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DELIVERED BY COURIER

Regional Hearing Clerk (E-19J)
U.S. EPA, Region 5
77 West Jackson Boulevard
Chicago, IL 60604

Dear Regional Hearing Clerk:

Re: *In the Matter of Liphatech, Inc.*
Docket No. FIFRA-05-2010-0016

On behalf of Respondent, Liphatech, Inc., I enclose for filing an original and two copies of Memorandum of Respondent Opposing Motion of Complainant for Accelerated Decision on Liability For Counts 2,141 through 2,183 of the Complaint.

Please file-stamp one of the enclosed copies and kindly return it to me in the enclosed postage prepaid envelope. Thank you for your assistance.

Respectfully submitted,

Michael H. Simpson

REINHART\5409296LNR:JES

Encs.

cc Honorable Barbara A. Gunning (w/encs., by courier)
Ms. Nidhi K. O'Meara (C-14J) (w/encs., by courier)
Mr. Carl Tanner (w/encs., by courier)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:	)	**Docket No. FIFRA-05-2010-0016**
	)	
Liphatech, Inc.	)	**Hon. Barbara A. Gunning**
Milwaukee, Wisconsin,	)	
	)	
Respondent.	)	
	)	
	)	

MEMORANDUM OF RESPONDENT OPPOSING MOTION OF COMPLAINANT FOR ACCELERATED DECISION ON LIABILITY FOR COUNTS 2,141 THROUGH 2,183 OF THE COMPLAINT

Respondent, Liphatech, Inc., pursuant to 40 C.F.R. §§ 22.16 and 22.20 of the Consolidated Rules of Practice governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits ("Consolidated Rules"), hereby respectfully requests that the Presiding Officer enter an order denying, in its entirety, 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 ("Complainant's Motion"). The bases for this request are discussed below.

I. Factual Background and Statutory and Regulatory Background.

A. Factual Background.

Complainant alleges that Respondent distributed or sold a rodenticide known as "Rozol Pocket Gopher Bait II" ("Rozol")[1] with claims made for it as part of its distribution or sale that were substantially different from the claims made for it as part of the statement required in connection with its registration under Section 3 of the Federal Insecticide,

[1] For ease of reference, Respondent will use "Rozol" in this Memorandum to refer to "Rozol Pocket Gopher Bait II" which also has an alternative name of "Rozol Pocket Gopher Burrow Builder Formula." The EPA registration number for Rozol is 7173-244.

Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136a, et seq. The "statement required in connection with its registration under Section 3" of FIFRA is hereinafter referred to as the "Registration Statement." Pursuant to the registration of Rozol, the Office of Pesticides Program, Registration Division approved the use of Rozol on pocket gophers. See Respondent's Exhibit (RX) 2.d. 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 the states of Kansas, Nebraska, Wyoming, Colorado Texas, and Oklahoma. See Complainant's Motion, 3.

B. Statutory and Regulatory Background.

Section 12(a)(1)(B) of FIFRA makes it unlawful for any person in any state to distribute or sell to any person

> any registered pesticide if any 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 this title.

FIFRA § 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B) (emphasis added).

Also important is FIFRA's definition of the "statement required" to be submitted for the registration of a product under FIFRA Section 3. Section 3(c)(1) of FIFRA defines the statement as follows:

> (c) **Procedure for registration.**
>
> (1) **Statement required.** Each applicant for registration of a pesticide shall file with the Administrator a statement which includes –
>
> **(A)** the name and address of the applicant and of any other person whose name will appear on the labeling;

> **(B)** the name of the pesticide;
>
> **(C)** a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;
>
> **(D)** the complete formula of the pesticide;
>
> **(E)** a request that the pesticide be classified for general use or for restricted use, or for both; and
>
> **(F)** except as otherwise provided in paragraph (2)(D), if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions . . . .[2]

As discussed in greater detail below, the Registration Statement encompasses much more than the product label.

