

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

IN THE MATTER OF:	)	
	)	
American Covers, Inc., d/b/a HandStands,	)	Docket No. FIFRA-HQ-2016-5017
	)	
Respondent.	)	
	)	

**CONSENT AGREEMENT AND FINAL ORDER**

**CONSENT AGREEMENT**

Complainant, United States Environmental Protection Agency (“EPA”) and Respondent, American Covers, Inc., d/b/a HandStands (“HandStands”), agree to this action and consent to the entry of this Consent Agreement and Final Order (“CAFO”) before taking testimony and without any adjudication of any issues of law or fact herein.

**I. NATURE OF ACTION**

1. This is a civil administrative action instituted under Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA” or the “Act”), as amended, 7 U.S.C. § 136l(a) and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (“Consolidated Rules”), 40 C.F.R. part 22. This action imposes civil penalties pursuant to Section 14(a) of FIFRA.
2. Complainant and Respondent have conferred for the purpose of settlement pursuant to 40 C.F.R. § 22.18, and desire to settle this action. Accordingly, before any testimony has been taken and without any admission of violation, or adjudication of any issue of fact or law, and in accordance with 40 C.F.R. § 22.13(b), Complainant and Respondent have agreed to the execution of this CAFO. Respondent hereby agrees to comply with the terms of this CAFO.

**II. THE PARTIES**

3. Gregory A. Sullivan, Acting Director, Waste and Chemical Enforcement Division, Office of Civil Enforcement, Office of Enforcement and Compliance Assurance, is authorized by lawful delegation to institute and settle civil administrative actions brought pursuant to Section 14(a) of FIFRA.

4. Respondent is a corporation doing business in Draper, Utah, with 2015 gross revenue in excess of \$47 million.

### **III. PRELIMINARY STATEMENT**

5. Respondent stipulates that Complainant has jurisdiction over the subject matter of this Consent Agreement.
6. Respondent waives any defenses it might have as to venue and jurisdiction.
7. Pursuant to 40 C.F.R. § 22.18(b)(2), Respondent waives its right to contest the allegations herein, its right to appeal the Final Order, and its right to request a judicial or administrative hearing on any issue of law or fact set forth in, and resolved by, this Consent Agreement.
8. Respondent neither admits nor denies the allegations and determinations set forth in Section V of this Consent Agreement.

### **IV. STATUTORY AND REGULATORY BACKGROUND**

9. Pursuant to FIFRA Section 12(a)(2)(Q), 7 U.S.C. § 136j(a)(2)(Q), it shall be unlawful for any person to falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observations made, or conclusions or opinion formed, submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by FIFRA.
10. 40 C.F.R. part 160 prescribes FIFRA Good Laboratory Practice Standards (“GLPS”) for use in conducting studies that support or are intended to support applications for research or marketing permits for pesticide products regulated by EPA.
11. 40 C.F.R. § 160.35(a) states that for any given study conducted in accordance with GLPS, the study’s quality assurance unit shall be entirely independent and separate from the personnel engaged in the direction and conduct of that study.
12. 40 C.F.R. § 160.12 states that any person who submits to EPA an application for a research or marketing permit and who, in connection with the application, submits data from a study to which this part applies shall include in the application a true and correct statement, signed by the applicant, the sponsor, and the study director, of one of the following types: (a) a statement that the study was conducted in accordance with part 160 (GLPS); or (b) a statement describing in detail all differences between the practices used in the study and those required by part 160; or (c) a statement that the person was not a sponsor of the study, did not conduct the study, and does not know whether the study was conducted in accordance with part 160.

13. 40 C.F.R. § 160.17(b) states that submission of a statement required by 40 C.F.R. § 160.12 that is false may form the basis for imposition of civil penalties under FIFRA Section 14.
14. The Administrator is authorized to assess a civil penalty against any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of FIFRA. The maximum statutory civil penalty is \$7,500 for each offense occurring after January 12, 2009. 7 U.S.C. § 136l(a)(1).
15. The term “person” means “any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.” 7 U.S.C. § 136(s).
16. The term “sponsor” means “(1) A person who initiates and supports, by provision of financial or other resources, a study; (2) A person who submits a study to the EPA in support of an application for a research or marketing permit; or (3) A testing facility, if it both initiates and actually conducts the study.” 40 C.F.R. § 160.3.
17. The term “study” means “any experiment at one or more test sites, in which a test substance is studied in a test system under laboratory conditions or in the environment to determine or help predict its effects, metabolism, product performance (efficacy studies only as required by 40 C.F.R. 158.400 or 161.640, as applicable), environmental and chemical fate, persistence and residue, or other characteristics in humans, other living organisms, or media.” 40 C.F.R. § 160.3.
18. The term “registrant” means “a person who has registered any pesticide pursuant to the provisions of [FIFRA].” 7 U.S.C. § 136(y).
19. The term “pesticide” means, in part: “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.” 7 U.S.C. § 136(u).

