UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 4
ATLANTA FEDERAL CENTER
61 FORSYTH STREET
ATLANTA, GEORGIA 30303-8960

MAR 12 2014

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Catherine D. Little
Attorney at Law
Hunton and Williams LLP
600 Peachtree Street, NE
Suite 4100
Atlanta, Georgia 30308-2216

Re: Zep, Inc.
Administrative Complaint
Docket No. FIFRA-04-2014-3000

Dear Ms. Little:

Enclosed is a copy of the Administrative Complaint filed in the above-referenced matter. The original Complaint has been filed with the Regional Hearing Clerk and served on the parties as directed in Section 22.13 of the Consolidated Rules of Practice, 40 C.F.R. Part 22.

Should you have any questions about this matter, please contact Ms. Lynda Crum, Associate Regional Counsel, at (404) 562-9524.

Sincerely,

Anthony G. Toney
Chief
Pesticides and Toxic
Substances Branch

Enclosures

cc: Joshua Wiley
Georgia Department of Agriculture

UNITED STATES
ENVIRONMENAL PROTECTION AGENCY
REGION 4
ATLANTA, GEORGIA

BEFORE THE ADMINISTRATOR

IN THE MATTER OF:	)	
	)	**CIVIL COMPLAINT**
	)	**and**
Zep, Inc.	)	**NOTICE OF OPPORTUNITY**
	)	**FOR HEARING**
Respondent.	)	
	)	**Docket No. FIFRA-04-2014-3000**
	)	

I. CIVIL COMPLAINT

A. Jurisdiction

1. This is a Civil Administrative Complaint issued under the authority of Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136*l*(a), and pursuant to the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits, 40 C.F.R. Part 22.

2. The Complainant, the Director of the Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, is authorized by the EPA Administrator and the EPA Regional Administrator for Region 4 to issue a Complaint on behalf of the Agency to persons alleged to be in violation of FIFRA. The Administrator of the EPA delegated this authority to the Regional Administrators, including the Regional Administrator of Region 4 by the EPA Delegation 5-14, dated May 11, 1994. The Region 4 Regional Administrator delegated this authority to the Director, Air, Pesticides and Toxics Management Division by the EPA Region 4 Delegation 5-14, dated September 7, 2005.

3. Respondent is hereby notified of the EPA's determination that Respondent has violated Section 12 of FIFRA, 7 U.S.C. § 136j.

B. Factual Allegations

4. The Respondent is Zep, Inc., a Delaware corporation doing business in the State of Georgia.

5. Respondent is located in various office buildings, laboratories, and warehouses on property located on Seaboard Industrial Blvd, Atlanta, Georgia, 30318, including but not limited to the buildings located at 1310, 1340 and 1420 Seaboard Industrial Blvd., Atlanta, Georgia, 30318, hereinafter collectively referred to as Respondent's "Seaboard Drive, Atlanta, Georgia" facility.

6. Respondent operates EPA Establishment Number 1270-GA-001, located on Seaboard Drive in Atlanta, Georgia.

7. Respondent is a "person," as defined by Section 2(s) of FIFRA, 7 U.S.C. § 136(s), and as such is subject to FIFRA and the regulations promulgated thereunder.

8. Respondent is a "registrant," as defined by Section 2(y) of FIFRA, 7 U.S.C. § 136(y), and as such is a person who has registered at least one pesticide pursuant to the provisions of FIFRA.

9. The term "pesticide," as defined by Section 2(u) of FIFRA, 7 U.S.C. § 136(u), means any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest.

10. The term "produce," as defined by Section 2(w) of FIFRA, 7 U.S.C. § 136(w), means to manufacture, prepare, compound, propogate, or process any pesticide or device or active ingredient used in producing a pesticide.

11. The term "batch," as defined by 40 C.F.R. § 169.1(b), means a quantity of a pesticide product or active ingredient used in producing a pesticide made in one operation or lot or if made in a continuous or semi-continuous process or cycle, the quantity produced during an interval of time to be specified by the producer.

12. The phrase "to distribute or sell" as defined by Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), means 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.

