of this Consent Agreement.

26. The provisions of this Consent Agreement and Final Order shall be binding upon both EPA and Respondent, its officers/officials, agents, authorized representatives and successors or assigns.

27. Any failure by Respondent to perform fully any requirement herein will be considered a violation of this CA/FO, and may subject Respondent to a civil judicial action by the United States to enforce the provisions of this CA/FO.

28. Each party hereto agrees to bear its own costs and fees in this matter.

29. Respondent consents to service upon itself of a copy of this Consent Agreement and Final Order by an EPA employee other than the Regional Hearing Clerk.

RESPONDENT:

BY: Charles Buchalter
(Signature)

NAME: Charles Buchalter

TITLE: President

COMPANY NAME: Pharmaceutical Innovations, Inc.

DATE: 9/19/2017

COMPLAINANT:

Dore LaPosta, Director
Division of Enforcement
and Compliance Assistance
U.S. Environmental Protection
Agency - Region 2

DATE: 9/20/17

In the Matter of Pharmaceutical Innovations, Inc., FIFRA-02-2017-5101

FINAL ORDER

The Regional Administrator of the U.S. Environmental Protection Agency, Region 2, ratifies the foregoing Consent Agreement. The Consent Agreement entered into by the parties to this matter, is hereby approved, incorporated herein, and issued as an Order pursuant to 40 C.F.R. § 22.18(b)(3). The effective date of this Order shall be the date of filing with the Regional Hearing Clerk, United States Environmental Protection Agency, Region 2, New York, New York.

CATHERINE R. MCCABE
Acting Regional Administrator
U.S. Environmental Protection
Agency - Region 2
290 Broadway
New York, New York 10007

DATE: 9/21/17

In the Matter of Pharmaceutical Innovations, Inc., FIFRA-02-2017-5101

CERTIFICATE OF SERVICE

I certify that I have this day caused to be sent the foregoing fully executed Consent Agreement and Final Order ("CA/FO"), bearing the above-referenced docket number, in the following manner to the respective addressees listed below:

Original and Copy
By Hand Delivery:

Office of the Regional Hearing Clerk
U.S. Environmental Protection
Agency, Region 2
290 Broadway, 16th Floor
New York, New York 10007-1866

Copy by Certified Mail/
Return Receipt Requested:

John Davis Conner, Jr.
Crowell & Moring LLP
10001 Pennsylvania Avenue, NW
Washington, DC 20004-2595

Dated: 9/22, 2017
New York, New York