## **V. EPA ALLEGATIONS AND DETERMINATIONS**

20. Respondent is a “person” as that term is defined by FIFRA, 7 U.S.C. § 136(s).
21. Respondent is the “registrant,” as that term is defined by FIFRA, 7 U.S.C. § 136(y), of Handstands Cleaner Spray, a pesticide currently registered under EPA Registration Number 89174-1.
22. Handstands Cleaner Spray is intended to destroy, repel, or mitigate pests, and is a “pesticide” as defined by FIFRA, 7 U.S.C. § 136(u).
23. Respondent is a “producer,” as that term is defined by FIFRA, 7 U.S.C. § 136(w), of Handstands Cleaner Spray.

24. Respondent is the “sponsor,” as that term is defined by 40 C.F.R. § 160.3, of a study entitled: “Ocular Irritation Assay for certain antimicrobial products making cleaning claims using the epi-ocular human cell construct,” MRID No. 49182506 (“the Study”).
25. On or about August 1, 2013, Respondent submitted the Study to EPA in support of the registration of Handstands Cleaner Spray as a pesticide.
26. With its application for registration of Handstands Cleaner Spray, Respondent submitted to EPA a signed statement stating that the Study “was conducted in compliance with the U.S. EPA GLP Standards (40 CFR 160) in all material aspects” with two exceptions.
27. The two exceptions Respondent acknowledged in the compliance statement were (1) that the identity, strength, purity and composition or other characteristics to define the test substance had not been determined by the testing facility, and (2) the stability of the substances under storage conditions had not been determined or included in the final report.
28. On or about June 29, 2015, to July 1, 2015, an authorized representative of EPA conducted an inspection of the In Vitro Sciences, Inc., laboratory facility, located at 30 W. Watkins Mill Road, Gaithersburg, MD 20878 (“Facility”) in order to determine compliance with the FIFRA GLPS, set forth at 40 C.F.R. part 160, and the Books and Records of Pesticide Production and Distribution regulations, set forth at 40 C.F.R. part 169 (“the Inspection”).
29. The Inspection revealed a lack of separation of the Quality Assurance Unit from the personnel engaged in the conduct of a study, or, specifically, that the manager of information systems/lead archivist/electronic archivist reports to the head of Quality Assurance, and that Quality Assurance personnel are responsible for the control of standard operating procedures.
30. The Inspection revealed that the Facility’s testing practices do not conform to the GLPS set forth at 40 C.F.R. § 160.35(a).
31. Respondent’s signed compliance statement submitted to EPA with the Study did not describe the Facility’s failure to meet the standard set forth at 40 C.F.R. § 160.35(a), and therefore, constitutes a false statement.
32. Respondent’s submission of a false compliance statement is a violation of FIFRA Section 12(a)(2)(Q), 7 U.S.C. § 136j(a)(2)(Q), and therefore, also pursuant to 40 C.F.R. § 160.17(b), may form the basis for imposition of civil penalties under FIFRA Section 14(a)(1), 7 U.S.C. § 136l(a)(1).

## VI. TERMS OF SETTLEMENT

33. Respondent consents to issuance of this Consent Agreement and to its terms, and consents, for the purposes of settlement, to the payment of the civil penalty set forth in Section VII.
34. Respondent's compliance with the terms of this CAFO shall fully settle all civil claims or civil causes of action alleged in Section V.
35. Compliance with this CAFO shall not be a defense to any subsequent action EPA may commence pursuant to federal law or regulation for violations occurring after the date of this Consent Agreement, or any violations of FIFRA not alleged in this Consent Agreement that may have occurred prior to the date that this Consent Agreement is fully executed by both Parties.
36. Nothing in this CAFO is intended to, nor shall be construed to operate in any way to, resolve any criminal liability of Respondent.