13. On May 26, 2011, duly authorized representatives of the EPA conducted an inspection of Respondent's Seaboard Drive, Atlanta, Georgia facility.

14. During the inspection referenced in paragraph 13, inspectors collected physical samples of the antimicrobial pesticide product, "Zep Formula 165," which bore the EPA Registration Number 49403-6-1270 on its label, and Respondent provided distribution or sales records related to this pesticide.

15. On September 28, 2011, and September 29, 2011, a duly authorized representative of the EPA conducted an inspection of the laboratory located at Respondent's Seaboard Drive, Atlanta, Georgia facility after providing Respondent with advance notice of the inspection by letter dated September 16, 2011.

16. During the inspection referenced in paragraph 15 above, the inspector reviewed three studies, conducted by Respondent at its Seaboard Drive, Atlanta, Georgia facility, which had been submitted to the EPA on or about March 25, 2009, which included:
    a. "Storage and Stability Testing and Chemical and Physical Properties Determination" for Enforcer RoachMax Bait (EPA Reg. No. 40849-76, MRID No. 47711801);
    b. "Storage and Stability Testing and Chemical and Physical Properties Determination" for Enforcer AntMax Bait (EPA Reg. No. 40849-75, MRID No. 47711802); and
    c. "Storage and Stability Testing and Chemical and Physical Properties Determination" for Enforcer Fire Ant Bait (EPA Reg. No. 40849-79, MRID No. 47711803).

17. The EPA conducted a lab test of the samples collected and referenced in paragraph 14 above. Based on the EPA's laboratory test results, which showed that the hospital disinfectant Zep Formula 165 was ineffective against *Mycobacterium tuberculosis*, on April 16, 2012, the EPA issued a Stop Sale, Use or Removal Order (SSURO), Docket Number FIFRA 04-2012-3265, to stop the sale and distribution by Respondent of Zep Formula 165.

18. In response to a request from Respondent, on April 26, 2012, the EPA amended the SSURO to allow Respondent to conduct a voluntary recall and to destroy all quantities of Zep Formula 165 under its ownership, custody, or control.

19. On May 2, 2012, a duly authorized representative of the EPA conducted an inspection of the warehouse and offices located at Respondent's Seaboard Drive, Atlanta, Georgia facility.

20. During the inspection referenced in paragraph 19, above, the inspector investigated the disposition of the pesticide product referenced in paragraph 14, above, "Zep Formula 165," which was the subject of the SSURO referenced in paragraph 17, above. The inspector also collected batch records and Respondent provided additional records documenting the distribution or sale of this pesticide.

DISTRIBUTION OR SALE OF AN UNREGISTERED PESTICIDE

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

22. Pursuant to 40 C.F.R. § 152.132, a registrant may distribute or sell its registered pesticide product under another person's name and address instead of (or in addition to) its own. Such distribution and sale is termed "supplemental distribution" and the product is referred to as a "distributor product".

23. Pursuant to 40 C.F.R. § 152.132, supplemental distribution is permitted upon notification to the EPA if all of the conditions listed in 40 C.F.R. § 152.132 are met, including, but not limited to, the following:

a. The registrant has submitted to the EPA 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. 40 C.F.R. § 152.132(a). The statement is also known as a "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5 (Rev. 8-94).

b. The distributor product is produced, packaged, and labeled in a registered establishment operated by the same producer (or under contract in accordance with Section 152.130) who produces, packages, and labels the registered product. 40 C.F.R. § 152.132(b).

24. A registrant may transfer the registration of a product to another person and the registered product may be distributed and sold without the requirement of a new application for registration by that other person, pursuant to 40 C.F.R. § 152.135, if the parties submit to the EPA the documents listed in 40 C.F.R. §§ 152.135(b) and (c) and receive the EPA approval as described in 40 C.F.R. § 152.135(d).

25. On or about June 30, 1997, Clariant Corporation submitted a Notice of Supplemental Distribution to the EPA pursuant to 40 C.F.R. § 152.132(a), that was signed by both Clariant, as producer, and Respondent, as supplemental distributor. The brand name to be used by Respondent was "Zep Formula 165," which was registered as a distributor product of Clariant Corporation's primary registration, EPA Registration Number 49403-6.