II. Overview of Respondent's Opposition to Complainant's Motion.

The following is a summary of the major reasons why Complainant's Motion should be denied:

A. Complainant relies upon an incorrect legal standard for determining if claims made by Respondent as part of the sale or distribution of Rozol were substantially different from claims made for Rozol as part of the Registration Statement. Complainant conclusorily asserts that a claim made as part of the sale or distribution of a registered pesticide product may not be made if the claim has not been approved for use on the label for the particular product. By doing so, Complainant confuses the requirements for

[2] The data requirements for pesticide registration are set forth at 40 C.F.R. Part 158 and are generally described on the EPA's website at http://www.epa.gov/opp0001/regulating/data_requirements.htm.

pesticide advertising with the requirements for pesticide labeling. Complainant's assertion is incorrect as a matter of law.

Section 12(a)(1)(B) of FIFRA provides that a claim that is made as part of the sale or distribution of Rozol cannot be substantially different from the claims made for Rozol as part of the Registration Statement. As can be seen by examining the plain wording of Section 3(c)(1) of FIFRA, the label is only a small portion of that overall statement. If, for the sake of discussion, one adopts the Complainant's suggested standard for determining whether claims made as part of the sale or distribution of a registered pesticide are substantially different from the Registration Statement because they cannot be found on the accepted label, such a stringent interpretation of Section 12(a)(1)(B) of FIFRA would violate Respondent's constitutional right to commercial free speech.

According to Complainant's incorrect interpretation of FIFRA, Section 12(a)(1)(B) would prohibit a person from stating the color of its product in advertising if that information was not approved by EPA on the product label. This would be an absurd result.

B. In addition to applying the wrong legal standard, Complainant has not introduced any admissible evidence in this proceeding that establishes that the claims that are alleged to have been made by Respondent for Rozol are substantially different from the claims made in the Registration Statement.

C. A number of the claims that Complainant alleges Respondent made as part of the sale or distribution of Rozol are either not claims for Rozol or they are factual assertions about Rozol for which an evidentiary hearing must be held to determine if those

claims are substantially different from the claims made as part of Respondent's Registration Statement for Rozol.

D. A number of the alleged sales or distributions of Rozol that Respondent made were either transfers made to employees of Respondent or occurred before any of the allegedly violative literature could have been sent to the recipients.

E. Complainant has failed to show the necessary nexus between the distribution of Respondent's literature and the sale or distribution of Rozol.

III. Standard of Review for Motions for Accelerated Decision.

Motions for accelerated decision under Section 22.20(a) of the Consolidated Rules are similar to the standard for granting summary judgment under Rule 56 of the Federal Rules of Civil Procedure ("FRCP"). Therefore, federal court decisions interpreting Rule 56 provide guidance for reviewing motions for accelerated decision. See *CWM Chemical Service*, 6 E.A.D. 1 (EAB 1995). The burden of showing that no genuine issue of material fact exists is on the party moving for summary judgment and the tribunal must construe the evidentiary material and inferences drawn therefrom in the light most favorable to the non-moving party. See *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1985).

Summary judgment is inappropriate where contradictory inferences may be drawn from the evidence. *Rogers Corp. v. EPA*, 275 F.3d 1096, 1103 (D.C. Cir. 2002). If a moving party fails to carry its burden to prove that it is entitled to summary judgment under established principles, no defense is even required by the non-moving party. *Adickes v. S.H. Kress Co.*, 398 U.S. 144, 156 (1970). If summary judgment is even

questionable, sound judicial policy supports denial of the motion so the case can be more fully developed at hearing. See *Roberts v. Browning*, 610 F.2d 528, 536 (8th Cir. 1979).

