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REPLY TO THE ATTENTION OF:

C-14J

Via UPS Overnight Delivery

November 18, 2010

Honorable Barbara A. Gunning
Office of Administrative Law Judges
U.S. Environmental Protection Agency
Mail Code 1900L
1099 14<sup>th</sup> Street, NW, Suite 350
Franklin Court
Washington, D.C. 20005

Re:

In the Matter of Liphatech, Inc.

Docket No. FIFRA-05-2010-0016

Dear Judge Gunning:

Please find enclosed a copy of Complainant's Motion for Accelerated Decision on Liability for Counts 2,141 through 2,183 of the Complaint, which was filed on November 18, 2010, in the above referenced-matter.

Sincerel

Nidhi K. O'Meara

Associate Regional Counsel

**Enclosures** 

cc:

Mr. Michael H. Simpson

Reinhart Boerner Van Deuren s.c 1000 North Water Street, Suite 1700

Milwaukee, WI 53202 (via UPS overnight)

### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY BEFORE THE ADMINISTRATOR FRAREGION S

IN THE MATTER OF:	) 5010 KON 18	PH 12: 41
Liphatech, Inc.	) Docket No. FIFRA-05-20	)10-0016
Milwaukee, Wisconsin  Respondent.	)	
	) Hon. Barbara A. Gunning	3
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	)	

### COMPLAINANT'S MOTION FOR ACCELERATED DECISION ON LIABILITY FOR COUNTS 2,141 THROUGH 2,183 OF THE COMPLAINT

### I. <u>Introduction</u>

This Motion addresses Counts 2,141 through 2,183 of the Complaint, which allege claims for the illegal distribution or sale of a rodenticide known as "Rozol Pocket Gopher Bait II" (Rozol). On least 43 separate occasions, Liphatech, Inc. (Respondent or Liphatech) distributed or sold Rozol with claims made for it as part of its distribution or sale that were substantially different from any claims made for it as part of the statement required with its registration under Section 3 of the Federal Fungicide, Insecticide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136a et seq. Complainant respectfully requests that this Court enter an order granting accelerated decision, as to Liphatech's liability for Counts 2,141 through 2,183.

#### II. General Statutory and Regulatory Background

FIFRA is a federal statute that regulates the manufacture, sale, distribution and use of pesticides. Section 12(a)(1)(B) of FIFRA makes it unlawful for any person in any State from distributing or selling to any person any registered pesticide if any claims made for the pesticide as part of its distribution or sale substantially differ from any claims made for the pesticide as

<sup>&</sup>lt;sup>1</sup> For ease of reference, Complainant will use Rozol in this Motion to refer to "Rozol Pocket Gopher Bait II" (Alternative name: "Rozol Pocket Gopher Burrow Builder Formula"), EPA Registration Number 7173-244.

part of the statement required in connection with its registration under Section 3 of FIFRA.

40 C.F.R. § 168.22 further states in pertinent part, that Section 12(a)(1)(B) of FIFRA makes it unlawful for any person to "offer for sale" any pesticide if claims made for it as part of its distribution or sale substantially differ from any claims made for it as part of the statement required in connection with its registration under Section 3 of FIFRA. The regulations also state that the United States Environmental Protection Agency (U.S. EPA) interprets 40 C.F.R. § 168.22 to extend to advertisements in advertising medium available to the general public. *In re Sporicidin Int'l*, 1991 EPA App. LEXIS 3, at \*40 (CJO, 1991).

Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), and 40 C.F.R. § 152.3 define "distribute or sell" broadly as "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."

#### III. Relevant Factual Background

On May 14, 2010, U.S. EPA (or Complainant) filed a civil administrative complaint against Respondent. With respect to Counts 2,141 through 2,183, the Complaint alleges that between October 1, 2007 and May 30, 2008, Respondent distributed Rozol with claims made for it as part of its distribution or sale that substantially differed from any claims made for Rozol as part of the statement required in connection with its registration under Section 3 of FIFRA. Section 12(a)(1)(B) of FIFRA.

Pursuant to the registration of Rozol, on or about March 2, 2005, the Office of Pesticides

Program, Registration Division sent Respondent a Notice of Pesticide Registration along with

the accepted label for Rozol. (CX<sup>2</sup> 1b). During calendar years 2007 and 2008, Rozol was also registered under the authority of Section 24(c) of FIFRA to control black-tailed prairie dogs under "Special Local Needs" supplemental labels (SLNs) for certain States<sup>3</sup>. These SLN labels can be found at CX 2g, 3e, 4g, 5c, 5e, 6b and 7b. The March 2, 2005 Notice of Pesticide Registration along with the accepted label for Rozol and the associated SLNs for Rozol identified the claims that Respondent could make regarding the product. Starting on September 26, 2007, Respondent began advertising Rozol using claims that substantially differed from any claims U.S. EPA approved for Rozol as part of its registration.

