

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION VII
901 NORTH 5TH STREET
KANSAS CITY, KANSAS 66101

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ENVIRONMENTAL PROTECTION
AGENCY REGION VII
REGIONAL HEARING CLERK

BEFORE THE ADMINISTRATOR

IN THE MATTER OF) Docket No. FIFRA-07-2007-0024
)
Revival Animal Health, Inc.)
)
Respondent)

**ANSWER AND REQUEST FOR HEARING OF
RESPONDENT REVIVAL ANIMAL HEALTH, INC.**

COMES NOW Respondent Revival Animal Health, Inc. (“Respondent” or “Revival”) and for its Answer to the Complaint and Request for Hearing states as follows (by paragraph number in the Complaint):

1. Respondent admits only that this paragraph of the Complaint purports to describe a certain administrative action being brought by Complainant United States Environmental Protection Agency (“Complainant” or “USEPA”) but denies the remaining allegations of this paragraph of the Complaint.

2. Respondent admits only that this paragraph of the Complaint purports to be USEPA’s notice of alleged violations of section 12 of the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), 7 U.S.C. §136j, but denies the remaining allegations of this paragraph of the Complaint.

3. Respondent is without sufficient information to form a belief as to the truth of the allegations in this paragraph of the Complaint and therefore denies them.

4. Respondent admits that it is located at 1700 Albany Place SE, Orange City, Iowa and is an Iowa corporation qualified to do business in the State of Iowa but denies the remainder of this paragraph of the Complaint.

5. This paragraph of the Complaint purports only to be an introduction to Complainant's further statement of alleged FIFRA violations and does not require a response. However, to the extent, if any, that a response is required, all statements in this paragraph are denied.

6. Respondent denies the allegations of this paragraph of the Complaint.

7. Respondent denies the allegations of this paragraph of the Complaint.

8. Respondent denies the allegations of this paragraph of the Complaint.

9. Respondent denies the allegations of this paragraph of the Complaint.

10. This paragraph of the Complaint purports only to re-state a certain provision in FIFRA and does not require a response. To the extent, if any, that a response is required, this paragraph is denied.

11. This paragraph of the Complaint purports only to re-state a certain provision in FIFRA and does not require a response. To the extent, if any, that a response is required, this paragraph is denied.

12. This paragraph of the Complaint purports only to re-state a certain provision in FIFRA and does not require a response. To the extent, if any, that a response is required, this paragraph is denied.

13. This paragraph of the Complaint purports only to re-state a certain provision in FIFRA and does not require a response. To the extent, if any, that a response is required, this paragraph is denied.

14. Respondent admits that Bayer Corporation manufactures or distributes certain Advantage products for dogs, but Respondent is without sufficient information to form a belief

as to the truth of the remaining allegations in this paragraph of the Complaint and therefore denies them.

15. Respondent admits that Merial Limited manufactures or distributes certain Frontline products for dogs, but Respondent is without sufficient information to form a belief as to the truth of the remaining allegations in this paragraph of the Complaint and therefore denies them.

16. Respondent admits that Bayer Corporation manufactures or distributes certain Advantage products for cats, but Respondent is without sufficient information to form a belief as to the truth of the remaining allegations in this paragraph of the Complaint and therefore denies them.

17. Respondent admits that Bayer Corporation manufactures or distributes certain Advantage pesticide products, but Respondent is without sufficient information to form a belief as to the truth of the remaining allegations in this paragraph of the Complaint and therefore denies them.

18. Respondent is without sufficient information to form a belief as to the truth of the allegations in this paragraph of the Complaint and therefore denies them.

19. Respondent is without sufficient information to form a belief as to the truth of the allegations in this paragraph of the Complaint and therefore denies them.

20. Respondent is without sufficient information to form a belief as to the truth of the allegations in this paragraph of the Complaint and therefore denies them.

21. Respondent is without sufficient information to form a belief as to the truth of the allegations in this paragraph of the Complaint and therefore denies them.

22. Respondent admits that on September 10, 2003 and October 8, 2003 a representative of the Iowa Department of Agriculture and Land Stewardship (IDALS) conducted certain inspections at Respondent's place of business in Orange City, Iowa but denies the remaining allegations of this paragraph of the Complaint.

23. Respondent denies the allegations of this paragraph of the Complaint.

24. Respondent is without sufficient information to form a belief as to the truth of the allegations in this paragraph of the Complaint and therefore denies them.

25. Respondent denies the allegations of this paragraph of the Complaint.

26. Respondent admits that on March 10, 2005 a representative of IDALS and representative of USEPA conducted a certain inspection at Respondent's place of business in Orange City, Iowa but denies the remaining allegations of this paragraph of the Complaint.

