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October 31, 2007

Via First-Class Mail

Regional Hearing Clerk
U.S. EPA Region 8
1595 Wynkoop Street (8RC)
Denver, CO 80202

Re: In the Matter of: American Biotech Labs, LLC
Docket No. FIFRA-08-2007-0013

Dear Sir or Madam:

On behalf of my client, American Biotech Labs, LLC, enclosed please find for filing an original and copy of American Biotech Labs, LLC's Answer to Penalty Complaint and Request for Hearing for the above-referenced docket. A copy of this pleading also is being served via first-class mail on counsel for U.S. EPA Region 8 in this matter, Eduardo Quintana.

Please contact me should you have any questions concerning this filing. Thank you for your attention to this matter.

Sincerely,

Michael T. Novak

Enclosures

cc: Eduardo Quintana, Senior Enforcement Attorney, U.S. EPA Region 8

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8

In the Matter of:	)	
	)	Docket No. FIFRA-08-2007-0013
American Biotech Labs, LLC.,	)	
80 West Canyon Crest Road	)	ANSWER AND REQUEST FOR HEARING
Alpine, Utah;	)	
	)	
Respondent.	)	

ANSWER TO PENALTY COMPLAINT

American Biotech Labs, LLC ("American Biotech"), by its attorneys Keller and Heckman LLP, for its Answer and affirmative defenses to the Penalty Complaint and Opportunity for Hearing ("Complaint") filed in this matter by Region 8 of the United States Environmental Protection Agency ("EPA" or "Complainant") hereby admits, denies and alleges as follows:

JURISDICTION

1. This civil administrative enforcement action is authorized by Congress in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). 7 U.S.C. § 136l(a). The rules for this proceeding are the "Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders and the Revocation, Termination or Suspension of Permits ("Rules of Practice")." 40 C.F.R. part 22, a copy of which is enclosed.

ANSWER: American Biotech admits that the Complaint purports to be a civil enforcement action under FIFRA. American Biotech denies the remaining allegations of Paragraph 1 of the Complaint.

2. The undersigned EPA officials have been properly delegated the authority to issue this action.

ANSWER: American Biotech admits the allegations of Paragraph 2 of the Complaint.

3. EPA alleges that Respondent has violated FIFRA by selling or distributing a misbranded pesticide and failing to produce documents required by law. For these violations, EPA proposes the assessment of a civil penalty as more full explained below.

ANSWER: American Biotech admits that EPA alleges in Paragraphs 8-21 of its Complaint that American Biotech violated FIFRA, and admits that EPA proposes a civil penalty in Paragraph 23 of its Complaint. American Biotech denies the remaining allegations of Paragraph 3 of the Complaint.

NOTICE OF OPPORTUNITY FOR A HEARING

4. Respondent has the right to a public hearing before an administrative law judge (ALJ) to disagree with (1) any fact alleged by EPA in the complaint, or (2) the appropriateness of the proposed penalty.

ANSWER: American Biotech admits the allegations of Paragraph 4 of the Complaint and, in accordance with 40 C.F.R. § 22.15(c), American Biotech requests such a hearing. This request is reproduced at the conclusion of this Answer.

5. To disagree with the complaint, and assert your right to a hearing, Respondent must file a written answer (and one copy) with the Regional Hearing Clerk, 1595 Wynkoop Street (8RC), Denver, Colorado 80202, within thirty (30) days of receiving this complaint. The answer must clearly admit, deny or explain the factual allegations of the complaint, the grounds for any defense, the facts you may dispute, and your specific request for a public hearing. Please see section 22.15 of the Rules of Practice for a complete description of what must be in your answer. ***FAILURE TO FILE AN ANSWER AND REQUEST FOR HEARING WITHIN THIRTY (30) DAYS MAY WAIVE RESPONDENT'S RIGHT TO DISAGREE WITH THE ALLEGATIONS OR PROPOSED PENALTY, AND RESULT IN A DEFAULT JUDGMENT AND ASSESSMENT OF THE PENALTY PROPOSED IN THE COMPLAINT***

ANSWER: Paragraph 5 of the Complaint is comprised solely of legal conclusions for which no response is required.

QUICK RESOLUTION

6. Respondent may resolve this proceeding at any time by paying the specific penalty proposed in this complaint. Such payment need not contain any response to, or admission of, the allegations in the complaint. Such payment constitutes a waiver of Respondent's right to contest the allegations and to appeal the final order. See section 22.18 of the Rules of Practice for a full explanation of the quick resolution process. If Respondent chooses to resolve this proceeding by paying the specific penalty proposed in this complaint, payment must be made, within thirty (30) calendar days of receipt of this complaint, by sending a certified or cashier's check, including the name and docket number of this case, payable to "Treasurer, United States of America," in care of:

US Environmental Protection Agency
Fines and Penalties
Cincinnati Finance Center
P.O. Box 979077
St. Louis, MO 63197-9000

A copy of the check must be mailed simultaneously to the attorney listed below.