#### IV. Standard of Review for Motions for Accelerated Decision

Under the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (Consolidated Rules) at 40 C.F.R. Part 22, an accelerated decision is appropriate "if no genuine issue of material fact exists and a party is entitled to judgment as a matter of law." 40 C.F.R. § 22.20(a). The regulation specifically provides that:

The Presiding Officer may at any time render an accelerated decision in favor of a party as to any or all parts of the proceeding, without further hearing or upon such limited additional evidence, such as affidavits, as he may require, if no genuine issue of material fact exists and a party is entitled to judgment as a matter of law.

40 C.F.R. § 22.20(a). As the Environmental Appeals Board (EAB) and U.S. EPA Administrative Law Judges have explained, the standard for deciding motions for accelerated decision is similar to the standard for granting summary judgment set forth in Rule 56 of the Federal Rules of Civil Procedure. See e.g., In re BWX Techs., Inc., 9 E.A.D. 61, 74-75 (EAB

<sup>&</sup>lt;sup>2</sup> As used in this Motion, "CX" means and refers to the exhibits submitted in Complainant's initial and rebuttal prehearing exchanges.

2000); In re Green Thumb Nursery, Inc., 6 E.A.D. 782, 793 (EAB 1997).

Summary judgment is appropriate for the moving party when "it demonstrates that the record shows no genuine issue as to any material fact and that it is entitled to judgment as a matter of law." Ass'n Benefit Servs. v. Caremark RX, 493 F.3d 841, 849 (7th Cir. 2007) (citations omitted). Although courts must resolve all evidentiary ambiguities and "must take the facts and all reasonable inferences from those facts in the light most favorable to the non-moving party," id., "the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-248 (1986). The non-moving party "may not avoid summary judgment by resting on the allegations of its pleadings; it must come forward with specific facts showing that there is a genuine issue for trial." Ass'n Benefit Servs., 493 F.3d at 849.

### V. <u>Complainant is Entitled to Accelerated Decision on Liability for Counts 2,141</u> through 2,183 of the Complaint

For each of these 43 counts in the Complaint, the Complainant must demonstrate that there is no genuine issue of material fact as to the following: (1) Liphatech is a "person," as defined by Section 2(s) of FIFRA; (2) Liphatech is located in a State; (3) Liphatech "distributed or sold," as that is defined in Section 2(gg) of FIFRA (4) a registered pesticide, in this case Rozol (5) using claims made for Rozol as part of its distribution or sale that substantially differed from claims made for Rozol as part of the statement required in connection with its registration.

Sporicidin, 1991 EPA App. LEXIS 3, 3 E.A.D. 589 (CJO 1991); In re Microban Prods. Co., 11 E.A.D. 425, 440 (EAB 2004)(Microban II).

<sup>&</sup>lt;sup>3</sup> These States included Kansas, Nebraska, Wyoming, Colorado, Texas and Oklahoma.

### A. There is No Genuine Issue of Material Fact Regarding the First Four Elements of Counts 2,141 through 2,183

The first four elements needed to establish Liphatech's liability for violations of Section 12(a)(1)(B) of FIFRA are easily satisfied. Liphatech admitted in its Answer that, at all times relevant to the Complaint, it was a "person" as defined by Section 2(s) of FIFRA. (Answer ¶ 22). It also admits in its Answer that it is a corporation doing business in the State of Wisconsin. (Id. ¶¶ 3, 23). Liphatech admitted in its Answer that during calendar years 2007 through 2008, Rozol was a product registered under Section 3 of FIFRA. (Id. ¶¶ 25, 135, 258). Similarly, Liphatech admitted that during calendar years 2007 and 2008, Rozol was also registered under the authority of Section 24(c) of FIFRA, to control black-tailed prairie dogs under SLNs for the states of Kansas, Nebraska, Wyoming, Colorado, Texas and Oklahoma. (Id. ¶ 30). Under Section 24(c) of FIFRA, a state registration for additional uses of a federally registered pesticide formulated for distribution and use within that State to meet a special local need is deemed a registration under Section 3 of FIFRA. 7 U.S.C. § 136v. Liphatech also admits that for calendar years 2007 and 2008, Rozol was a "pesticide" as that term is defined at Section 2(s) of FIFRA. (Id. ¶ 32). Finally, Liphatech admits that it distributed or sold Rozol to its customers on 40 of the 43 separate occasions alleged in the Complaint, starting on October 1, 2007 and continuing through May 30, 2008. (Id. ¶¶ 213-15, 217-49, 252-56). For one alleged distribution or sale alleged in paragraph 251 of the Complaint, Liphatech admits that it distributed or sold Rozol to Estes on April 25, 2010 rather than April 2, 2008. (*Id.* ¶ 251).

For the remaining two alleged distributions or sales alleged in paragraphs 216 and 250 of the Complaint, Liphatech denies that it distributed or sold Rozol to these recipients because both recipients were Liphatech company representatives. Liphatech asserts that for this reason, it did not distribute or sell Rozol to these recipients as that term is defined in FIFRA.

Under FIFRA, when determining if a product is distributed or sold, the focus is movement of the product, not the recipient of the product. Therefore for purposes of FIFRA, it is irrelevant that the recipients of Rozol in counts 2,144 and 2,178 were Liphatech representatives.

On February 5, 2009, Ms. Niess of U.S. EPA, Region 5, received the distribution or sale records in question from Liphatech's Manager of Regulatory Affairs, Mr. Thomas Schmit. (CX 23). With respect to the two shipments alleged in counts 2,144 and 2,178, Mr. Schmit specifically stated as follows: "Two shipments were made by United Parcel Service ('UPS') for which there is no Bill of Lading. For these two shipments, we attach a copy of the 'customer order picklist.' This document shows the quantity, date of shipment, and consignee of the shipment, and also contains the receipt printed by the UPS computer software" (*Id.*, EPA000491-492 (emphasis added)).

The term "distribute and sell" is broadly defined in FIFRA. Specifically, Section 2(gg) of FIFRA defines "distribute or sell" as "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." 7 U.S.C. § 136(gg) (emphasis added). By Liphatech's own admission, there can be no dispute that Liphatech shipped and therefore distributed Rozol to Mr. Knuth on or about October 29, 2007, and to Mr. Mark Newman on or about April 18, 2008, within its common meaning of the word<sup>4</sup> and in accordance with the definition of the "distribution or sale" in FIFRA. *Microban II*, 11 E.A.D at 428.

<sup>&</sup>lt;sup>4</sup> The Merriam-Webster Dictionary defines "distribute" as "to divide amongst several or many" or "to give out or deliver especially to members of a group." See http://www.merriam-webster.com/dictionary/distribute.

Based on the evidence in the record and the admissions made by Liphatech in its Answer, Complainant has clearly demonstrated that there is no genuine issue of material fact as to the first four elements that Complainant must prove to establish Liphatech's liability for the violations alleged in Counts 2,141 through 2,183 of the Complaint.

### B. There is No Genuine Issue of Material Fact Regarding the Fifth Element of Counts 2,141 through 2,183

As to the fifth element, Complainant must show that Liphatech made claims for Rozol as part of its distribution or sale that substantially differed from claims made for Rozol as part of the statement required in connection with its registration. To determine whether Complainant is entitled to accelerated decision on this element, Complainant respectfully submits that the Court should focus its inquiry on the following three questions: (1) what claims did Liphatech make regarding Rozol; (2) were the claims that Liphatech made substantially different from claims made for Rozol as part of the statement required in connection with its registration; and (3) were the claims made as part of Rozol's distribution or sale?

### 1. What claims did Liphatech make regarding Rozol?

Counts 2,141 through 2,183 are based on claims that were made by Liphatech in three different media: (1) Print advertisements circulated through direct mail packages that Liphatech sent to its customers in Colorado, Kansas, Nebraska, Oklahoma, Texas and Wyoming (CX 14a); (2) Radio advertisements that were broadcast to the general listening public in the states of Kansas, Nebraska, and Texas (Complaint, Attachments A-D; CX 14a), and (3) Internet advertisements through its website, www.liphatech.com, that were available to the general public (CX 52). Pursuant to 40 C.F.R. §168.22, U.S. EPA interprets "the prohibition of section 12(a)(1)(B) as extending to 'advertisements in any medium to which pesticide users or the

general public have access." *Sporicidin*, 1991 EPA App. LEXIS at \*40. Therefore, Section 12(a)(1)(B) applies to all three forms of advertisements utilized by Liphatech.

On June 19, 2008, a Wisconsin Department of Agriculture, Trade and Consumer Protection (WDATCP) inspector collected direct mail packages from Liphatech (CX 14a; Answer ¶140). Liphatech was sending these direct mail packages to its customers to advertise Rozol. (Answer ¶145 and CX 14a, EPA000150). In its Answer, Liphatech admits that its direct mail packages included the following advertising documents: (1) a cover letter, entitled "SUBJECT - ROZOL ® POCKET GOPHER BAIT" dated October 31, 2007 (hereinafter, "cover letter") (Answer ¶ 141-42) and (2) sales literature entitled "Black-tailed Prairie Dog Control - Research Bulletin," dated October 17, 2007 (hereinafter "research bulletin") (Answer ¶ 143-44). The direct mail packages also included (1) a copy of the state-appropriate 24(c) special local needs (SLN) labeling and (2) a brochure entitled "Control Pocket Gophers & Black-Tailed Prairie Dogs" (hereinafter "brochure"). Liphatech further admits that it distributed its direct mail packages to recipients in the states of Colorado, Kansas, Nebraska, Oklahoma, Texas and Wyoming in one single mailing in November of 2007. (CX 14a, EPA 000150).