Moreover, Complainant's speculation and conjecture cannot support its motion for summary judgment. See *Gorbitz v. Corvilla, Inc.*, 196 F.3d 879 (7th Cir. 1999) (upholding dismissal of action on summary judgment where plaintiff's evidence was pure speculation). "One cannot rely on speculation or conjecture or inadmissible hearsay, but must offer admissible evidence or evidence that can be submitted at trial in admissible form." *Ayantola v. Community Technical Colleges*, 2007 WL 963178 (D. Conn. 2007). As discussed in greater detail below, Complainant has failed to establish sufficient facts to support its motion for accelerated decision. Therefore, Complainant's Motion should be denied.

IV. Complainant Relies Upon an Incorrect Legal Standard for Determining If Claims Made by Respondent for Rozol as Part of Its Sale or Distribution Are Substantially Different From the Claims Made for It as Part of Its Registration Statement.

On several occasions Complainant's Motion incorrectly states the standard for determining whether claims made for Rozol as part of its sale or distribution are substantially different from its Registration Statement. According to Complainant, claims made in advertising are compared only to the accepted product label. See, for example, Complainant's Motion at 3, 11. The appropriate analysis is not to simply compare advertising claims to the accepted label for Rozol but to compare the claims with the entire Registration Statement, of which the label is a small part.

The only legal support Complainant cites for its extremely narrow interpretation of FIFRA Section 12(a)(1)(B) is an order issued *In the Matter of Microban Products*

Company, Docket No. FIFRA-98-H-01 at 8 (September 18, 1998) ("*Microban Order*"). Under the circumstances of that case, the ALJ stated that

> [E]stablishment 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 Microban made any claims as part of its distribution or sale which substantially differ from those made in connection with its registration approval."

Complainant's Motion, 11. Contrary to Complainant's assertion, a careful review of the *Microban Order* reveals that its analysis is not particularly instructive in this case.

Microban involved a product that had been registered "as . . . effective only against non-health related organisms . . . ." *Microban Order*, 4. In fact, EPA alerted Microban that its product was only being accepted "as a preservative and bacteriostatic agent effective only against non-health related organisms which may contribute to deterioration of the treated articles or to control odors by such organisms." *Id.* In that case EPA showed that Microban was making health-related claims by stating that the product was also "effective against microorganisms infectious to man, such as Salmonella, E. Coli, Strep or Staph N5" – microorganisms for which use of the pesticide was not authorized by EPA.

Contrary to the notice of pesticide registration that it received, Microban was clearly making public health claims when EPA had expressly directed Microban that its product was not approved for such use. In *Microban*, the presiding officer referred to the notice of pesticide registration as the "base line" from which to judge violations of Section 12(a)(1)(B), because in that case Microban was making claims that its pesticide was effective against a pest for which use of the product was not approved.

Whereas Microban made claims about its product for use against an unapproved pest, Respondent's statements that are the subject of Complainant's Motion regarding

Rozol involved the characteristics of Rozol when used to control the pest which EPA approved it to control – Black-Tailed Prairie Dogs.[3] According to Henry Jacoby, a long-time former EPA employee and pesticide registration expert, the appropriate standard for reviewing advertising material is the Registration Statement, including all of the studies, documents and data generated for the product, not simply the "accepted label," as erroneously asserted by Complainant. See Jacoby Declaration attached hereto as Exhibit A.

Therefore, Complainant has offered the incorrect legal standard for determining whether any of the claims made by Respondent for Rozol as part of its sale or distribution differed substantially from the claims made in its Registration Statement. On this basis alone, Complainant's Motion should be denied.