ANSWER: Paragraph 6 of the Complaint is comprised solely of legal conclusions for which no response is required.

SETTLEMENT NEGOTIATIONS

7. EPA encourages discussing whether cases can be settled through informal settlement conferences. If you want to pursue the possibility of settling this matter, or have any other questions, contact Senior Enforcement Attorney Eduardo Quintana at (303) 312-6924 or the address below. ***Please note that calling or requesting a settlement conference does NOT delay the running of the thirty (30) day period for filing an answer and requesting a hearing.***

ANSWER: Paragraph 7 of the Complaint is comprised solely of legal conclusions for which no response is required.

GENERAL ALLEGATIONS

8. FIFRA makes it unlawful to sell or distribute a pesticide that is misbranded. 7 U.S.C. § 136j (a)(1)(B)

ANSWER: Paragraph 8 of the Complaint is comprised solely of legal conclusions for which no response is required. To the extent an answer is required, American Biotech denies the allegations of Paragraph 8.

9. Under FIFRA, a pesticide is misbranded if its labeling contains any statement that is false or misleading. 7 U.S.C. § 136(q)(1)(A).

ANSWER: Paragraph 9 of the Complaint is comprised solely of legal conclusions for which no response is required. To the extent an answer is required, American Biotech denies the allegations of Paragraph 9.

10. Respondent, a Utah limited liability company, is the owner and operator of a company located at 80 West Canyon Crest Road, Alpine, Utah 84004.

ANSWER: American Biotech admits the allegations of Paragraph 10 of the Complaint.

11. Respondent produces the pesticide "ASAP-AGX-32." EPA registration number 73499-2.

ANSWER: American Biotech admits the allegations of Paragraph 11 of the Complaint.

12. The label of this pesticide product claims that it is a hospital disinfectant effective against the pathogenic organisms Pseudomonas aeruginosa and Staphylococcus aureus.

ANSWER: American Biotech admits the allegations of Paragraph 12 of the Complaint.

13. On at least 29 occasions during the month of February 2006, Respondent distributed or sold the pesticide.

ANSWER: American Biotech admits the allegations of Paragraph 13 of the Complaint.

14. EPA tested the effectiveness of the pesticide in 2006.

ANSWER: American Biotech admits that laboratories at Michigan State University, at the request of EPA, performed tests conducted under the AOAC Use-Dilution Method on samples from a single lot of ASAP-AGX-32 in 2006. American Biotech denies the remaining allegations of Paragraph 14 of the Complaint, and specifically denies any implication that the AOAC Use-Dilution Method is accurate or reliable or that said testing is representative of ASAP-AGX-32's efficacy against pathogens such as *Pseudomonas aeruginosa* and *Staphylococcus aureus*.

15. The product was not effective against the pathogenic organisms Pseudomonas aeruginosa and Staphylococcus aureus.

ANSWER: American Biotech denies the allegations of Paragraph 15 of the Complaint.

16. Respondent is a "person" within the meaning of the statute, 7 U.S.C. § 136(s), and therefore subject to the requirements of the statute and/or regulations.

ANSWER: Paragraph 16 of the Complaint is comprised solely of legal conclusions for which no response is required. To the extent that a response is required, American Biotech denies the allegations of Paragraph 16.

17. Respondent is a "producer" as defined by the statute, 7 U.S.C. § 136(w), and a "distributor/seller" as defined by the statute, 7 U.S.C. § 136(2)(gg), of a "pesticide" as defined by the statute, 7 U.S.C. § 136(2)(u).

ANSWER: Paragraph 17 of the Complaint is comprised solely of legal conclusions for which no response is required. To the extent that a response is required, American Biotech denies the allegations of Paragraph 17.

18. Respondent's 29 distributions or sales of ASAP-AGX-32, EPA registration number 73499-2, with a label claiming it was effective against Pseudomonas aeruginosa and Staphylococcus aureus, constitutes 29 violations of FIFRA. 7 U.S.C. 136j(a)(1)(F).

ANSWER: Paragraph 18 of the Complaint is comprised solely of legal conclusions for which no response is required. To the extent that a response is required, American Biotech denies the allegations of Paragraph 18.

19. Under FIFRA, a pesticide producer is required to keep records showing shipment information of pesticides produced. 7 U.S.C. § 136(f), 40 C.F.R. § 169.

ANSWER: Paragraph 18 of the Complaint is comprised solely of legal conclusions for which no response is required.

20. On March 23, 2007, the EPA requested shipment information. Specifically, EPA requested the names and addresses of consignees, dates, and quantities shipped of Respondent's ASAP-AGX-32 pesticide associated with the 2006 effectiveness test.

ANSWER: American Biotech admits the allegations of Paragraph 20 of the Complaint.

21. As of the date of this complaint, Respondent has not submitted the requested shipment information to EPA. Respondent's failure to provide the shipment information of ASAP-AGX-32, constitutes one violation of FIFRA. 7 U.S.C. 136j(a)(2)(B)(i).