The direct mail advertising packages were fraught with claims that were of concern to the U.S. EPA because the advertising claims were substantially different than the claims that were authorized by U.S. EPA in connection with Rozol's registration. Samplings of these claims are included in the Complaint.<sup>5</sup> For example, the cover letter included claims such as:

(1) "provides the most control available in a <u>single application</u>" (emphasis in original),

<sup>&</sup>lt;sup>5</sup> For purposes of brevity, the Complaint did not encompass an exhaustive list of claims that were of concern to U.S. EPA nor did it list every piece of advertising, such as the brochure, that it believed contained claims that were substantially different than claims that Liphatech was approved to make through the registration process. The brochure contained many of the same violative claims that can be found in the cover letter and the research bulletin.

- (2) "[p]oses low primary poisoning potential to birds and other non-targets" (emphasis in original), and
- (3) "both restricted-use and general-use Rozol products are formulated using proven anticoagulant chlorophacinone at 50 PPM (parts per million) unlike other half-strength, diaphacinone-based baits containing as low as 25 PPM."

(CX 14a, EPA000171-72, 190-91, 209-10, 228-29, 247-48 and 266-67).

In addition, the research bulletin included claims such as:

- (1) "Rozol consistently controlled Prairie Dog populations using a single application,"
- (2) "Conclusion: Rozol delivers proven single application effectiveness" (emphasis in original),
- (3) "Secondary Hazard/Nearly all Prairie dogs expired underground," "Conclusion: Above-ground exposure risk to nontargets from Rozol is insignificant" (emphasis in original),
- (4) "Over all sites, 95% average population reduction was achieved as measured by the 'plugged burrow' census method,"
- (5) "Over all sites, 94% average population reduction was achieved when measured by the 'visual count' census method,"
- (6) "Traditional control products such as zinc phosphide or Diphacinone-based anticoagulants have not proven to effectively prevent population recovery, leading to the need for costly retreatment,"
- (7) "Kaput-D Prairie Dog Bait (22 PPM) achieved only 53% to 56% control,"
- (8) "Kaput-D Pocket Gopher Bait\* (50 PPM) 2X the rate of active ingredient, achieved only 56% to 57% control. \*Not labeled for Black-Tailed Prairie Dog." (footnote in original),
- (9) "Comparative Toxicity Profile Overall Risk to Birds and Mammals/Rozol is ranked over 50% lower than zinc phosphide in the EPA's overall risk index and 1/3 lower than Diphacinone (Kaput-D),

- (10) "Rozol's active ingredients (chlorophacinone) is ten times (10X) less toxic to dogs as Kaput-D's (diphacinone),"
- (11) "Chlorophacinone is over 100X more effective on mice than diphacinone,"
- (12) "Conclusion: Rozol the lowest risk profile among Black Tailed Prairie Dog bait alternatives ... Why risk potential harm to employees, livestock, birds, pets or other nontargets?" (emphasis in the original), and
- (13) the chart entitled "Compare the products for yourself there are many differences."

(CX 14a, EPA000175-80, 194-99, 213-18, 232-37, 251-56, and 270-75).

Liphatech admits that it made all of these claims in its direct mail advertising packages. (Answer ¶ 140-46, 149, 152, 155, 158, 161, 164, 167, 170, 173, 176, 179, 182, 185, 188, 191 and 194). Therefore, there is no dispute as to the claims that Liphatech made in its direct mail advertising packages.

Liphatech also admits it made claims on its radio advertisements that it began broadcasting on or about September 26, 2007. It admits that these claims included:

- (1) "Rozol proven single application effectiveness for the control of black-tailed prairie dogs," and
- (2) "Proven in university studies on over 10,000 burrows to get 94% control with a single treatment."

(Answer ¶¶ 199 and 202).

Finally, many of these same claims referenced above were also being made by Liphatech on its website at www.liphatech.com on January 22, 2008. (CX 52).

2. Were the claims that Liphatech made substantially different from the claims made for Rozol as part of the statement required in connection with its registration?

The next question is whether the claims that Liphatech made in its print, radio and internet advertisements are substantially different than the claims made for Rozol as part of the statement required in connection with its registration. To answer this question, U.S. EPA looks to the Notice of Pesticide Registration (which includes the accepted label and any associated accepted labels) to determine what claims were approved in connection with the products' registration. (CX 1b, 2g, 3e, 4g, 5c, 5e, 6b and 7b).

In an Order on Motions for Discovery, Filing of Sur-Reply and Partial Accelerated

Decision for *In the Matter Of Microban Products Company*, Docket No. FIFRA 98-H-01 at 8

(Sept. 18, 1998) (*Microban Order*), the ALJ stated that the "notice of pesticide registration represents the base line from which allegations of Section 12(a)(1)(B) violation must be measured." The ALJ went on to state that the "establishment of this violation 'involves holding up, on the one hand, the terms of the EPA's registration approval and then, per Section 136j(a)(1)(B), determining whether [the Respondent] made any claims as part of its distribution or sale which substantially differ from those made in connection with its registration approval."