Importantly, Complainant's interpretation of Section 12(a)(1)(B) of FIFRA conflicts with EPA's own regulations regarding advertising. 40 C.F.R. § 168.22(b)(5) states that, " as a matter of policy, the Agency will not regard as unlawful the advertisement of uses permitted by FIFRA Section 2(ee) provided the product is not an antimicrobial pesticide targeted against human pathogens." Among other things, Section 2(ee) expressly allows pesticides to be applied to pests not specified on the labeling under certain conditions. FIFRA § 2(ee)(2). Therefore, as a matter of EPA policy, a person can

[3] A review of case law interpreting Section 12(a)(1)(B) of FIFRA reveals that violations of it have only been found where a person was making claims that its product was effective in controlling a pest for which the product was not approved or that expanded available uses of the product. See e.g., *Microban Order*, No. 98-H-01, 1998 WL 743912 (respondent was found to be making claims that the product provided effective control of bacteria including E. Coli, Salmonella, Staph. and Strep when EPA had not approved those uses); *In re Sporicidin International*, 3 E.A.D. 589 (EAB 1991) (respondent claimed disinfectant was effective against Hepatitis B and AIDS while the approved label did not authorize use against Hepatitis or AIDS); *In re: Johnson Pacific, Inc.*, 1993 EPA ALJ LEXIS 471 (ALJ 1993) (respondent claimed its product could be used in spas when it was only approved for use in pools). Liphatech never claimed Rozol could be applied to control any pest other than pests for which it was approved.

advertise a pesticide for use against a pest not approved by EPA on the product label without violating FIFRA § 12(a)(1)(B). Complainant's position in this case is entirely inconsistent with EPA's policy as set forth in the Code of Federal Regulations.[4]

If the Presiding Officer has any doubt that pesticide advertising claims must be reviewed in light of the entire Registration Statement, Respondent respectfully contends that limiting the review to the "accepted label" would be an interpretation that is contrary to FIFRA. Further, such an interpretation would violate Respondent's right to commercial free speech under the First Amendment to the United States Constitution.

A narrow interpretation of the claims which a pesticide manufacturer can include in its advertising material would impermissibly infringe on the First Amendment free speech right of a pesticide manufacturer to truthfully advertise its products. See *United States ex rel. Attorney Gen. v. Delaware A. Hudson Co.*, 213 U.S. 366, 407 (1909) ("when the constitutionality of a statute is assailed, if the statute be reasonable susceptible of two interpretations . . . it is our plain duty to adopt the construction which will save the statute from constitutional infirmity."); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371 (2002) ("if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so."). Therefore, the Presiding Officer should not interpret FIFRA in the manner suggested by Complainant.

[4] Note that 40 C.F.R. § 168.22(b)(5) is consistent with the *Microban Order* because Microban advertised its antimicrobial product as effective against human pathogens – the only exception to EPA's policy.

V. Complainant Has Not Introduced Any Admissible Evidence That the Claims Made by Respondent for Liphatech as Part of Its Sale or Distribution of Rozol Are Substantially Different From the Claims Made for It In Its Registration Statement.

Complainant's Motion at pages 8-11 cites a number of claims that Respondent made regarding Rozol and other pesticide products. Complainant then asserts that all of these claims are substantially different from the claims that were authorized by the EPA for Respondent to make on its "accepted label." Complainant's Motion, 11. Specifically, Complainant stated:

> The next question is whether the claims that Liphatech made . . . 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.

Id. Complainant then cites to certain exhibits in its pre-hearing information exchange which are the approved labels for the Rozol product at both the federal and state regulatory levels. Therefore, there can be no question that the incorrect standard of comparison suggested by Complainant is to the accepted label, not to the Registration Statement as required by FIFRA.[5]

Under Complainant's construction of this provision, a violation would occur whenever any claim is made that is not specifically included in the approved product labeling. This severe construction of FIFRA Section 12(a)(1)(B) is not supported by the literal language of the provision or by any of the precedents cited by Complainant.

[5] As noted above, Complainant's "method" for establishing differing claims is entirely inconsistent with EPA's own advertising policy set forth at 40 C.F.R. 168.22(b)(5).

In any case, the approved product labeling is much too legally narrow a base of comparison. A plain reading of FIFRA Section 12(a)(1)(B) requires that the entire Registration Statement be reviewed to determine if claims made for Rozol as part of its sale or distribution are substantially different. Complainant has introduced no admissible evidence that establishes that the claims made by Respondent for Rozol as part of its sale or distribution of the product are substantially different from the Registration Statement. All of Complainant's comparisons are to the accepted label for Rozol, not to the Registration Statement.