Answer to Allegations in Count 1

27. Respondent re-alleges and incorporates its answers to paragraphs 6 through 26 as if fully restated herein.

28. Respondent denies the allegations of this paragraph of the Complaint.

29. Respondent denies the allegations of this paragraph of the Complaint.

30. This paragraph of the Complaint purports to summarize a regulation at 40 C.F.R. §152.44 and does not require a response. However, to the extent any response is required, the allegations in this paragraph of the Complaint are denied.

31. Respondent denies the allegations of this paragraph of the Complaint.

32. Respondent denies the allegations of this paragraph of the Complaint.

Answer to Allegations in Count 2

33. Respondent re-alleges and incorporates its answers to paragraphs 6 through 26 as if fully restated herein.

34. Respondent denies the allegations of this paragraph of the Complaint.

35. Respondent denies the allegations of this paragraph of the Complaint.

36. Respondent denies the allegations of this paragraph of the Complaint.

37. Respondent denies the allegations of this paragraph of the Complaint.

Answer to Allegations in Count 3

38. Respondent re-alleges and incorporates its answers to paragraphs 6 through 26 as if fully restated herein.

39. Respondent denies the allegations of this paragraph of the Complaint.

40. Respondent denies the allegations of this paragraph of the Complaint.

41. This paragraph of the Complaint purports to summarize a regulation at 40 C.F.R. §152.44 and does not require a response. However, to the extent any response is required, the allegations in this paragraph of the Complaint are denied.

42. Respondent denies the allegations of this paragraph of the Complaint.

43. Respondent denies the allegations of this paragraph of the Complaint.

Answer to Allegations in Count 4

44. Respondent re-alleges and incorporates its answers to paragraphs 6 through 26 as if fully restated herein.

45. Respondent denies the allegations of this paragraph of the Complaint.

46. Respondent denies the allegations of this paragraph of the Complaint.

47. Respondent denies the allegations of this paragraph of the Complaint.

48. Respondent denies the allegations of this paragraph of the Complaint.

Answer to Allegations in Count 5

49. Respondent re-alleges and incorporates its answers to paragraphs 6 through 26 as if fully restated herein.

50. Respondent denies the allegations of this paragraph of the Complaint.

51. Respondent denies the allegations of this paragraph of the Complaint.

52. This paragraph of the Complaint purports to summarize a regulation at 40 C.F.R. §152.44 and does not require a response. However, to the extent any response is required, the allegations in this paragraph of the Complaint are denied.

53. Respondent denies the allegations of this paragraph of the Complaint.

54. Respondent denies the allegations of this paragraph of the Complaint.

Answer to Allegations in Count 6

55. Respondent re-alleges and incorporates its answers to paragraphs 6 through 26 as if fully restated herein.

56. Respondent denies the allegations of this paragraph of the Complaint.

57. Respondent denies the allegations of this paragraph of the Complaint.

58. Respondent denies the allegations of this paragraph of the Complaint.

59. Respondent denies the allegations of this paragraph of the Complaint.

Answer to Allegations in Count 7

60. Respondent re-alleges and incorporates its answers to paragraphs 6 through 26 as if fully restated herein.

61. Respondent denies the allegations of this paragraph of the Complaint.

62. Respondent denies the allegations of this paragraph of the Complaint.

63. This paragraph of the Complaint purports to summarize a regulation at 40 C.F.R. §152.44 and does not require a response. However, to the extent any response is required, the allegations in this paragraph of the Complaint are denied.

64. Respondent denies the allegations of this paragraph of the Complaint.

65. Respondent denies the allegations of this paragraph of the Complaint.

Answer to Allegations in Count 8

66. Respondent re-alleges and incorporates its answers to paragraphs 6 through 26 as if fully restated herein.

67. Respondent denies the allegations of this paragraph of the Complaint.

68. Respondent denies the allegations of this paragraph of the Complaint.

69. Respondent denies the allegations of this paragraph of the Complaint.

70. Respondent denies the allegations of this paragraph of the Complaint.

Answer to Allegations in Count 9

71. Respondent re-alleges and incorporates its answers to paragraphs 6 through 26 as if fully restated herein..

72. Respondent denies the allegations of this paragraph of the Complaint.

73. Respondent denies the allegations of this paragraph of the Complaint.

74. This paragraph of the Complaint purports to summarize a regulation at 40 C.F.R. §152.44 and does not require a response. However, to the extent any response is required, the allegations in this paragraph of the Complaint are denied.