Id. (footnote omitted) (quoting the ALJ's Order of April 3, 1998). Although this case was appealed to the EAB, the issue of how to determine whether claims substantially differed was not the subject of the appeal and remained unchallenged by the parties and undisturbed by the EAB.

Therefore, the ALJ's statements in the *Microban Order* are particularly instructive here.

Rozol was registered with the U.S. EPA on March 2, 2005. (CX 1b). On that same date, U.S. EPA sent Liphatech a Notice of Pesticide Registration along with the accepted label for Rozol.<sup>6</sup> (*Id.*) In addition, when determining what claims were approved by U.S. EPA, U.S. EPA

<sup>&</sup>lt;sup>6</sup> The label was subsequently updated to add an alternate name (CX 1c) and again to add the language "if swallowed" to the "first aid" section of the label (CX 1d). Neither of these two amendments resulted in any significant changes in claims that were approved for Rozol.

also looked to Liphatech's SLN labels. (CX 2g, 3e, 4g, 5c, 5e, 6b and 7b<sup>7</sup>). Liphatech makes a number of claims in its direct mail packages, its radio broadcasts and on its website (for ease of reference, these will collectively be referred to as "marketing advertisements") informing the consumer that Rozol "delivers proven single application effectiveness." (CX 14a, EPA000171-72, 175 190-91, 194 209-10, 213, 228-29, 232, 247-48, 251, 266-67 and 270 and Answer ¶ 146, 155, 158, 199 and 202). These efficacy claims are contrary to the specific language that was approved for use in the Rozol's SLN labels, which includes "reapplication" directions. (CX 2g, 3e, 4g, 5c, 5e, 6b and 7b).

Liphatech's marketing advertisements also state that the "above ground exposure risk to non-targets from Rozol is insignificant.8" (CX 14a, EPA000171-72, 175-80, 190-91, 194-99, 209-10, 213-18, 228-29, 232-37, 247-48, 251-56, 266-67 and 270-75 and Answer ¶ 149, 161, 164, 191 and 194). These safety claims contradict Rozol's own label. (*Compare* (CX 14a, EPA000171-72, 175-80, 190-91, 194-99, 209-10, 213-18, 228-29, 232-37, 247-48, 251-56, 266-67 and 270-75 and Answer ¶ 149, 161, 164, 191 and 194 *with* CX 1b, 2g, 3e, 4g, 5c, 5e, 6b and 7b). The label alerts the consumer of the dangers of Rozol by stating "Restricted Use Pesticide Due to Potential Secondary Toxicity to Nontarget Organisms" while the marketing advertisements suggest to consumers that the product is much safer.

The claims made by Liphatech in its marketing advertisements include efficacy and safety claims that have not been approved by U.S. EPA. Liphatech also makes additional claims in its research bulletin that make comparisons to other products and active ingredients that would

<sup>&</sup>lt;sup>7</sup> For the purpose of this discussion, the label for each SLN is largely the same.

<sup>&</sup>lt;sup>8</sup> This safety claim varies in Liphatech numerous advertisements. For example, in the cover letter, Liphatech states "[p]oses low primary poisoning potential to birds and other non-targets." (EPA 000172, 210, 229, 248 and 267). These varying statements essentially send the consumer the same safety message: that Rozol poses little exposure risk to non-targets.

not have been permitted in an accepted label. See Request for an "Enforcement Case Review" (ECR) at CX 18 and the response at CX 19.

Liphatech easily could have avoided the violations alleged in the Complaint by simply complying with straight forward statutory and regulatory requirements. For purposes of the "claims differ" violations at issue in this motion, Liphatech easily could have sought approval of the claims for its advertising materials; "a request for approval of the instant brochure would have eliminated the basis for this proceeding.<sup>9</sup>" *In re Mid-Am. Research Chem. Corp.*, 1977 EPA ALJ LEXIS 18, at\*13 (ALJ 1977). Liphatech's failure to do so increased the potential for misuse of Rozol and thus increased the potential for harm because its advertising tactics contradicted the label itself on critical issues such as efficacy and safety.

The potential for consumers to ignore the label directions (which mitigated the hazards related with Rozol) was certainly present. *Id.* at \*12. The broad and immediate nature of the misleading advertisement undermined the purpose of the required label. Liphatech's extensive media campaign bypassed the statutory and regulatory labeling requirements under FIFRA and substantially differed from the claims approved by U.S. EPA during the registration of Rozol.<sup>10</sup>

3. Were the claims made as part of its distribution or sale?

The final question that remains is if Liphatech made these claims as part of its distribution or sale. Based on the totality of the circumstances, which the EAB has held must be considered, *Microban II*, 11 E.A.D. 425, clearly the answer is "yes."