## VII. CIVIL PENALTY

37. Complainant has calculated a penalty pursuant to the statutory penalty factors listed in Section 14(a)(3) of FIFRA, 7 U.S.C. §136l(a)(3), the Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act Good Laboratory Practice Regulations ("GLP ERP") (September 1991), and the Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act (December 2009) ("FIFRA ERP").
38. Based upon the information gathered as a result of Complainant's Inspection referenced in Section V, and in accordance with the penalty adjustments allowed under the FIFRA ERP, Complainant has derived a penalty of \$5,720.00.
39. The penalty agreed upon by the Parties for settlement purposes is \$5,720.00.
40. Not more than sixty (60) calendar days following execution of the Final Order by the Environmental Appeals Board, Respondent shall either:
  - a) Dispatch a cashier's or certified check payable to the order of the "Treasurer of the United States of America" in the amount of \$ 5,720.00 and bearing the notation, "HandStands, Civil Penalty Docket No. FIFRA HQ-2016-5017" to the following address:

U.S. Environmental Protection Agency  
Fines and Penalties  
Docket No. FIFRA-HQ-2012-5017  
Cincinnati Finance Center  
PO Box 979077

St. Louis, MO 63197-9000

or

- b) Make an electronic payment by wire transfer in the amount of \$ 5,720.00 with the notation, "HandStands, Civil Penalty Docket No. FIFRA HQ-2016-5017," by using the following instructions:

Federal Reserve Bank of New York  
ABA = 021030004  
Account = 68010727  
SWIFT address = FRNYUS33  
33 Liberty Street  
New York, NY 10045  
Field Tag 4200 of the Fedwire message should read:  
"D 68010727 Environmental Protection Agency."

41. To ensure a record of compliance with this Consent Agreement, Respondent shall forward a copy of the check or wire transfer to EPA to the attention of:

Joseph Varco  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W. (Mail Code 2843)  
Washington, DC 20460-0001

and

Headquarters Hearing Clerk  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W. (Mail Code 1900R)  
Washington, DC 20460-0001

42. If Respondent fails to pay the civil penalty of \$ 5,720.00 within sixty (60) calendar days of the execution of the Final Order, then Respondent shall pay an additional stipulated penalty of \$5,000 per calendar day, plus interest, at the statutory judgment rate provided for in 31 U.S.C. § 3717, as in effect on the date of execution of the Final Order, unless Complainant in writing excuses or mitigates the stipulated penalty. Complainant may excuse or mitigate the stipulated penalty if Complainant determines in its sole discretion, that failure to comply occurred despite Respondent's exercise of good faith and due diligence. If additional stipulated penalties are due, Complainant will dispatch to Respondent a demand letter via certified mail, return receipt requested, which specifies the total amount due and owed by Respondent, including any interest allowed by law. Within fourteen (14) calendar days following Respondent's receipt of such demand letter, Respondent shall pay the stipulated penalty in the manner specified in this Section.

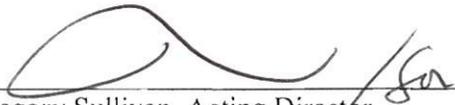
43. Failure to remit the civil penalty, or any stipulated penalty plus interest provided herein, may result in this matter being forwarded to the United States Department of Justice to recover such amount by action in federal court under Section 14(a)(5) of FIFRA, 7 U.S.C. § 1361(a)(5). The validity, amount and appropriateness of the civil penalty are not reviewable in a collection action.
44. This civil penalty is not deductible for federal tax purposes.

### **VIII. OTHER MATTERS**

45. Nothing in this CAFO shall relieve Respondent of the duty to comply with all applicable provisions of FIFRA and with other federal, state, tribal, and local laws and regulations.
46. This CAFO shall bind both Parties. This includes each Party's officers, directors, employees, successors, and assigns. The undersigned representative of each Party to this CAFO certifies that he or she is duly authorized to represent and bind the Party whom he or she claims to represent.
47. This CAFO shall bind the Parties in full effect upon execution of the Final Order by EPA's Environmental Appeals Board.
48. Respondent's obligations under this CAFO shall terminate when Respondent has paid the civil penalty, and any applicable interest or late charges, as specified in Section VII of the Consent Agreement in accordance with the Final Order.
49. Each Party agrees to bear its own costs and attorney fees in this matter.

WE AGREE TO THIS:

FOR COMPLAINANT:

  
\_\_\_\_\_  
Gregory Sullivan, Acting Director  
Waste and Chemical Enforcement Division  
Office of Civil Enforcement  
Office of Enforcement and Compliance Assurance  
United States Environmental Protection Agency

8/17/16  
Date:

  
\_\_\_\_\_  
Christina E. Cobb, Attorney  
Waste and Chemical Enforcement Division  
Office of Civil Enforcement  
Office of Enforcement and Compliance Assurance  
United States Environmental Protection Agency

06-30-2016  
Date:

FOR RESPONDENT:

  
\_\_\_\_\_  
President and Chief Executive Officer  
American Covers, Inc., d/b/a HandStands

June 30, 2016  
\_\_\_\_\_  
Date:

  
\_\_\_\_\_  
Attorney  
Counsel for American Covers, Inc., d/b/a HandStands

August 12, 2016  
\_\_\_\_\_  
Date: