



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 5

77 WEST JACKSON BOULEVARD

CHICAGO, IL 60604-3590

March 29, 2021

VIA EMAIL

Hu-Friedy Mfg. Co. LLC
c/o
Ms. Lisa M. Campbell
Partner
Bergeson & Campbell PC
2200 Pennsylvania Avenue, Northwest
Suite 100 West
Washington, D.C. 20037

LCAMPBELL@lawbc.com

Re: Consent Agreement and Final Order In the Matter of Hu-Friedy Mfg. Co. LLC
Docket Number **FIFRA-05-2021-0011**

Ms. Campbell:

Enclosed please find a copy of a fully executed Consent Agreement and Final Order in resolution of the above case. This document was filed on March 29, 2021 with the Regional Hearing Clerk.

The civil penalty in the amount of \$464,737.50 is to be paid in the manner described in paragraphs 68-69. Please be certain that the docket number is written on both the transmittal letter and entered in the comment or description field of the electronic funds transfer. Payment is due within 30 calendar days of the filing date.

Thank you for your cooperation in resolving this matter.

Sincerely,

**ABIGAIL
WESLEY**

Digitally signed by
ABIGAIL WESLEY
Date: 2021.03.25
06:32:27 -05'00'

Abigail Wesley
Pesticides & Toxics Compliance Section
U.S. EPA, Region 5

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5**

In the Matter of:)	Docket No. FIFRA-05-2021-0011
)	
Hu-Friedy Mfg. Co. LLC)	
Chicago, Illinois)	Proceeding to Assess a Civil Penalty
)	Under Section 14(a) of the Federal
)	Insecticide, Fungicide, and Rodenticide
Respondent.)	Act, 7 U.S.C. § 136l(a)
<hr/>		

Consent Agreement and Final Order
Preliminary Statement

1. This is an administrative action commenced and concluded under Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136l(a), and Sections 22.13(b) and 22.18(b)(2) and (3) of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (Consolidated Rules) as codified at 40 C.F.R. Part 22.

2. The Complainant is, by lawful delegation, the Director of the Enforcement and Compliance Assurance Division, United States Environmental Protection Agency (EPA), Region 5.

3. The Respondent is Hu-Friedy Mfg. Co. LLC (Hu-Friedy), a corporation doing business in the State of Illinois.

4. Where the parties agree to settle one or more causes of action before the filing of a complaint, the administrative action may be commenced and concluded simultaneously by the issuance of a consent agreement and final order (CAFO). 40 C.F.R. § 22.13(b).

5. The parties agree that settling this action without the filing of a complaint or the adjudication of any issue of fact or law is in their interest and in the public interest.

6. Respondent consents to the assessment of the civil penalty specified in this CAFO, and to the terms of this CAFO.

Jurisdiction and Waiver of Right to Hearing

7. Respondent admits the jurisdictional allegations in this CAFO and neither admits nor denies the factual allegations in this CAFO.

8. Respondent waives its right to request a hearing as provided at 40 C.F.R. § 22.15(c), any right to contest the allegations in this CAFO, and its right to appeal this CAFO.

9. Respondent certifies that it is complying with FIFRA, 7 U.S.C. §§ 136 to 136y.

Statutory and Regulatory Background

10. Section 2(s) of FIFRA, 7 U.S.C. § 136(s), defines the term “person” as “any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.”

11. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines the term “distribute or sell” 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.” Also see 40 C.F.R. §152.3.

12. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines the term “pesticide” as, among other things, “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.” Also see 40 C.F.R. §152.3.

13. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines the term “pest” as any insect, rodent, nematode, fungus, weed, or any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism which the Administrator [of the EPA] declares to be a pest under Section 25(c)(1) of FIFRA. Also see 40 C.F.R. §152.5.

14. Section 2(p)(1) of FIFRA, 7 U.S.C. § 136(p)(1), defines a “label” as written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

15. Section 2(p)(2) of FIFRA, 7 U.S.C. § 136(p)(2), defines “labeling” as all labels and all other written, printed, or graphic matter accompanying the pesticide or device at any time or to which reference is made on the label or in literature accompanying the pesticide or device.

16. Section 3(a) of FIFRA, 7 U.S.C. § 136a(a), states that no person in any State may distribute or sell to any person any pesticide that is not registered under Section 3 of FIFRA.

17. 40 C.F.R. § 152.132 states that a registrant may distribute or sell his registered product under another person’s name and address instead of (or in addition to) his own. Such distribution and sale is termed “supplemental distribution” and the product is referred to as a “distributor product.”

18. 40 C.F.R. § 152.132 states that supplemental distribution is permitted upon notification to the Agency if all of the following conditions are met: (a) The registrant has submitted to the Agency for each distributor product a statement signed by both the registrant and the distributor listing the names and addresses of the registrant and the distributor, the distributor’s company number, the additional brand name(s) to be used, and the registration number of the registered product, (b) The distributor product is produced, packaged and labeled in a registered establishment operated by the same producer who produces, packages, and labels the registered product, (c) The distributor product is not repackaged (remains in the producer’s unopened containers), (d) The label of the distributor product is the same as that of the registered product, except that the product name of the distributor product may be different, the name and address of the distributor may appear instead of that of the registrant, the registration number of

the registered product must be followed by a dash, followed by the distributor's company number, the establishment number must be that of the final establishment at which the product was produced, and specific claims may be deleted, provided that no other changes are necessary, and (e) Voluntary cancellation of a product applies to the registered product and all distributor products distributed or sold under that registration number.

19. 40 C.F.R. § 152.132 also specifies that a distributor is considered an agent of the registrant for all intents and purposes under FIFRA, and both the registrant and the distributor may be held liable for violations pertaining to the distributor product.

20. Section 3(c)(1) of FIFRA, 7 U.S.C. § 136a(c)(1), states, in pertinent part, "each applicant for registration of a pesticide shall file with the Administrator a statement which includes...(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use."

21. 40 C.F.R § 156.10(a)(1) states that every pesticide product shall bear a label containing the information specified by FIFRA and the regulations in 40 C.F.R Part 156.

22. 40 C.F.R § 156.10(b)(2)(ii) states that no name, brand, or trademark may appear on the label which has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 152.132.

23. 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 or misleading in any particular.

24. 40 C.F.R § 156.10(a)(5) states, in pertinent part, that a pesticide or a device is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims.

25. 40 C.F.R § 156.10(a)(5)(ix) states, in pertinent part, examples of statements or representation in the labeling which constitute misbranding include claims as to the safety of the pesticide or its ingredients.

26. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), states it is unlawful for any person in any state to distribute or sell to any person any pesticide that is not registered under Section 3 of FIFRA.

27. Section 12(a)(1)(B) of FIFRA, 7. U.S.C. §136j(a)(1)(B), states, in pertinent part, that it is unlawful for any person in any state to distribute or sell to any person “any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as part of the statement required in connection with its registration under [Section 3 of FIFRA].”

28. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), states it is unlawful for any person in any state to distribute or sell to any person “any pesticide which is adulterated or misbranded.”

29. Section 14(a)(1) of FIFRA, 7 U.S.C. § 136l(a)(1), states that any registrant, commercial applicator, wholesaler, dealer, retailer or other distributor who violates any provision of FIFRA may be assessed a civil penalty by EPA of not more than \$7,500 for each offense that occurred after January 12, 2009 through November 2, 2015. The Federal Civil Penalties Inflation Adjustment Act of 1990, as amended through 2015, 28 U.S.C. § 2461, and its implementing regulations at 40 C.F.R. Part 19, increased the amount that can be assessed to \$20,528 for each offense occurring after November 2, 2015 and assessed after December 23, 2020. See 85 Fed. Reg. 247 (December 23, 2020).

