

November 2, 2012

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Wanda I. Santiago  
Regional Hearing Clerk  
U.S. Environmental Protection Agency – Region 1  
5 Post Office Square – Suite 100 (ORA 18-1)  
Boston, MA 02109-3912

Re: In the Matter of Exergen Corporation, Docket No. FIFRA-01-2012-0066

Dear Ms. Santiago,

Enclosed for filing in the referenced action, please find the original and one copy of Respondent's Answer to Complaint and Request for Hearing. Also enclosed is a certificate of service.

Thank you for your attention in this matter.

Very truly yours,



Adam D. Riedel  
Counsel for Respondent

Enclosures

cc: Hugh Martinez, Senior Enforcement Counsel  
James G. Votaw

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 1**

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In the Matter of: )  
)  
Exergen Corporation )  
400 Pleasant Street )  
Watertown, MA 02472, )  
)  
Respondent. )  
)  
Proceedings under Section )  
14(a) of the Federal )  
Insecticide, Fungicide, and )  
Rodenticide Act, as amended, )  
7 U.S.C. Section 136l(a). )  
\_\_\_\_\_ )

Docket No. FIFRA-01-2012-0066

**ANSWER TO COMPLAINT AND  
REQUEST FOR HEARING**

Respondent, Exergen Corporation, through counsel and pursuant to 40 C.F.R. §22.15, responds to the Complaint and Notice of Opportunity for hearing pursuant to as follows:

**GENERAL ALLEGATIONS**

1. The allegations in Paragraph 1 constitute conclusions of law to which no response is necessary. By way of further response, Respondent denies violating Section 12(a)(1)(A) of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136j(a)(1)(A), as amended, or any other provision of FIFRA or its implementing regulations. Respondent lacks sufficient knowledge to respond to the allegation that Complainant has any lawfully delegated authority.

2. The allegations in paragraph 2 are admitted.

3. The allegations in Paragraph 3 constitute conclusions of law to which no response is necessary.

4. Respondent admits that it sold the listed temporal scanner thermometers during the period specified. The remaining allegations in Paragraph 4 constitute conclusions of law to which no response is necessary.

5. Respondent admits that each of the TAT-2000C, TAT-5000 and TAT-2000 products (collectively "Products") are medical devices regulated by the U.S. Food and Drug Administration that consist of a temporal scanner thermometer for consumer use (TAT-2000C)

or professional use (TAT-5000 and TAT-2000), and that each of these products has a probe tip that incorporates, as an ancillary feature, a FIFRA-registered antimicrobial compound designed to mitigate the growth of bacteria on the probe tip. The remaining allegations in paragraph 5 are denied.

6. Respondent admits that it has advertising and labeling material associated with the Products, and with respect to the content of these materials, such content speaks for itself.

7. The allegations in paragraph 7 constitute conclusions of law to which no response is necessary.

8. The allegations in paragraph 8 constitute conclusions of law to which no response is necessary.

9. Respondent admits that its products are medical devices regulated by the U.S. Food and Drug Administration that consist of a temporal scanner thermometer for consumer use (TAT-2000C) or professional use (TAT-5000 and TAT-2000), and that each of these products has a probe tip that incorporates, as an ancillary feature, a FIFRA-registered antimicrobial compound designed to mitigate the growth of bacteria on the product. Respondent denies that the Products were pesticides as defined by FIFRA. Respondent further denies the allegation that the Products are not exempt from regulation under FIFRA.

10. The allegations in paragraph 10 constitute conclusions of law to which no response is necessary.

11. Respondent admits the allegation in paragraph 11 that on September 21, 2010 three people representing themselves to be EPA inspectors appeared at respondent's facility in Watertown, MA. The legal authority by which such persons appeared is a conclusion of law to which no response is necessary.

12. Respondent cannot respond to the allegations in paragraph 12 because the phrase "physical samples and/or documentary samples" is too vague and nonspecific, and therefore the allegations in paragraph 12 are denied.

13. Respondent cannot respond to the allegation in paragraph 13 because it is vague, conclusory and non-specific as to what items are being referred to in the allegation, and therefore the allegation in paragraph 13 is denied.

14. The allegations in paragraph 14 contain conclusions of law to which no response is necessary. Respondent admits that it voluntarily provided to EPA certain sales records, and with regard to the content of such sales records, the content speaks for itself.

15. Respondent can not respond to the allegations in paragraph 15 because it is unclear which "sales records" are being referred to, and therefore the allegations are denied. By way of further response, with respect to the content of any records collected by the EPA inspectors, such sales records speak for themselves.

16. The allegations in paragraph 16 are admitted. By way of further response, Respondent states that no such registration was required.

17. Respondent admits that on April 17, 2012 it received from EPA a “Stop Sale, Use, or Removal Order” dated April 11, 2012. The legal authority by which EPA issued such a letter constitutes a conclusion of law to which no response is necessary.

### **COUNT I**

#### **Unregistered Pesticides: TAT-2000C**

18. Respondent incorporates herein by reference as if fully set forth in its responses to paragraphs 1- 17.

19. The allegation in paragraph 19 contains conclusions of law to which no response is necessary. By way of further response, Respondent denies the allegation, as it is vague in that it is unclear what is meant by “Inspectors documented.” Respondent further denies that the Products were pesticides subject to FIFRA registration requirements.

20. Respondent lacks sufficient knowledge to admit or deny the allegations in paragraph 20 since Respondent cannot know EPA’s internal “determinations”, and the allegations do not specifically what “further investigation,” or “review of records” took place, and therefore the allegations are denied.

21. The allegations in paragraph 21 constitute conclusions of law to which no response is necessary. By way of further response, Respondent denies that it violated Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), or regulations promulgated pursuant to FIFRA, including 40 C.F.R. Part 152.

### **COUNT II**

#### **Unregistered Pesticides: TAT-5000**

22. Respondent incorporates herein by reference as if fully set forth in its responses to paragraphs 1 – 21.

23. The allegation in paragraph 23 contains conclusions of law to which no response is necessary. By way of further response, Respondent denies the allegation, as it is vague in that it is unclear what is meant by “Inspectors documented.” Respondent further denies that the Products were pesticides subject to FIFRA registration requirements.

24. Respondent lacks sufficient knowledge to admit or deny the allegations in paragraph 24 since Respondent cannot know EPA’s internal “determinations”, and the allegations do not specifically what “further investigation,” or “review of records” took place, and therefore the allegations are denied.

25. The allegations in paragraph 25 constitute conclusions of law to which no response is necessary. By way of further response, Respondent denies that it violated Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), or regulations promulgated pursuant to FIFRA, including 40 C.F.R. Part 152.

### **COUNT III**

#### **Unregistered Pesticides: TAT-2000**

26. Respondent incorporates herein by reference as if fully set forth in its responses to paragraphs 1 – 25.

27. The allegation in paragraph 27 contains conclusions of law to which no response is necessary. By way of further response, Respondent denies the allegation, as it is vague in that it is unclear what is meant by “Inspectors documented.” Respondent further denies that the Products were pesticides subject to FIFRA registration requirements.

28. Respondent lacks sufficient knowledge to admit or deny the allegations in paragraph 28 since Respondent cannot know EPA’s internal “determinations”, and the allegations do not specifically what “further investigation,” or “review of records” took place, and therefore the allegations are denied.

29. The allegations in paragraph 29 constitute conclusions of law to which no response is necessary. By way of further response, Respondent denies that it violated Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), or regulations promulgated pursuant to FIFRA, including 40 C.F.R. Part 152.

### **CIVIL PENALTY**

30. The allegations in paragraph 30 constitute conclusions of law to which no response is necessary.

31. The statements in paragraph 31 require no response.

32. The allegations contained in paragraph 32 constitute conclusions of law to which no response is necessary. By way of further response, Respondent denies that the Products were pesticides subject to FIFRA registration requirements.

33. The statements in paragraph 33 require no response.

34. The statements in paragraph 34 require no response.

35. The allegations in paragraph 35 constitute conclusions of law to which no response is necessary.

**OPPORTUNITY TO REQUEST A HEARING**

36. The allegations in paragraphs 36 - 42 constitute conclusions of law to which no response is necessary. By way of further response, Respondent requests a hearing to contest the material facts set forth in the Complaint, including the allegations of liability and the appropriateness of any penalty assessed. By way of further response, Respondent asserts the defenses set forth in paragraph 38.

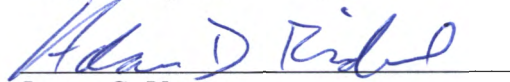
37. All allegations and other matters in the complaint not specifically admitted by Respondent herein are denied.

**ADDITIONAL DEFENSES**

38. Complainant is precluded from enforcing FIFRA with regard to the Products, which are medical devices subject to the controlling jurisdiction of FDA.

WHEREFORE, for the foregoing reasons, Respondent requests that no violation of FIFRA be found, that no penalty be assessed and that the complaint be dismissed.

Respectfully submitted,



James G. Votaw  
Adam D. Riedel  
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Suite 1100  
Washington, D.C. 20005  
(P) 202-585-6610  
(F) 202-585-6600

**CERTIFICATE OF SERVICE**

I hereby certify that the foregoing Answer to Complaint and Request for Hearing was delivered in the following manner to the addresses listed below:

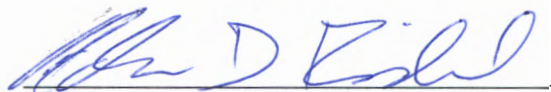
Original and One Copy via  
FedEx, to:

Wanda I. Santiago  
Regional Hearing Clerk  
Environmental Protection Agency  
5 Post Office Square, Suite 100 (ORA 18-1)  
Boston, MA 02109-3912

One Copy by Certified Mail,  
Return Receipt Requested, to:

Hugh W. Martinez  
Senior Enforcement Counsel  
Office of Environmental Stewardship  
Environmental Protection Agency, Region 1  
5 Post Office Square, Suite 100 (OES 04-3)  
Boston, MA 02109-3912

Signed:



Adam D. Riedel  
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Washington, D.C., 20005  
Phone: 202-585-6522  
Fax: 202-637-1520

Date:

11/2/2012