26. On April 21, 2010, the primary registration for EPA Registration Number 49403-6 was transferred in accordance with 40 C.F.R. § 152.135, from Clariant Corporation to Lanxess Corporation. At this time and pursuant to 40 C.F.R. § 152.135, EPA Registration Number 49403-6 became invalid. The new product number, which reflected the primary registration of Lanxess Corporation, became EPA Registration Number 39967-81.

27. Approximately two years later, on or about January 6, 2012, Lanxess Corporation submitted a Notice of Supplemental Distribution with the EPA pursuant to 40 C.F.R. § 152.132 that was signed by both Lanxess Corporation and Respondent. The brand name to be used by Respondent was "Zep Formula 165," which was registered as a distributor product of Lanxess Corporation's primary registration, which could then be sold by Respondent using EPA Registration Number 39967-81-1720.

28. "Zep Formula 165" was registered as a distributor product of Clariant Corporation until April 21, 2010, and later with Lanxess beginning on January 6, 2012. For purposes of this Complaint, the EPA refers to the period between registrations as a distributor product as the "unregistered period".

29. As documented by the batch records Respondent provided to the EPA during its May 2, 2012, inspection, as described in paragraph 19 above, Respondent produced at least 11 batches of Zep Formula 165 during the unregistered period. The 11 batches produced during the unregistered period shall hereafter be known as the "unregistered batches".

30. The first unregistered batch of Zep Formula 165 produced during the unregistered period was produced on May 28, 2010.

31. The Zep Formula 165 that was produced during the unregistered period was not registered under FIFRA.

32. As documented by the distribution or sales records referenced in paragraphs 14 and 20 above, Respondent distributed or sold Zep Formula 165 at least 308 separate times during the unregistered period beginning on the production date of the first unregistered batch and ending on the date that the Notice of Supplemental Distribution was submitted to the EPA by the registrant.

33. Each of the 308 sales or distributions of Zep Formula 165 that was not registered is a separate violation of Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), and constitutes a separate count under this Complaint.

34. Therefore, Respondent violated Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), at least 308 separate times by selling or distributing unregistered Zep Formula 165 and is therefore subject to the assessment of civil penalties under Section 14 of FIFRA, 7 U.S.C. § 136*l*.

DISTRIBUTION OR SALE OF A MISBRANDED PESTICIDE

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

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

37. A pesticide is misbranded pursuant to 40 C.F.R. § 156.10(a)(5), if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims.

38. Pursuant to 40 C.F.R. § 156.10(a)(5)(i) and (ii), statements or representations in the labeling which constitute misbranding include false or misleading statements concerning the composition of the product and false or misleading statements concerning the effectiveness of the product as a pesticide.

39. Pursuant to 40 C.F.R. § 156.10(e), the registration number assigned to the pesticide product shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No."

40. At the time of the May 26, 2011, and May 2, 2012, inspections referenced in paragraphs 13 and 19 above, the label for Zep Formula 165 bore the statement "EPA Reg. No. 49403-6-1270" which was the distributor product registration number associated with Clariant Corporation, which terminated on April 21, 2010.

41. The Zep Formula 165 that was produced during the unregistered period was not registered under FIFRA; however the label bore an EPA registration number in the style of a registered pesticide, and therefore "EPA Reg. No. 49403-6-1270" was a false or misleading statement.

42. At the time of the inspection referenced in paragraph 13 above, the label for Zep Formula 165 stated that it contained 1.25% of the active ingredient para-tertiary-amyl phenol.

43. Analytical results of the EPA laboratory testing of the sample of Zep Formula 165 obtained during the inspection referenced in paragraph 13 above, showed that the product contained 1.41% of the active ingredient para-tertiary-amyl phenol, which exceeded the stated percentage on the label. Therefore, the label statement on the Zep Formula 165 product that the product contained 1.25% of the active ingredient para-tertiary-amyl phenol was a false or misleading statement.

44. At the time of the inspection referenced in paragraph 13 above, the label on Zep Formula 165 provided "Hospital Use Directions" that stated "Zep Formula 165 qualifies as disinfectant for hospital use and is effective against *Mycobacterium tuberculosis*", and under "General Precautions and Restrictions" the label bore claims that "this will provide disinfection against…*Mycobacterium tuberculosis*".

45. Analytical results of the EPA's laboratory testing of the sample of Zep Formula 165 obtained during the inspection referenced in paragraph 13 above, conducted as part of the EPA Antimicrobial Efficacy Testing Program, showed that Zep Formula 165 was ineffective against *Mycobacterium tuberculosis* when used according to label directions. The label's statement of effectiveness against *Mycobacterium tuberculosis* was therefore a false or misleading statement.

46. As documented by the distribution or sales records referenced in paragraphs 14 and 20 above, Respondent distributed or sold Zep Formula 165 at least 308 times during the unregistered period with false or misleading statements.

47. Each of the 308 sales or distributions of Zep Formula 165 that bore false or misleading statements is a separate violation of Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), and constitutes a separate count under this Complaint.

48. Therefore, during the unregistered period, Respondent distributed or sold Zep Formula 165 at least 308 times with one or more false or misleading statements in violation of Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), and is therefore subject to the assessment of civil penalties under Section 14 of FIFRA, 7 U.S.C. § 136*l*.

SUBMISSION OF FALSE COMPLIANCE CERTIFICATION STATEMENTS

49. Section 12(a)(2)(Q) of FIFRA, 7 U.S.C. § 136j(a)(2)(Q), makes it 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, observation made, or conclusion 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.

50. 40 C.F.R. Part 160, prescribes good laboratory practice (GLP) standards for conducting studies that support or are intended to support applications for research or marketing permits for pesticide products regulated by the EPA. This part is intended to ensure the quality and integrity of data submitted pursuant to Sections 3, 4, 5, 8, 18 and 24(c) of FIFRA, 7 U.S.C. §§ 136a, 136b, 136c, 136f, 136p, 136v(c).

51. Pursuant to 40 C.F.R. § 160.3, an application for research or marketing permit means any of the following, including an application for registration, amended registration, or re-registration of a pesticide product under FIFRA Sections 3, 4 or 24(c), 7 U.S.C. §§ 136a, 136b, 136v(c).

52. Respondent submitted applications to the EPA for registration, amended registration, or re-registration of Enforcer RoachMax Bait, Enforcer AntMax Bait and Enforcer Fire Ant Bait, which qualify as Applications for Research or Marketing under 40 C.F.R. § 160.3.

53. Pursuant to 40 C.F.R. § 160.12, any person who submits to the EPA an application for a research or marketing permit and who, in connection with the application, submits data from a study to which Part 160 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 40 C.F.R. Part 160; or
    b. A statement describing in detail all differences between the practices used in the study and those required by this part; 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 this part.

54. Pursuant to 40 C.F.R. § 160.135(a), all provisions of the GLP standards shall apply to physical and chemical characterization studies designed to determine stability, solubility, octanol water partition coefficient, volatility and persistence (such as biodegradation, photodegredation and chemical degredation studies) of test, control or reference substances.

55. At the time of the inspection referenced in paragraph 15 above, Respondent was a producer and held a valid registration for Enforcer RoachMax Station (EPA Reg.

No. 40849-76), Enforcer AntMax Bait Station (EPA Reg. No. 40849-75), and Enforcer Fire Ant Bait (EPA Reg. No. 40849-79), also known as "RoachMax Station," "AntMax Bait Station," and "Fire Ant Bait," respectively, which are intended to destroy, repel, or mitigate pests and are therefore "pesticides" within the meaning of Section 2(u) of FIFRA, 7 U.S.C. § 136(u).

56. On March 25, 2009, Respondent submitted data to the EPA from each of the three studies referenced in paragraph 16 above.