Liphatech began making unapproved claims regarding the efficacy and safety of Rozol

<sup>&</sup>lt;sup>9</sup> It should be noted that many of the claims made by Liphatech would likely not have been approved by the registration division because they were contrary to the claims made on the label and language that is allowed under 40 C.F.R. Section 156.10(a)(5). However, if Liphatech had sought the approval of these claims, it could have at least made an informed decision as what would be appropriate advertising for Rozol.

<sup>&</sup>lt;sup>10</sup>The approved claims can be found in the Rozol Notice of Pesticide Registration, along with its accepted label (See

through its radio advertisements starting on at least September 26, 2007. (Complaint ¶¶ 48, 199 and 202). All the violations alleged in Counts 2,141 through 2,183 occurred after this date. Furthermore, there can be no dispute that the direct mail packages were clearly being sent to potential customers to induce sales. This is evident by Liphatech's own description of its "direct mail packages" in a letter dated, June 16, 2008, that it sent to Complainant. (CX 14, EPA000148-49).

In its June 16, 2008 letter, Liphatech explained that it "does only a small amount of print and broadcast advertising. Advertising materials, along with flyers and other product literature, are produced by the two people who make up the 'marketing department.'" (*Id.*, (emphasis added)). In that letter, Liphatech further explained that the advertising materials are accompanied by supplemental labels for the varying states. (*Id.*) "Because these labels are state-specific and vary from state to state, product label(s) is always included when we distribute any printed materials. For direct mail or invoice stuffers, the label included is the appropriate label for address. Liphatech sales representatives ensure that the dealers understand the importance of providing the correct supplemental label for the state where the product will be used. At dealer locations, labels are provided for all states where potential purchasers could reasonably be expected to use the product." (*Id.*, (emphasis added)). In reference to the direct mail packages, Liphatech also explains that "these were distributed in a single mailing done in November of 2007." (CX 14a, EPA000150).

Additionally, as a result of Stop Sale, Use and Removal Order (SSURO) (CX 15) that was issued to Liphatech regarding Rozol, Liphatech informed U.S. EPA that it planned to "[r]equest that distributors destroy all non-compliant advertising and literature." (CX 17,

EPA000371). Specifically, it stated "[w]e are advising our distributor companies that all of the advertising and literature in their possession concerning Rozol Prairie Dog Bait must be destroyed, to be replaced with updated materials as soon as possible. Attached is a sample letter, which will be sent..." (CX 17, EPA000371). In the letter sent to its distributors, it stated: "Liphatech, Inc. requests your help; In order to ensure that Liphatech, Inc. complies with EPA standards, regarding literature used to promote Rozol for the control of Black Tailed Prairie Dogs (BTPD) we need to update our sales literature." (CX 17, EPA000407). It went on to request that the following advertising literature be discarded: (1) "Black-tailed Prairie Dog Control - Research Bulletin," dated October 17, 2007; (2) "Livestock Weight Gain and Prairies Dogs: ESA Frontiers In Ecology & the Environment, Nov 2006 Reprint; and (3) "True Cost' of Black - tailed Prairie Dog Control (Whitepaper)," dated November 5, 2007. (CX 17, EPA000407).

A conversation between Liphatech's Manager of Regulatory Affairs, Mr. Thomas Schmit and U.S. EPA's enforcement officer, Ms. Claudia Niess, reinforces the fact that Liphatech was sending these advertisements to induce sales. During his telephone conversation with Ms. Niess on November 12, 2008, Mr. Schmit was trying to find out when U.S. EPA was going to allow Liphatech to distribute its violative advertising material because it was "expensive" and Liphatech wanted to be able to distribute the material. (CX 25). Based on Mr. Schmit's inquiry, there can be no doubt that Liphatech was distributing its violative advertisements to its customers to induce the sale of Rozol.

Liphatech also provided a list of customers to which it was sending its direct mail

advertising packages.<sup>11</sup> (See CX 17, EPA 000378). Along with the list, Liphatech provided a contact name associated with each customer. The identification of the contact is significant because it too provides an indication of Liphatech's intended purpose of sending the direct mail packages to these customers. The contact persons in the list of distributors are persons of authority in the company such as the president, vice president of purchasing or manager of the company. (Attachment A, Ms. Niess' Declaration). These persons of authority are the ones making decisions as to purchasing, which further confirm Liphatech's intent to promote Rozol to induce sales. In determining whether the respondent intended to induce sales when it distributed advertising materials to its customers, the CJO in *Sporicidin* Court stated that the position of the person to whom the respondent directs its advertisements is probative: "[i]t gave the packet to current users ... including individuals who are in a position to influence the hospital's decision whether to purchase them." *Sporicidin*, 1991 EPA App. LEXIS 3, at \*34 (footnote omitted).

Given the timing of the radio advertisements, the dates of the direct mail package, the claims made on its website, the dates that Rozol was distributed or sold to Liphatech's customer or sales representatives, and the fact that these direct mail packages were directed to individuals in the position to influence purchasing, there can be no doubt that the unapproved claims were made "as part" of the distribution or sale of Rozol. This conclusion is consistent with administrative case law that has previously addressed this issue.