As testified by Thomas Schmit in his Declaration that is attached hereto as Exhibit B, he will demonstrate by reference to materials in Respondent's Prehearing Information Exchange that the claims made in the Registration Statement support the claims made by Respondent as part of its sale or distribution of Rozol. Consequently, there is no basis for the Presiding Officer to grant Complainant's Motion.

VI. A Number of Alleged Claims Asserted by Complainant Are Either Not Claims for Rozol or Are Factual Matters About Rozol That Must Be Addressed At a Hearing to Determine if Those Claims Are Substantially Different From the Claims Made as Part of Respondent's Registration Statement.

FIFRA Section 12(a)(1)(B) makes it unlawful for any person in any state to distribute or sell to any person "any registered pesticide if any claims made for it as part of its distribution or sale substantially differ." The word "it" can only reasonably be read to refer to the registered pesticide itself. The word "it" does not refer to other products or things mentioned by Respondent in literature, advertising or otherwise.

Complainant's Motion, at page 9, cites the following "claims:"

> (6) "Traditional control products such as zinc phospide 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."

The above three quoted alleged "claims" are statements made by Respondent about pesticide products other than Rozol itself. Therefore, under a plain reading of the statute, these cannot constitute claims for Rozol subject to FIFRA Section 12(a)(1)(B).

The EPA is not the exclusive governmental agency with jurisdiction to regulate advertising of commercial products. As far as FIFRA § 12(a)(1)(B) is concerned, the limited jurisdiction of the EPA ends with claims made for the registered pesticide as part of the sale or distribution of the product. Complainant is attempting improperly to expand the EPA's authority far beyond that provided to it by statute. FIFRA does not grant EPA authority to regulate all advertising associated with registered pesticides.

In addition, the other "claims" that are listed in Complainant's Motion at pages 9-11 are factual assertions which Respondent contends are supported by the claims made for Rozol in its Registration Statement and included in Respondent's Prehearing Information Exchange. See e.g., RX 1-12; Schmit Declaration. Moreover, in addition to being supported by the Registration Statement, many of the allegedly violative claims identified by Complainant are supported by publicly available information – some of which is even published by EPA. *Id.* As testified by Thomas Schmit in his Declaration that is attached as Exhibit B, he will show that the claims made in the Registration Statement support the claims made by Respondent as part of its sale or distribution of Rozol.

Because the alleged claims for Rozol that Complainant asserts violated FIFRA Section 12(a)(1)(B) involve questions of material fact and are in genuine dispute, the Presiding Officer cannot grant Complainant's Motion.

VII. A Number of Alleged Sales or Distributions of Rozol Were Made to Employees of Respondent or Were Made Before Any of the Allegedly Violative Literature Was Sent by Respondent to Its Distributors. Therefore, These Counts Cannot Constitute Violations of FIFRA.

Complainant alleges erroneously that the product distributions that are described in paragraphs 216 and 250 of the Complaint constitute "sales," "distributions" or "shipments" that are covered under FIFRA Section 12(a)(1)(B). These are product transfers that were made by Respondent to two of its employees. As set forth in the attached Declaration of Alan Smith, attached as Exhibit C to this Memorandum, Mr. Smith testifies that Jim Knuth, located at 104 Applewood Court, Council Bluffs, Iowa 51503 (see Complaint paragraph 216) and Mark Newman, 6702 Silver Bell Lane, Amarillo, Texas 79124 (see Complaint paragraph 250), were employees of Respondent. See also CX 14a., EPA 000266 (noting Mr. Knuth's and Mr. Newman's respective positions within Liphatech). Complainant conclusorily asserts, without any citation to any authority, that

> 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.

Complainant's interpretation of FIFRA Section 12(a)(1)(B) is incorrect. This section of the statute states that it is unlawful for "any person . . . to distribute or sell to any person . . . ." It is impossible to "sell," "distribute" or "ship" products to oneself. The transfers of the Rozol products to Messrs. Knuth and Newman were to employees of the company. No

violation of FIFRA Section 12(a)(1)(B) occurred when Respondent transferred Rozol from its facility in Wisconsin to one employee in Texas and to another employee in Iowa.

Importantly, 40 C.F.R. § 152.30(a) contemplates that intracompany transfers of a pesticide are not even subject to the prohibition of sale or distribution of an unregistered pesticide in FIFRA § 12(a)(1)(A). According to that section, even an unregistered pesticide may be lawfully transferred between registered establishments operated by the same producer. Respondent's intracompany transfers were of a registered pesticide.

Furthermore, Respondent, as a matter of law, is a single "person." FIFRA Section 2(s) defines a "person" to be a corporation which includes its employees. See e.g. *Saucier v. Coldwell Banker JME Realty*, 644 F. Supp. 2d 769, 784 (S.D. Miss. 2007) (holding that in the context of conspiracy law, a corporation cannot conspire with itself and the acts of employees are acts of the corporation). Therefore, as a matter of law, these two transfers of Rozol cannot constitute sales/distributions/shipments under FIFRA Section 12(a)(1)(B).

If Complainant's position is accepted and the Presiding Officer simply looks at the "movement of the product," this would mean that any transfer of products by a company from, for example, one manufacturing location to another or from its manufacturing location to its distribution warehouse would violate FIFRA should there be "differing claims" literature in the marketplace.

Such a result would be absurd. Federal statutes should not be construed in such a way as to produce absurd results. *Compton v. Unified School District v. Addison*, 598 F.3d 1181, 1184 (9th Cir. 2010) ("we read statutes as a whole, and avoid statutory interpretations which would produce absurd results"); *Rouse v. Law Office of Rory Clark*,

603 F.3d 699, 704 (9th Cir. 2010) ("when a statute is ambiguous, a court should construe it in a way to avoid an absurd result"). Even if the Presiding Officer concludes that such product transfers are distributions under FIFRA, as discussed below, it is clear that they are not violations of FIFRA because there could not be any nexus between the transfers and Liphatech's literature.

Complainant's Motion also states on page 5 that "Liphatech admits that it distributed or sold Rozol to its customers, starting on October 1, 2007 and continuing through May 30, 2008." Specifically with respect to four distributions, Respondent admits that those distributions took place between October 1 and October 29, 2007. See Complaint and Answer ¶¶ 213-216. The Declaration of Mr. Alan Smith, attached as Exhibit C, states that the literature that the Complainant is alleging violated FIFRA Section 12(a)(1)(B) was distributed no earlier than October 31, 2007. Therefore, there can be no nexus between the distribution of this literature and the sale/distribution of Rozol to these four distributors before October 31, 2007.

Complainant will no doubt allege that between October 1 and October 31, 2007, Respondent's general broadcast ads and print ads constituted part of the "sale or distribution" of Rozol to these four distributors. However, there is no evidence that these distributors ever heard any of the radio broadcasts during this period of time. Nor is there any evidence that they read or even received any of the print advertisements that were published by Respondent during this period of time. Likewise, there is no evidence that any of these distributors viewed any information that may have been on Respondent's

website between October 1 and October 30, 2007.[6] Moreover, Respondent's website is a "passive" website in that no orders could be placed or business transacted, and "passive" websites do not constitute an "offer for sale." Complainant's speculation and conjecture are not admissible evidence and cannot support its conclusory assertions.[7]

Therefore, Complainant has made no evidentiary showing that any claims for Rozol which may have been substantially different were made as part of the sale or distribution of Rozol to these four distributors.

VIII. Claims for Rozol Were Not Made as Part of Its Distribution or Sale.

As stated above, advertising to the general public (Respondent's print and broadcast advertisements) were not directed to any individual or organization. Therefore, such advertising could not be part of any sale or distribution of Rozol. Complainant has failed to prove a sufficient nexus between Liphatech's advertising and subsequent distributions of Rozol.

In order to support its assertion that Liphatech violated FIFRA Section 12(a)(1)(B), Complainant must prove that Liphatech (1) made claims that were substantially different than the Registration Statement and (2) that those claims were part of the sale or distribution of Rozol. In order to show the requisite "nexus" between any claim and a subsequent sale, Complainant must show that a distributor that purchased Rozol to be sold for use on Black-Tailed Prairie Dogs actually received, read or listened to the allegedly violative advertisements. See e.g., *Sporicidin International*, 3 E.A.D. 589 (holding the

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[6] Notably, Complainant does not even identify what claims on the website allegedly violated FIFRA. To this end, Complainant fails to state a claim upon which relief may be granted.

[7] Complainant also conclusorily asserts that the allegedly violative literature could create confusion among potential customers without providing any evidence that this occurred. See Complainant's Motion, 13. Respondent submits that no confusion can occur because Rozol can only be purchased by certified pesticide applicators who are trained and licensed on how to read labels and apply restricted use pesticides.

violative advertising must be an integral element of the sale); *In re: Microban Products Co.*, 2004 WL 1658591 (EAB 2004) (holding there must be a sufficiently close link between the unapproved claims and distributions of the product).

The only assertion by Complainant that addresses the requisite nexus is a reference to a list of distributors that were authorized to sell Rozol for use on Black-Tailed Prairie Dogs. Complainant's Motion, 15-16; CX 17, EPA 000378. Complainant mistakenly asserts that this is a list of distributors that received Direct Mail Packages when it is not. Complainant would mistakenly have the Presiding Officer believe that all informative literature is part of the sale or distribution of a product. This is not true.

Mr. Carl Tanner testifies that the direct mail packages that were sent to distributors were not sent to induce sales but to educate the distributors so they would be able to answer questions that may be asked by potential purchasers of Rozol – certified pesticide applicators. See Declaration of Carl Tanner, Chief Executive Officer of Respondent, attached as Exhibit D. This literature was designed to inform distributors of Rozol about essential information that these certified applicators may ask. In addition, this literature did not include a price list or purchase order form. *Id.*

On the other hand, Complainant repeatedly asserts, again without evidentiary foundation, that this literature was being used to induce sales from these distributors. For example, Complainant's Motion asserts at page 14:

> Furthermore, there can be no dispute that the direct mail packages were clearly being sent to potential customers to induce sales.

Complainant then quotes extensively from a letter sent by Respondent to Complainant and Complainant simply concludes that the clear intent of this literature was to induce sales.

At the hearing on this matter, Carl Tanner will testify that this literature was not to induce sales, but to educate and inform Respondent's distributors about Rozol. *Id.*

Complainant's Motion asserts at pages 14-15 that the individuals to whom Respondent sent a letter asking that potentially violative literature be destroyed in order to comply with a Stop Sale Order issued by the Complainant were the same individuals who received the direct mail literature. Complainant's Motion further states at page 15 that these individuals were persons in authority who were "the ones making decisions as to purchasing . . . ." However, there is no admissible evidence in the record to support these conclusory assertions. Federal courts have held that conclusory statements without substantiation must be ignored when deciding summary judgment motions. See *Gorbitz v. Corvilla, Inc.*, 196 F.3d 879 (7th Cir. 1999) (upholding the district court's dismissal of the action where proffered evidence was pure speculation).

Finally, Complainant ignores the fact that Rozol is approved for the control of pocket gophers under EPA Reg. No. 7173-244 and, if accompanied with an appropriate SLN label, in an appropriate jurisdiction, Rozol may be used to control Black-Tailed Prairie Dogs. Complainant has not shown that any of the product distributed as referenced in Counts 2,141 through 2,183 was purchased for use on Black-Tailed Prairie Dogs. Complainant could not establish any nexus between an allegedly violative claim regarding Rozol's application to Black-Tailed Prairie Dogs and subsequent distributions of the product for use on pocket gophers.