57. The inspection of Respondent's laboratory, referenced in paragraphs 15 and 16 above, and subsequent review revealed that the study, "Storage and Stability Testing and Chemical and Physical Properties Determination" for Enforcer RoachMax Bait (EPA Reg. No. 40849-76, MRID No. 47711801), did not comply with 40 C.F.R. Part 160 in that Respondent:
   a. Failed to include a description of the experimental design, including methods for the control of bias in its study protocol, in violation of 40 C.F.R. § 160.120(a)(8);
   b. Failed to include the date of approval of the protocol by the sponsor and the dated signature of the study director in its study protocol, in violation of 40 C.F.R. § 160.120(a)(14);
   c. Failed to include a statement of the proposed statistical method to be used in its study protocol, in violation of 40 C.F.R. § 160.120(a)(15); and
   d. Failed to record all underlying raw data generated during the conduct of the study directly, promptly and legibly in ink, in violation of 40 C.F.R. § 160.130(e).

58. The inspection of Respondent's laboratory, referenced in paragraphs 15 and 16 above, and subsequent review revealed that the study, "Storage and Stability Testing and Chemical and Physical Properties Determination" for Enforcer AntMax Bait (EPA Reg. No. 40849-75, MRID No. 47711802), did not comply with 40 C.F.R. Part 160 in that Respondent:
   a. Failed to include a description of the experimental design, including methods for the control of bias in its study protocol, in violation of 40 C.F.R. § 160.120(a)(8);
   b. Failed to include the date of approval of the protocol by the sponsor and the dated signature of the study director in its study protocol, in violation of 40 C.F.R. § 160.120(a)(14);
   c. Failed to include a statement of the proposed statistical method to be used in its study protocol, in violation of 40 C.F.R. § 160.120(a)(15); and
   d. Failed to record all underlying raw data generated during the conduct of the study directly, promptly and legibly in ink, in violation of 40 C.F.R. § 160.130(e).

59. The inspection of Respondent's laboratory, referenced in paragraphs 15 and 16 above, and subsequent review revealed the study, "Storage and Stability Testing and Chemical and Physical Properties Determination" for Enforcer Fire Ant Bait (EPA Reg. No. 40849-79, MRID No. 47711803), did not comply with 40 C.F.R. Part 160 in that Respondent:
   a. Failed to assure that the final study report accurately described the methods and standard operating procedures, and that the reported results accurately reflected the raw data of the study, in violation of 40 C.F.R. § 160.35(b)(6).

b. Failed to include a description of the experimental design, including methods for the control of bias in its study protocol, in violation of 40 C.F.R. § 160.120(a)(8);
c. Failed to include the date of approval of the protocol by the sponsor and the dated signature of the study director in its study protocol, in violation of 40 C.F.R. § 160.120(a)(14);
d. Failed to include a statement of the proposed statistical method to be used in its study protocol, in violation of 40 C.F.R. § 160.120(a)(15); and
e. Failed to record all underlying raw data generated during the conduct of the study directly, promptly and legibly in ink, in violation of 40 C.F.R. § 160.130(e).

60. On March 25, 2009, Respondent submitted three signed statements to the EPA, pursuant to 40 C.F.R. § 160.12, which certified Respondent had conducted the studies listed in paragraphs 57, 58 and 59 above, in compliance with the FIFRA GLP standards set forth in 40 C.F.R. Part 160.

61. As set forth in paragraphs 57, 58 and 59 above, Respondent did not conduct the studies in full compliance with the applicable requirements of 40 C.F.R. Part 160. Therefore, Respondents' compliance statements referenced in paragraph 60 above were false.

62. Therefore, Respondent violated Section 12(a)(2)(Q) of FIFRA, 7 U.S.C. § 136j(a)(2)(Q), on at least three occasions by submitting three separate false compliance statements to the EPA and is therefore subject to the assessment of civil penalties under Section 14 of FIFRA, 7 U.S.C. § 136*l*.

C. Proposed Penalty

63. Pursuant to Section 14(a) of FIFRA, 7 U.S.C. § 136*l*(a), the 2008 and 2013 Civil Monetary Penalty Inflation Adjustment Rules, 73 *Fed. Reg.* 75340 (Dec. 11, 2008), 78 *Fed. Reg.* 66643 (Nov. 6, 2013); and 40 C.F.R. § 22.14(a)(4)(i), any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of FIFRA may be assessed a civil penalty by the Administrator of up to $7,500 per violation.