The requirements of Section 12(a)(1)(B) are consistent with the goals of FIFRA, which include consumer protection goals "intended to protect purchasers from being induced into

<sup>&</sup>lt;sup>11</sup> Note that this list does not appear to be an exhaustive list. On the one hand, Liphatech provided copies of direct mail packages for six different states (CX 14a). On the other hand, however, the list of distributors provided does not encompasses customers in each of these states (CX 17). Interestingly, one of the customers provided on the list is located in Iowa, a state that did not allow the distribution of Rozol for the control of black-tailed prairie dogs. (CX 17, EPA000378).

purchasing a pesticide based on unapproved claims." In re Microban Products Company, 9

E.A.D. 674, 686 (EAB, 2001) (Microban I). As to the issue of truthfulness, "[t]he EAB pointed out that a Section 12(a)(1)(B) is not necessarily a claim about truthfulness, but rather relates to claims that have been made prematurely, as pesticide sellers and distributors cannot make claims about their products until the EPA has determined that they have been adequately substantiated by test data. Microban Order, supra at 8 (discussing Sporicidin, 1991 EPA App. LEXIS 3, at \*30) (emphasis in original).

The EAB has defined "as part of its distribution of sale" in the context of Section 12(a)(1)(B). The court in *Sporicidin* stated "[w]here a statute is remedial, it should be construed liberally so as to effectuate its purpose. *See Jonas and Co v EPA*, 666 F.2d 833 (3d Cir. 1981). Broadly construing the phrase 'part of its distribution or sale' so as not to require a contemporaneous sale or distribution furthers the overall purposes of FIFRA." Sporicidin, 1991 EPA App. LEXIS at \*38. In *Microban I*, the EAB stated:

[t]he statutory term "as part of" requires that a nexus exist between the unapproved claims and the distribution or sale of the pesticide. The Chief Judicial Officer in *In re Sporicidin International, Inc.*, 3 E.A.D. 589, 602-02 (CJO 1991) ruled that a 'sufficiently close link' existed between the claims and sales and distributions of pesticides in that case. He construed the statutory phrase broadly, and ruled that claims and corresponding distributions or sales need not be contemporaneous. *Sporicidin* at 603. It follows, therefore, that a rigid test, applicable to all situations, for determining whether claims have been made as part of the distribution or sale of a pesticide is not contemplated as part of the statutory scheme. Rather, it is necessary to examine all of the surrounding facts and circumstances to make such a determination.

Microban I, 9 E.A.D. at 688.

Considering all the relevant facts in the record, it is clear that the unapproved claims in Liphatech's advertising materials were made as part of the distribution or sale of Rozol.

"Common sense suggests that a claim followed by a sale evinces nothing more than a normal

cause-and-effect relationship, and that a time interval spanning the two events is common."

Sporicidin, 1991 EPA App. LEXIS 3, at \*35. Therefore there can be no genuine issue of

material fact that Liphatech made claims for Rozol as part of its distribution or sale that

substantially differed from claims made for Rozol as part of statement required in connection

with its registration.

VI. <u>Conclusion</u>

Based on the current pleadings, admissions, and declarations on file, there is no genuine

issue as to any material fact regarding Respondent's liability for the alleged violations in Counts

2,141 through 2,183 of the Complaint. The Complainant is therefore entitled to judgment as a

matter of law as to liability for violations alleged Counts 2,141 through 2,183 of the Complaint.

Complainant respectfully requests that this Court grant this motion in its entirety.

DATED: November 18, 2010

X/V///

Respectfully submitted,

. Nidhi K. O'Meara Erik H. Olson

Associate Regional Counsels

Gary E. Steinbauer

**Assistant Regional Counsel** 

United States EPA - ORC Region 5

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(312) 886-4306

Attorneys for Complainant

### **List of Attachments**

Attachment A Declaration of Claudia Niess

## ATTACHMENT A

Declaration of Ms. Claudia Niess

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY BEFORE THE ADMINISTRATOR

IN THE MATTER OF:	)
	)
Liphatech, Inc.	) Docket No. FIFRA-05-2010-0016
Milwaukee, Wisconsin	)
	) Hon. Barbara A. Gunning
Respondent.	)
	)
	)

#### **DECLARATION OF MS. CLAUDIA NIESS**

State of Illinois County of Cook

- I, Claudia Niess, declare and state as follows:
- 1. The statements made in this declaration (which consists of four pages) are based on my personal knowledge.
- 2. In 2005, I received a Bachelor of Science degree in Environmental Engineering from Northwestern University.
- 3. I am currently employed as an Environmental Engineer and I am credentialed as an Enforcement Officer with the Pesticides/Toxics Compliance Section of the Chemicals Management Branch, Land and Chemicals Division, U.S. EPA, Region 5. The Pesticides/Toxics Compliance Section was formerly known as the Pesticides & Toxics Enforcement Section. I have been employed as an Environmental Engineer and Enforcement Officer in this capacity since 2005.
- 4. As an Environmental Engineer and Enforcement Officer in the

  Pesticides/Toxics Compliance Section, my duties include conducting inspections and

  other investigative work to determine compliance with the Federal Insecticide, Fungicide

and Rodenticide Act (FIFRA), as well as other environmental statutes. I have conducted approximately 50 inspections under FIFRA.