EPA Factual Allegations and Alleged Violations

30. Respondent is a “person” as that term is defined at Section 2(s) of FIFRA, 7 U.S.C. § 136(s).
31. At all times relevant to the CAFO, Hu-Friedy owned or operated a place of business located at 3232 North Rockwell Street, Chicago, Illinois 60618 and 1666 East Touhy Avenue, Des Plaines, Illinois 60018 (“Respondent’s Facilities”).
32. On or about May 2, 2018, two inspectors employed with the EPA and one inspector employed with the Office of Indiana State Chemist and Seed Commissioner (OISC), conducted an inspection at the Hu-Friedy facilities.
33. During the May 2, 2018 inspection, the inspectors collected labeling, receiving, and distribution records for Team Vista Dental Waterline Cleaner Combo Pack.
34. Team Vista Dental Waterline Cleaner Combo Pack, product code IMS-1450, was identified as containing two products:
- a. Vista Tab Dental Waterline Cleaner Tablets, EPA Registration Number (EPA Reg. No.) 70060-25-75372; and
 - b. Vista Clean Irrigant Solution Concentrate.
35. Outer carton labeling for Team Vista Dental Waterline Cleaner Combo Pack, collected during the May 2, 2018 inspections, identified the following, among other things:
- a. “TEAM VISTA DENTAL WATERLINE CLEANER by Hu-Friedy;
 - b. IMS-1450 | COMBO PACK;
 - c. Product A: VistaClean Irrigant Solution Concentrate;
 - d. Product B: VistaTab Dental Waterline Cleaner Tablets;
 - e. GENERAL PURPOSE IRRIGANT CLEANER

VistaClean is an aqueous cleaner derived from citrus botanicals designed for use in dental waterlines. As an aqueous cleaner it has the ability to emulsify organic and inorganic contaminants, soils and oxidation products. It provides lubrication as an irrigant while also protecting lines and system components from deposits and scale. It may be used in waterlines in contact with patients continuously or intermittently as desired. It is non-toxic, non-corrosive and has no negative effect on bond strength. NEVER USE FULL STRENGTH.”

f. VISTACLEAN IRRIGANT SOLUTION CONCENTRATE DIRECTIONS FOR USE

Daily Use: 1. Add at least 1 drop of VistaClean to each 750 ml bottle of clean water. 2. Return bottle to manifold and use with patients. Add drops each time the bottle is filled. (For other size bottles, see inside); and

g. Website: Hu-Friedy.com.”

36. Insert inside carton for Team Vista Dental Waterline Cleaner Combo Pack, collected during the May 2, 2018 inspections, identified the following, among other things:

- a. “Team Vista is a convenience combo pack that contains two different products. VistaClean is a general-purpose irrigant and cleaner that provides lubrication as an irrigant while also protecting lines and system components from deposits and scale. VistaTab is designed for the cleaning and control of microbial contaminants in dental unit waterlines. VistaClean is an FDA cleared irrigant and VistaTab is an EPA registered antimicrobial in all states.;

- b. When used properly, VistaClean is completely non-toxic, safe for the environment, non-corrosive, simple to use and has no negative effect on bonding.;
- c. Hu-Friedy.com; and
- d. Description Team Vista Part Code IMS-1450.”

37. Labeling for Team Vista Dental Waterline Cleaner Combo Pack, collected during the May 2, 2018 inspections, identified “Hu-Friedy.com.”

38. At all times relevant to this Complaint, Hu-Friedy owned or operated a website, located at www.hu-friedy.com (“Respondent’s Website”).

39. On or about April 3, 2018, an EPA representative reviewed Respondent’s website located at Hu-Friedy.com.

40. Three brochures were downloaded by the EPA representative during the April 3, 2018 review of Respondent’s website:

- a. Waterline Brochure;
- b. Team Vista Step by Step Instructions; and
- c. Dental Waterline Solutions Sell Sheet.

41. The Waterline Brochure, downloaded during the April 3, 2018 review of Respondent’s website, identified the following, among other things:

- a. “Team Vista Dental Waterline Cleaner by Hu-Friedy;
- b. Introducing Team Vista by Hu-Friedy
The complete waterline security system;
- c. Team Vista Dental Waterline Cleaner IMS-1450;
- d. Simply maintaining the waterlines is not enough; it is a two part process of

cleaning and maintenance. Over time, bacteria can overwhelm the waterline environment and begin to create microbial deposits. Using a daily irrigant, like VistaClean, and cleaning the waterlines regularly with an EPA approved antimicrobial, like VistaTab, will clean and control microbial contaminants to provide improved water quality while helping to protect patients, staff, and equipment.;

- e. Team Vista provides a more effective and economical way to keep waterlines safer and cleaner. This easy-to-use system is designed for the quick cleaning and control of microbial contamination in dental unit waterlines. It's the only system that provides both an organic irrigant and registered antimicrobial cleaner for enhanced patient care.;
- f. It is important to properly treat your dental unit waterlines as a component of a total infection control program. Team Vista is an easy, effective system to both periodically clean and maintain dental unit waterlines.;
- g. VistaClean is a daily irrigant solution derived from organic citrus botanicals and is safe for use with patients. ... VistaClean leaves no taste or odor and is completely non-toxic, environmentally friendly, noncorrosive, and has no negative effect on bond strength.; and
- h. When placed in water, the solid tablet quickly dissolves to create a non-corrosive solution that is seven times more effective than bleach.”

42. The Team Vista Step by Step Instructions, downloaded during the April 3, 2018 review of Respondent's website, identified the following, among other things:

- a. “TEAM VISTA DENTAL WATERLINE CLEANER BY HU-FRIEDY THE

COMPLETE WATERLINE SECURITY SYSTEM;

- b. Simply maintaining the waterlines is not enough; it is a two part process of cleaning and maintenance. Over time, bacteria can overwhelm the waterline environment and begin to create microbial deposits. Using a daily irrigant, like VistaClean, and cleaning the waterlines regularly with an EPA approved antimicrobial, like VistaTab tablets, will clean and control microbial contaminants to provide improved water quality while helping to protect patients, staff, and equipment.; and
- c. Team Vista Dental Waterline Cleaner IMS-1450. This complete system contains: 1 – One Ounce Bottle of VistaClean Irrigant Solution; 15 – VistaTab Cleaner Tablets.”

43. The Dental Waterline Solutions Sell Sheet, downloaded during the April 3, 2018 review of Respondent’s website, identified the following, among other things:

- a. “TEAM VISTA BY HU-FRIEDY The Complete Waterline Security System;
- b. Team Vista provides a more effective and economical way to keep waterlines safe and clean. This easy-to-use solution is the **only system that provides both an organic irrigant and registered antimicrobial cleaner** for enhanced patient care.;
- c. When used as directed VistaClean leaves no taste or odor and is **completely non-toxic, environmentally friendly**, noncorrosive, and has no negative effect on bond strength.;
- d. It is important to properly treat your dental unit waterlines as a component of a total infection control program. Team Vista is an easy, effective system to both

periodically clean and maintain dental unit waterlines.;

- e. Simply maintaining the waterlines is not enough; it is a two part process of cleaning and maintenance. Over time, bacteria can overwhelm the waterline environment and begin to create microbial deposits. Using a daily irrigant, like VistaClean, and cleaning the waterlines regularly with an antimicrobial, like VistaTab, will clean and control microbial contaminants to provide improved water quality while helping to protect patients, staff, and equipment.;
- f. Team Vista Dental Waterline Cleaner IMS-1450. This complete system contains: 1 – One Ounce Bottle of VistaClean Irrigant Solution; 15 – VistaTab Cleaner Tablets.”

44. On or about April 4, 2018, an EPA representative reviewed Respondent’s website located at hu-friedy.com.

45. Two videos, which were embedded into Respondent’s website, were viewed and transcribed by the EPA representative during the April 4, 2018 review of Respondent’s website:

- a. Be Safe and Confident; and
- b. Team Vista.

46. The Be Safe and Confident video, viewed and transcribed during the April 4, 2018 review of Respondent’s website, identified the following, among other things:

- a. “Team Vista offers an economical dental waterline treatment system for the cleaning and control of microbial contamination.”

47. The Team Vista video, viewed and transcribed during the April 4, 2018 review of Respondent’s website, identified the following, among other things:

- a. “Unlike other products both Team Vista cleaners are completely non-toxic and

environmentally friendly so they can go straight into the drain with no additional steps required. Simply put the Team Vista combination is the easier, most effective and least expensive way to keep water lines clean and safe.”

48. On or about September 3, 2019, an EPA representative reviewed Respondent’s website located at hu-friedy.com.

49. One poster, identified as Treating Waterlines Poster, was downloaded by the EPA representative during the September 3, 2019 review of Respondent’s website.

50. The Treating Waterlines Poster, downloaded during the September 3, 2019 review of Respondent’s website, identified the following, among other things:

- a. “Team Vista Dental Unit Waterline Cleaner provides an effective & economical way to keep waterlines safe & clean for enhanced patient care; and
- b. Learn more at hu-friedy.com/infectionprevention.”

51. Reviews for Team Vista Dental Unit Waterline Cleaner were downloaded by the EPA representative during the September 3, 2019 review of Respondent’s website.

52. Reviews, downloaded during the September 3, 2019 review of Respondent’s website, identified the following, among other things:

- a. “It is important to properly treat your dental unit waterlines as a component of a total infection control program. Team Vista is an easy, effective system to both periodically clean and maintain dental unit waterlines.;
- b. The Team Vista Line Cleaner is a simple way to clean and disinfect waterlines.;
- and
- c. Fortunately a number of effective strategies are available to the profession for controlling the development and growth of waterborne organisms like using

Hu-Friedy's Team Vista Dental Unit Waterline Cleaner.”

Unregistered Pesticide Allegations

53. EPA Reg. No. 70060-25 is assigned to a pesticide product belonging to BASF Corporation, identified as Aseptrol Dental Water Treatment, that was registered by EPA on or about March 3, 2005.

54. On or about January 8, 2009, Vista Tab Dental Waterline Cleaner Tablets was registered as a distributor product, under Hu-Friedy, and assigned EPA Reg. No. 70060-25-75372.

55. On or about November 6, 2012, EPA accepted a label Notification for Aseptrol Dental Water Treatment, EPA Reg. No. 70060-25.

56. Team Vista Dental Waterline Cleaner Combo Pack is a “pesticide” as that term is defined in Section 2(u) of FIFRA, 7 U.S.C. § 136(u), because it is intended for preventing, destroying, repelling, or mitigating certain pests.

57. Team Vista Dental Waterline Cleaner Combo Pack, containing Vista Tab Dental Waterline Cleaner Tablets, EPA Reg. No. 70060-25-75372 and Vista Clean Irrigant Solution Concentrate, was not registered with the EPA at all times relevant to this CAFO.

58. Team Vista Dental Waterline Cleaner Combo Pack is not a registered pesticide as required by Section 3 of FIFRA and its underlying regulations.

59. During the May 2, 2018 inspection, EPA collected records showing Respondent distributed or sold Team Vista Dental Waterline Cleaner Combo Pack.

60. Respondent’s distribution or sale of the unregistered pesticide, Team Vista Dental Waterline Cleaner Combo Pack, constitutes unlawful acts pursuant to Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).

Misbranded Pesticide Allegations

61. Vista Tab Dental Waterline Cleaner Tablets, EPA Reg. No. 70060-25-75372, which was contained within the unregistered Team Vista Dental Waterline Cleaner Combo Pack, contained claims that differed substantially from those accepted under the EPA pesticide registration for the basic registrant's product, Aseptrol Dental Water Treatment, EPA Reg. No. 70060-25, and as such, was misbranded, as it contained false or misleading claims as to the safety of the pesticide or its ingredients and comparative statement with other pesticides.

62. The label notification for Aseptrol Dental Water Treatment, EPA Reg. No. 70060-25, accepted by EPA on or about November 6, 2012, did not contain the following claims, as identified on the labeling for Vista Tab Dental Waterline Cleaner Tablets, EPA Reg. No. 70060-25-75372, also referenced as Team Vista Dental Unit Waterline Cleaner, collected during the inspection of Respondent's facilities and review of Respondent's website:

- a. "...cleaning the waterlines regularly with an EPA approved antimicrobial, like VistaTab, will clean and control microbial contaminants to provide improved water quality while helping to protect patients, staff, and equipment.;
- b. It is important to properly treat your dental unit waterlines as a component of a total infection control program. Team Vista is an easy, effective system to both periodically clean and maintain dental unit waterlines.;
- c. This easy-to-use solution is the only system that provides both an organic irrigant and registered antimicrobial cleaner for enhanced patient care.;
- d. It's the only system that provides both an organic irrigant and registered antimicrobial cleaner for enhanced patient care.;
- e. VistaTab tablets, will clean and control microbial contaminants to provide

improved water quality while helping to protect patients, staff, and equipment.;
and

- f. Fortunately a number of effective strategies are available to the profession for controlling the development and growth of waterborne organisms like using Hu-Friedy's Team Vista Dental Unit Waterline Cleaner.”

63. Labeling for Team Vista Dental Waterline Cleaner, EPA Reg. No. 70060-25-75372 collected during the inspection of Respondent’s facilities and review of Respondent’s website, contained the following false or misleading claims as to the safety of the pesticide or its ingredients:

- a. “Team Vista provides a more effective and economical way to keep waterlines safer and cleaner.;
- b. Team Vista provides a more effective and economical way to keep waterlines safe and clean.;
- c. Unlike other products both Team Vista cleaners are completely non-toxic and environmentally friendly so they can go straight into the drain with no additional steps required. Simply put the Team Vista combination is the easier, most effective and least expensive way to keep water lines clean and safe.;
- d. When used properly, VistaClean is completely non-toxic, safe for the environment, non-corrosive, simple to use and has no negative effect on bonding.; and
- e. Unlike other products both Team Vista cleaners are completely non-toxic and environmentally friendly so they can go straight into the drain with no additional steps required.”

64. Labeling for Team Vista Dental Waterline Cleaner, EPA Reg. No. 70060-25-75372 collected during the inspection of Respondent's facilities and review of Respondent's website, contained the following false or misleading claims that were comparative with other pesticides:

- a. "Simply put the Team Vista combination is the easier, most effective and least expensive way to keep water lines clean and safe.; and
- b. When placed in water, the solid tablet quickly dissolves to create a non-corrosive solution that is seven times more effective than bleach."

65. During the May 2, 2018 inspection, EPA collected records showing Respondent distributed or sold Team Vista Dental Waterline Cleaner, EPA Reg. No. 70060-25-75372.

66. Respondent's distribution or sale of Team Vista Dental Waterline Cleaner, EPA Reg. No. 70060-25-75372, with claims that substantially differ from those accepted under its EPA product registration, constitutes unlawful acts pursuant to Section 12(a)(1)(B) of FIFRA, 7 U.S.C. § 136j(a)(1)(B).

67. Respondent's distribution or sale of misbranded Team Vista Dental Waterline Cleaner, EPA Reg. No. 70060-25-75372, with false or misleading claims as to the safety of the pesticide or its ingredients and with comparative statement to other pesticides, constitutes unlawful acts pursuant to Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

Civil Penalty

68. Pursuant to Section 14(a)(4) of FIFRA, 7 U.S.C. § 136l(4), Complainant determined that an appropriate civil penalty to settle this action is \$464,737.50. In determining the penalty amount, Complainant considered the appropriateness of the penalty to the size of Respondent's business, the effect on Respondent's ability to continue in business, and the gravity of the violation. Complainant also considered EPA's FIFRA Enforcement Response Policy, dated

December 2009.

69. Within 30 days after the effective date of this CAFO, Respondent must pay a \$464,737.50 civil penalty for the FIFRA violations by sending a cashier's or certified check, payable to "Treasurer, United States of America," by regular U.S. Postal Service mail to:

U.S. EPA
Fines and Penalties
Cincinnati Finance
Center
P.O. Box 979077
St. Louis, Missouri 63197-9000

If sending the payment by express mail, then send a cashier's or certified checks, payable to "Treasurer, United States of America," to:

U.S. Bank
Government Lockbox 979077 U.S. EPA Fines and Penalties
1005 Convention Plaza
Mail Station SL-MO-C2-GL
St. Louis, Missouri 63101

The check must note "Hu-Friedy Mfg. Co. LLC." and the docket number of this CAFO. To pay on-line, go to www.pay.gov. Use the Search Public Forms option on the tool bar and enter SFO 1.1 in the search field. Open the form and complete the required fields.