64. On the basis of the violations of FIFRA alleged above, Complainant has determined that Respondent is subject to penalties under Section 14(a) of FIFRA, 7 U.S.C. § 136*l*(a).

65. Pursuant to 40 C.F.R. § 22.14(a)(4)(ii), Complainant is not proposing a specific penalty at this time, but is proposing that Respondent pay a penalty of up to the statutory maximum of $7,500 for each of the 619 violations stated above in this Complaint. In accordance with 40 C.F.R. § 22.19(a)(4), Complainant will file a document after the prehearing exchange of information has occurred, specifying the proposed penalty and explaining how the proposed penalty was calculated. Also, since Complainant is not proposing a specific penalty at this time, Complainant has included below a brief explanation of the severity of the violations as required by 40 C.F.R. § 22.14(a)(4)(ii).

D. Severity of the Violations

Distribution or Sale of an Unregistered Pesticide

66. Respondent distributed or sold Zep Formula 165, an unregistered pesticide, numerous times in violation of Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A). As noted above in paragraphs 1 through 34, Complainant currently has specific evidence of 308 distributions or sales of Zep Formula 165.

67. Registration of pesticides is a fundamental requirement of the FIFRA framework for regulating pesticides. Even though Respondent was a registrant of other pesticides, Respondent failed to take the required steps to ensure that Zep Formula 165 was registered as a distributor product with Lanxess, and continued to manufacture and sell or distribute the product without the proper registration. Ignoring a fundamental requirement for pesticide registration compromises the integrity of the FIFRA program, and therefore, the EPA believes that each distribution or sale constitutes a serious violation of FIFRA.

Distribution or Sale of a Misbranded Pesticide

68. Respondent distributed or sold Zep Formula 165, a misbranded pesticide, numerous times in violation of Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E). As noted above in Paragraphs 1 through 20 and 35 through 48, Complainant currently has specific evidence of 308 distributions or sales of Zep Formula 165.

69. Pesticide labeling that is false or misleading strikes at the very heart of the integrity of FIFRA because it can result in the public having incorrect, inaccurate, and potentially harmful information about the product and its safety and effectiveness. By selling and distributing Zep Formula 165 with labels that included a registration number when the pesticide was unregistered, inaccurate composition numbers, and a statement indicating it was effective against *Mycobacterium tuberculosis* when it was not, Respondent not only violated key requirements of the pesticide laws enacted by Congress and the EPA, but also violated the public trust which relies on manufacturers and sellers of pesticides to properly inform consumers and users about the effectiveness of the product. As such, the EPA believes these are serious violations of FIFRA.

Submission of False Compliance Certification Statements

70. Respondent submitted false statements to the EPA, certifying full compliance with good laboratory practice (GLP) standards for conducting studies when they were not in compliance with those standards, in violation of Section 12(a)(2)(Q) of FIFRA, 7 U.S.C. § 136j(a)(2)(Q). As noted above in Paragraphs 1 through 20 and 49 through 62, Complainant currently has specific evidence of three false statements.

71. The statements were false because Respondent certified that it had conducted the pesticide studies in full compliance with GLP standards when, as noted in Paragraphs 57, 58 and 59, the studies were not conducted in full compliance with GLP standards.

Truthful, complete and accurate certification of compliance are fundamental requirements to ensure the quality and integrity of the data submitted to the EPA pursuant to Sections 3, 4, 5, 8, 18 and 24(c) of FIFRA, 7 U.S.C. §§ 136a, 136b, 136c, 136f, 136p, 136v(c). False certification of compliance with GLP standards is potentially a serious violation as it could have compromised the EPA's ability to review the data.

II. NOTICE OF OPPORTUNITY FOR HEARING

A. Answer and Right to Request a Hearing

72. Pursuant to 40 C.F.R. §§ 22.15(a) and 22.17(a), if the Respondent wishes to avoid being found in default, Respondent must file a written Answer to this Complaint within 30 days of service of this Complaint with the:

Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 4
Atlanta Federal Center
61 Forsyth Street, S.W.
Atlanta, Georgia 30303-3104.