75. Respondent denies the allegations of this paragraph of the Complaint.

76. Respondent denies the allegations of this paragraph of the Complaint.

Answer to Allegations in Count 10

77. Respondent re-alleges and incorporates its answers to paragraphs 6 through 26 as if fully restated herein

78. Respondent denies the allegations of this paragraph of the Complaint.

79. Respondent denies the allegations of this paragraph of the Complaint.

80. Respondent denies the allegations of this paragraph of the Complaint.

81. Respondent denies the allegations of this paragraph of the Complaint.

Answer to Allegations in Count 11

82. Respondent re-alleges and incorporates its answers to paragraphs 6 through 26 as if fully restated herein

83. Respondent denies the allegations of this paragraph of the Complaint.

84. Respondent denies the allegations of this paragraph of the Complaint.

85. This paragraph of the Complaint purports to summarize a regulation at 40 C.F.R. §152.44 and does not require a response. However, to the extent any response is required, the allegations in this paragraph of the Complaint are denied.

86. Respondent denies the allegations of this paragraph of the Complaint.

87. Respondent denies the allegations of this paragraph of the Complaint.

Answer to Allegations in Count 12

88. Respondent re-alleges and incorporates its answers to paragraphs 6 through 26 as if fully restated herein.

89. Respondent denies the allegations of this paragraph of the Complaint.

90. Respondent denies the allegations of this paragraph of the Complaint.

91. Respondent denies the allegations of this paragraph of the Complaint.

92. Respondent denies the allegations of this paragraph of the Complaint.

Answer to Section IV: USEPA's Total Proposed Penalty

93. Respondent denies the allegations of this paragraph of the Complaint.

Respondent denies that it is liable under FIFRA for any penalty.

Answer to Section IV: Alleged Appropriateness of Proposed Penalty

94. Respondent denies the allegations of this paragraph of the Complaint.

Respondent denies that any penalty is appropriate.

95. Respondent denies the allegations of this paragraph of the Complaint.

Respondent denies that any penalty is appropriate.

96. This paragraph purports to advise Respondent of a certain right and does not require a response. However, to the extent any response is required, Respondent denies that it is liable for any penalty in this matter and denies that any penalty is appropriate.

97. This paragraph does not require a response because it purports only to advise Respondent of circumstances in which USEPA's alleged proposed penalty constitutes a demand. However, to the extent that a response may be required, Respondent states that it has raised *bona fide* defenses relevant to determination of a final alleged penalty and denies it is liable under FIFRA. Respondent further denies that it is liable for any penalty in this matter and denies that any penalty is appropriate.

98. This paragraph purports to advise Respondent of circumstances in which USEPA's alleged proposed penalty constitutes a demand and does not require a response. However, to the extent that a response may be required, Respondent states that it has previously advised USEPA of certain *bona fide* defenses relevant to determination of a final alleged penalty, reserves the right to raise additional such defenses as discovery proceeds, and denies it is liable

under FIFRA. To the extent any response to this paragraph is required, Respondent denies that it is liable for any penalty in this matter and denies that any penalty is appropriate.

99. This paragraph advises Respondent of the manner of paying USEPA's proposed penalty and does not require a response. To the extent a response may be required, Respondent denies that it is liable for a penalty and denies that any penalty is appropriate.

100. This paragraph advises Respondent of the manner of paying USEPA's proposed penalty and does not require a response. To the extent a response may be required, Respondent denies that it is liable for a penalty and denies that any penalty is appropriate. Respondent contests the findings and assessments referenced in this paragraph, as stated above.

RESPONDENT'S REQUEST FOR HEARING

101 – 104. In response to USEPA's Notice and Opportunity for Hearing (paragraphs 101-104 of the Complaint), Respondent requests a hearing pursuant to Section 14(a) of FIFRA, 7 U.S.C. §136(a) to contest alleged material facts and to contest the appropriateness of USEPA's proposed penalty. This Answer and Request for Hearing is timely filed pursuant to the Order granting Respondent's motion for extension of time in which to answer and request a hearing until December 17, 2007.

RESPONDENT'S REQUEST FOR FURTHER SETTLEMENT CONFERENCE

105-107. Respondent has previously requested and had settlement conferences through Ms. Jennifer Trotter at USEPA, most recently on December 6, 2007, and believes that a further settlement conference may be productive. Therefore, Respondent requests a further settlement conference.

GENERAL DENIAL

Respondent denies each and every allegation in USEPA's Complaint not specifically admitted herein.

AFFIRMATIVE DEFENSES

First Affirmative Defense. USEPA fails to state a claim upon which relief can be granted and therefore its Complaint should be dismissed.

Second Affirmative Defense. USEPA's claims stated in its Complaint may be barred by the applicable statutes of limitations.

Third Affirmative Defense. Respondent is exempted from FIFRA liability by the guaranty exemption to FIFRA liability at 7 U.S.C. §136j(b)(1), and thus the penalties proposed by USEPA in its Complaint do not apply.