70. Respondent must send a notice of payment that states Respondent's name and the case docket number to EPA at the following addresses when it pays the penalty:

Regional Hearing Clerk (E-19J)
U.S. EPA, Region 5
77 W. Jackson Blvd.
Chicago, IL 60604
whitehead.lawdawn@epa.gov
whitehead.ladawn@epa.gov

Abigail Wesley (ECP-17J)
Pesticides and Toxics Compliance Section
U.S. EPA, Region 5
77 W. Jackson Blvd.
Chicago, IL 60604
wesley.abigail@epa.gov

Jacqueline Clark (C-14J)
Office of Regional Counsel
U.S. EPA, Region 5
77 W. Jackson Blvd.
Chicago, IL 60604
clark.jacqueline@epa.gov

71. This civil penalty is not deductible for federal tax purposes.

72. If Respondent does not pay timely the civil penalty, EPA may refer the matter to the Attorney General who will recover such amount by action in the appropriate United States district court under Section 14(a)(5) of FIFRA, 7 U.S.C. § 136l(a)(5). The validity, amount, and appropriateness of the civil penalty are not reviewable in a collection action.

73. Pursuant to 31 C.F.R. § 901.9, Respondent must pay the following on any amount overdue under this CAFO. Interest will accrue on any amount overdue from the date payment was due at a rate established by the Secretary of the Treasury. Respondent must pay a \$15 handling charge each month that any portion of the penalty is more than 30 days past due. In addition, Respondent must pay a 6 percent per year penalty on any principal amount 90 days past due.

General Provisions

74. Consistent with the Standing Order Authorizing E-Mail Service of Orders and Other Documents Issued by the Regional Administrator or Regional Judicial Officer Under the Consolidated Rules, dated March 27, 2015, the parties consent to service of this CAFO by e-mail at the following valid e-mail addresses: clark.jacqueline@epa.gov (for Complainant), and

LCAMPBELL@lawbc.com (for Respondent). The parties waive their right to service by the methods specified in 40 C.F.R. § 22.6.

75. This CAFO resolves only Respondent's liability for federal civil penalties for the violations and facts alleged in the CAFO.

76. This CAFO does not affect the rights of EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law.

77. This CAFO does not affect Respondent's responsibility to comply with FIFRA and other applicable federal, state, and local laws.

78. This CAFO is a "final order" for purposes of EPA's FIFRA Enforcement Response Policy.

79. The terms of this CAFO bind Respondent, its successors, and assigns.

80. Each person signing this agreement certifies that he or she has the authority to sign for the party whom he or she represents and to bind that party to its terms.

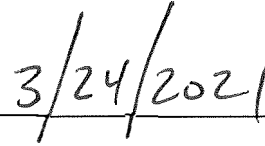
81. Each party agrees to bear its own costs and attorney's fees, in this action.

82. This CAFO constitutes the entire agreement between the parties

Hu-Friedy Mfg. Co. LLC, Respondent



Andrew Xilas
President
Hu-Friedy Mfg. Co. LLC



Date

United States Environmental Protection Agency, Complainant

**MICHAEL
HARRIS**

Digitally signed by
MICHAEL HARRIS
Date: 2021.03.26
14:45:24 -05'00'

Michael D. Harris
Division Director
Enforcement and Compliance Assurance Division

In the Matter of:
Hu-Friedy Mfg. Co. LLC
Docket No. FIFRA-05-2021-0011

Final Order

This Consent Agreement and Final Order, as agreed to by the parties, shall become effective immediately upon filing with the Regional Hearing Clerk. This Final Order concludes this proceeding pursuant to 40 C.F.R. §§ 22.18 and 22.31. IT IS SO ORDERED.

ANN COYLE Digitally signed by ANN
COYLE
Date: 2021.03.29
12:23:46 -05'00'

Ann L. Coyle
Regional Judicial Officer
United States Environmental Protection Agency
Region 5