73. Pursuant to 40 C.F.R. § 22.15(b), the Answer must clearly and directly admit, deny or explain each of the factual allegations contained in the Complaint with respect to which the Respondent has any knowledge, or clearly state that the Respondent has no knowledge as to particular factual allegations in the Complaint. The Answer also must state the circumstances or arguments that are alleged to constitute grounds of defense, and facts which the Respondent intends to place at issue.

74. Pursuant to 40 C.F.R. § 22.15(d), the Respondent's failure to admit, deny or explain any material factual allegation in its Answer to this Complaint constitutes admission of the allegation.

75. Pursuant to 40 C.F.R. § 22.15(c), the Respondent has the right to request a hearing in the Answer to contest any material fact contained in this Complaint, or to contest the appropriateness of the proposed penalty. Any hearing that Respondent requests regarding this Complaint will be held and conducted in accordance with the provisions of 40 C.F.R. Part 22.

76. A copy of this Answer and any subsequent documents that the Respondent files in this action should be sent to:

Ms. Lynda C. Crum
Associate Regional Counsel
EPA Region 4
61 Forsyth Street, SW
Atlanta, GA 30303
(404) 562-9524.

77. If the Respondent fails to file a written Answer within 30 calendar days of receipt of this Complaint, a Default Order may be issued by the Presiding Officer upon motion by the Complainant. Issuance of a Default Order will constitute an admission of all factual allegations made in the Complaint and a waiver of Respondent's right to contest such factual allegations, pursuant to 40 C.F.R. § 22.17(a). Any penalty assessed in the Default Order shall become due and payable by the Respondent without further proceedings 30 days after the Default Order becomes a Final Order. Pursuant to 40 C.F.R. § 22.27(c), a Default Order will become a Final Order 45 days after its service upon the Respondent and without further proceeding unless the Respondent moves to reopen the hearing, appeals the initial decision to the Environmental Appeals Board, moves to set aside a Default Order, or the Environmental Appeals Board elects to review the initial decision on its own initiative.

78. Neither assessment nor payment of an administrative civil penalty under Section 14 of FIFRA will affect the Respondent's continuing obligation to comply with FIFRA, or any other federal, State or local law or regulation.

B. Settlement Conference

79. Whether or not Respondent requests a hearing, an informal conference may be requested in order to discuss the facts of this case and to arrive at a settlement. To request a settlement conference, please contact:

Ms. Lynda Crum
Associate Regional Counsel
EPA Region 4
61 Forsyth Street, SW
Atlanta, GA 30303
(404) 562-9524.

80. Respondent's request for an informal settlement conference does not extend the 30 day period during which a written Answer and Request for Hearing must be submitted.

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Respondent may pursue the informal conference procedure simultaneously with the adjudicatory hearing procedure. The Complainant encourages all parties facing civil penalties to pursue settlement through an informal conference. The Complainant, however, will not reduce the penalty simply because such a conference is held. Any settlement that may be reached as a result of such conference will be embodied in a Consent Agreement and Final Order. Respondent's consent to a Consent Agreement and Final Order will constitute a waiver of the right to request a hearing on any matter stipulated to therein.

COMPLAINANT:

Date: 3-11-14

Beverly H. Banister
Director
Air, Pesticides and Toxics
Management Division
U.S. EPA Region 4

I hereby certify that on the date set out below, I filed the original and one copy of the foregoing Civil Complaint and Notice of Opportunity for Hearing and served a true and correct copy of the foregoing Civil Complaint and Notice of Opportunity for Hearing, In the Matter of Zep, Inc., Docket Number: FIFRA-04-2014-3000, to the addressees listed below:

Catherine D. Little, Esq.
Hunton and Williams LLP
600 Peachtree Street, NE
Suite 4100
Atlanta, Georgia 30308-2216

(via Certified Mail, Return Receipt Requested)

Molly Miller
Pesticides Section
U.S. EPA Region 4
61 Forsyth Street
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