Fourth Affirmative Defense. USEPA has incorrectly applied its Enforcement Response Policy for FIFRA and has reached incorrect conclusions concerning, *inter alia*, gravity adjustments for alleged pesticide toxicity, alleged harm to human health, and alleged environmental harm. Proper application of USEPA's Enforcement Response Policy for FIFRA would result in no penalty.

Fifth Affirmative Defense. Respondent has no culpability in this matter, and EPA agrees that it has no culpability. Proper recognition of Respondent's total lack of culpability in application of USEPA's Enforcement Response Policy for FIFRA would result in no penalty.

Sixth Affirmative Defense. Upon being made aware of the alleged counterfeit nature of product from an upstream supplier, Respondent immediately and in good faith made every effort to identify the allegedly counterfeit product from the upstream supplier and segregate it from Respondent's product inventory. The allegedly counterfeit products comprised only a small

portion of Respondent's total product inventory. Specifically, once the product was discovered to be counterfeit on September 10, 2003, Respondent took numerous actions, including without limitation the following measures:

- (1) Respondent segregated and quarantined allegedly counterfeit product immediately in accordance with the investigator's instructions.
- (2) The quarantined products were placed "on hold" at that time in the computer system to prevent additional sales.
- (3) Resources were identified that would provide educational materials for staff to identify allegedly counterfeit Advantage and Frontline.
- (4) Informational documents provided by the US manufacturers of Advantage and Frontline (Bayer and Merial) were obtained, and distributed to Respondent's personnel, including customer service personnel.
- (5) Respondent instituted a policy not to purchase topical or digestible type products from overseas suppliers.
- (6) Because no guidance was provided by the inspector regarding disposal, Respondent's purchaser contacted both manufacturers to determine if they would take this product for disposal. One agreed to; the other did not. After a period of time of communications, discussion, and uncertainty, finally it was decided to dispose of the product locally.
- (7) At Respondent's expense, the counterfeit product was disposed via a "special waste authorization" from the Sioux County Landfill.

In addition, Revival cooperated with EPA officials in trying to identify and locate other domestic sellers who may also have received potentially or allegedly counterfeit product from the same

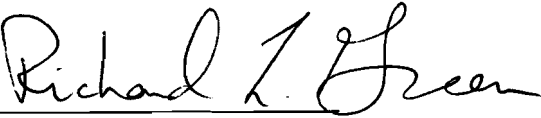
upstream supplier or from foreign sources. Proper recognition of these and other good faith efforts of Respondent to comply with FIFRA, cooperate with USEPA's investigation of allegedly counterfeit product, and assisting USEPA in its effective administration of the FIFRA program would result in no penalty being assessed under USEPA's Enforcement Response Policy for FIFRA.

Seventh Affirmative Defense. Respondent was a victim of an upstream supplier of allegedly counterfeit pesticide product containing all the indicia of proper labeling and EPA registration required by regulations. Respondent had no intent to sell or offer to sell counterfeit product. USEPA does not allege any such intent. Revival believes it had no more way of knowing the product was counterfeit than an innocent recipient of counterfeit U.S. currency would know the money was not genuine. Respondent in good faith made every effort to cooperate with officials. It is inequitable for the downstream innocent purchaser (Respondent) to bear all the brunt of civil penalty enforcement while the upstream supplier and others in a position to have known of a potential problem, including without limitation U.S. Customs Officials, do not bear any burden or suffer any consequence. Proper recognition of the equities would result in no penalty being assessed against Respondent under USEPA's Enforcement Response Policy for FIFRA.

WHEREFORE, Respondent requests entry of the following relief:

- A. Dismiss USEPA's Complaint with prejudice;
- B. Enter a final order in favor of Respondent and against USEPA;
- C. Award Respondent its costs, expenses, and attorneys' fees incurred in defending this action; and
- D. Grant all other relief deemed just and equitable in favor of Respondent.

Dated: December 17, 2007

By 

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COUNSEL FOR RESPONDENT REVIVAL
ANIMAL HEALTH, INC.


CERTIFICATE OF SERVICE

I hereby certify that on December 17, 2007, the foregoing Answer and Request for Hearing was hand-delivered to

Ms. Kathy Robinson (original and one copy)
Regional Hearing Clerk
In Counsel
United States Environmental Protection Agency, Region VII
901 North 5th Street
Kansas City, Kansas 66101

Ms. Jennifer Trotter (one copy)
Assistant Regional Counsel
United States Environmental Protection Agency, Region VII
901 North 5th Street
Kansas City, Kansas 66101

Mr. Robert L. Patrick (one copy)
Regional Judicial Officer
United States Environmental Protection Agency, Region VII
901 North 5th Street
Kansas City, Kansas 66101


Attorney for Respondent Revival Animal Health, Inc.