- 5. On October 7, 2010, I began searching publicly available information regarding the positions and responsibilities of the individuals listed for each of Liphatech's product distributors.
- 6. This information was provided to me by Mr. Thomas Schmit, the Manager of Regulatory Affairs for Liphatech, Inc, in a letter dated August 5, 2008 (Complainant's Exhibit (CX) 17).
- 7. I first searched for each of the companies' listed contacts on their respective websites. Using this method, I was able to document the positions of the following individuals:
  - A. Kelly Venable, Manger, Pro Chem Sales;
  - B. Larry Trantham, Manager, Pro Chem Sales; and
  - C. Dan Watson, Vice President Specialty Division, Van Diest Supply Company.
- 8. A majority of the distributor companies either did not include contact information on its websites or included only a general email address or phone number for the public to contact.
- 9. I then searched the Dun and Bradstreet Portal and was able to document the positions of the following individuals:

- A. Bob Stewart, Manager, Helena Chemical;
- B. Todd Martin, Branch Manager, Helena Chemical<sup>1</sup>;
- C. Garry Rich, President, Pro Chem Sales; and
- D. Danny Pawlick, Manager, Helena Chemical Company.
- 10. Next, I searched for any news articles, websites, or profiles that were publicly available by searching using google.com. I was able to document the positions for the following individuals:
  - A. Dean Taake, Purchasing Manager, Helena Chemical;
  - B. Phil Sullins, West Texas Area Manager, Wilbur-Ellis Company;
  - C. Jeff Wagner, Vice President Purchasing, Estes, Inc.<sup>2</sup>;
  - D. Arnold Frost, Manager, Estes, Inc.; and
  - E. Tyson Eckroat, Manager, Eckroat Seed Company.
- 11. Copies of the print outs showing the documented titles for each individual listed above are attached to this declaration.
- 12. The assertions I make in this declaration are truthful, and, if called to testify as a witness, I am prepared to testify under oath to the accuracy of the observations and statements contained in this declaration, based on my personal knowledge.

<sup>&</sup>lt;sup>1</sup> The address for Todd Martin of Helena Chemical provided in the August 5, 2008 letter is "N. Hwy 385/87, Hartley, TX 79044." The address provided in the Dun and Bradstreet Portal is "410 4<sup>th</sup> Street, Hartley, TX 79044." A map of 410 4<sup>th</sup> St, Hartley, TX 79044 shows this address is in the very near proximity of the intersection of N. Hwy 385 and Hwy. 87. A copy of this map is included with the Dun and Bradstreet Portal print-out.

Zoominfo.com provides a link to Estes's website (www.estesinc.com) that was cached on March 18, 2010. This cache shows Mr. Wagner was the Vice President of Purchasing for Estes, Inc. Mr. Wagner's name does not appear on Estes's current website. I printed a copy of the cached and the current website on October 7, 2010.

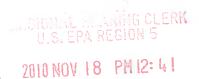
I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed on: Nountar 18, 2010

Bv

Claudia Niess Environmental Engineer Enforcement Officer

### In the Matter of Liphatech, Inc. Docket No. FIFRA-05-2010-0016



### **CERTIFICATE OF SERVICE**

I hereby certify that the original and one true, accurate and complete copy of Complainant's Motion for Accelerated Decision on Liability for Counts 2,141 through 2,183 of the Complaint, was filed with the Regional Hearing Clerk, U.S. EPA, Region 5, on the date indicated below. True, accurate and complete copies were sent to Honorable Barbara Gunning, Administrative Law Judge (via UPS overnight delivery) at the following address:

Honorable Barbara A. Gunning
Office of Administrative Law Judges
U.S. Environmental Protection Agency
Mail Code 1900L
1099 14<sup>th</sup> Street, NW, Suite 350
Franklin Court
Washington, D.C. 20005

and to Mr. Michael H. Simpson, Counsel for Respondent, Liphatech, Inc., (via UPS overnight delivery), at the following address:

Mr. Michael H. Simpson Reinhart Boerner Van Deuren s.c 1000 North Water Street, Suite 1700 Milwaukee, WI 53202

on the date indicated below:

Dated in Chicago, Illinois, this 18 th day of November, 2010.

Satricia Jaface - Harwell Patricia Jeffres - Harwell

Legal Technican

U.S. EPA, Region 5 Mail Code C-14J

77 West Jackson Blvd.

Chicago, IL 60604

(312) 353-7464