ANSWER: American Biotech denies the allegations of Paragraph 21 of the Complaint stating that it has failed to provide shipment information. American Biotech provided EPA Region 8 with shipment information on October 1 and October 3, 2007.

PROPOSED CIVIL PENALTY

22. FIFRA 7 U.S.C. § 136l(a)(1), authorizes the assessment of a civil penalty of up to $6,500.00 per day for each violation. In arriving at the penalty proposed below, EPA, as required by the statute, 7 U.S.C. § 136l(a)(4), has taken into consideration, to the extent known, (1) the size of Respondent's business; (2) Respondent's ability to continue in business in light of the proposed penalty; and (3) the gravity of the alleged violations.

ANSWER: The first sentence of Paragraph 22 of the Complaint is comprised solely of legal conclusions for which no response is required. American Biotech lacks information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 22, and therefore denies these allegations.

23. EPA's approach to calculating appropriate penalties is outlined in its Enforcement Response Policy for the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), July 2, 1990 (enclosed), which provides a rational, consistent, and equitable method for applying these statutory factors to the facts and circumstances of specific cases. Using the policies to apply the statutory factors to the facts of this case, ***EPA proposes that a penalty of $157,300 be assessed against Respondent for the violations alleged above.*** *EPA's penalty calculation/narrative is enclosed and incorporated as Complainant's Exhibit 1 to this complaint. Additionally, Complainant has enclosed a copy of "Information for Small Businesses."*

ANSWER: Paragraph 23 of the Complaint is comprised solely of legal conclusions for which no response is required. To the extent that a response is required, American Biotech denies the allegations of Paragraph 23, and specifically denies that EPA's proposed penalty is appropriate in this instance.

24. The ALJ is not bound by EPA's penalty policy of the penalty proposed by Complainant, and may assess a penalty above the proposed amount, up to the maximum amount authorized in the statute.

ANSWER: Paragraph 24 of the Complaint is comprised solely of legal conclusions for which no response is required. To the extent that a response is required, American Biotech denies the allegations of Paragraph 24.

AFFIRMATIVE DEFENSES

American Biotech states the following affirmative defenses, and expressly reserves the right to amend this Answer to raise additional defenses as may arise during the course of discovery and information exchange in this matter:

FIRST AFFIRMATIVE DEFENSE

American Biotech at all times acted reasonably and in good faith, based on all relevant facts and circumstances it knew at the time.

SECOND AFFIRMATIVE DEFENSE

Complainant has failed to state a claim upon which relief can be granted. Specifically, the AOAC Use-Dilution Method employed by laboratories at Michigan State University in 2006 is inaccurate and unreliable, both generally and as applied to the 2006 testing of one lot of ASAP-AGX-32. As a result, said testing is wholly unrepresentative of ASAP-AGX-32's actual efficacy against *Pseudomonas aeruginosa* and *Staphylococcus aureus*.

THIRD AFFIRMATIVE DEFENSE

With regard to Count 30 of the Complaint, Complainant has failed to state a claim upon which relief can be granted because American Biotech did in fact submit to EPA the shipment data it requested.

FOURTH AFFIRMATIVE DEFENSE

Complainant's allegations constitute agency action that is arbitrary and capricious, and an abuse of discretion under the Administrative Procedure Act, 5 U.S.C. §§ 553 and 706(2).

FIFTH AFFIRMATIVE DEFENSE

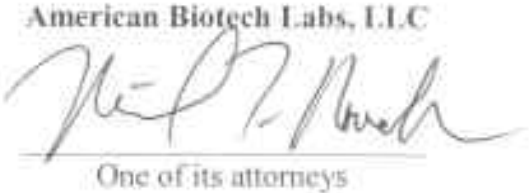
Complainant has no right to relief. 40 C.F.R. §§ 22.4(c)(7), 22.20(a).

REQUEST FOR HEARING

In accordance with 40 C.F.R. § 22.15(c), American Biotech hereby requests a public hearing before an administrative law judge in order to dispute EPA's claims in this Complaint, as described above.

Respectfully submitted,

American Biotech Labs, LLC



One of its attorneys

Date: October 31, 2007

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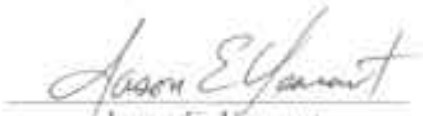
*Admitted to practice in Illinois

CERTIFICATE OF SERVICE

I, Jason E. Yearout, an attorney, hereby certify that on October 31, 2007 I served copies of American Biotech Labs, LLC's Answer to USEPA's Penalty Complaint and Request for Hearing on the following persons via first-class mail:

Regional Hearing Clerk
U.S. EPA Region 8
1595 Wynkoop Street (8RC)
Denver, Colorado 80202

Eduardo Quintana
Senior Enforcement Attorney
U.S. EPA Region 8
1595 Wynkoop Street (8RC)
Denver, Colorado 80202



Jason E. Yearout