Moreover, Complainant ignored the fact that many of the allegedly violative distributions occurred after the use season to control Black-Tailed Prairie Dogs expired as set forth on the state specific SLN label.

All SLN labels for Rozol have use seasons that expire on or before May 1. CX 17, EPA000372-EPA000377. Only Texas and Oklahoma have use seasons that extend beyond March 15. *Id.* Therefore, Counts 2161, 2170-2172, 2174-2175, 2177 and 2180-2183 of the Complaint refer to distributions of Rozol to states after the time period when Rozol could be applied to Black-Tailed Prairie Dogs had expired. The only logical conclusion is that these were purchases of the product for use on pocket gophers, not Black-Tailed Prairie Dogs, and therefore they could not lead to a violation of Section 12(a)(1)(B).

IX. EPA Does Not Routinely Review Advertising Claims.

Complainant asserts that this situation regarding "differing claims" allegations could have been easily avoided if only Respondent had submitted its "advertising" claims to EPA for review and approval. However, EPA does not routinely approve pesticide advertisements. In fact, EPA's current position is that it "does not routinely review advertising in connection with the registration" of a pesticide product. See EPA Label Review Manual, Ch. 12 at 12-11.

Complainant also continues to assert that Respondent's advertising claims are false and/or misleading. See Complainant's Motion at 12-13 and footnote 9. However, Complainant has filed a motion to amend the Complaint to eliminate all allegations that Rozol was misbranded. Therefore, the false or misleading standard applicable to pesticide labels is no longer at issue in this case. Complainant is simply mixing legal standards, like "apples and oranges," by bringing this concept back into play. Moreover, there has been no finding that any of the claims made by Respondent were either false or misleading.

Further, Complainant misquotes *Mid-Am Research Chem. Corp,*. EPA ALJ LEXIS (ALJ 1977). That case involved labeling, not advertising claims, and the ALJ concluded

his opinion by stating that "I would assume a request for approval of the instant brochure would have eliminated the basis for this proceeding" (emphasis added). *Id.* at *13. Since EPA does not routinely review advertising claims, the ALJ's assumption in that 1977 case would be incorrect today.

X. Conclusion.

Based on the pleadings, evidence submitted and declarations on file, Complainant's Motion must be denied. For many of Complainant's conclusory statements and assertions that are discussed above, Complainant has not introduced any supporting admissible evidence and genuine issues exist as to other disputed material facts. Moreover, Complainant uses an incorrect legal standard in an attempt to establish that claims made for Rozol as part of its sale or distribution differed substantially from claims made for Rozol in its Registration Statement. For these reasons, Complainant's Motion should be denied in its entirety.

Dated this 3rd day of December, 2010.

Respectfully submitted,

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Attorneys for Respondent Liphatech, Inc.

EXHIBIT A

See Attached Declaration of Henry Jacoby

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:	)	**Docket No. FIFRA-05-2010-0016**
	)	
Liphatech, Inc.	)	
Milwaukee, Wisconsin,	)	
	)	
Respondent.	)	
	)	
	)	

DECLARATION OF MR. HENRY M. JACOBY

State of Maryland
County of Frederick

I, Henry M. Jacoby, declare and state as follows:

1. The statements I make in this declaration are based on my personal knowledge and belief.

2. I received a Bachelor of Science Degree in Chemistry from St. Norbert College, DePere, Wisconsin in 1962 and a Masters Degree in Management from Frostburg State University, Frostburg, Maryland in 1976.

3. From 1991 through 1997, I served as Branch Chief, Environmental Fate and Ground Water Branch, Environmental Fate and Effects Division (EFED), Office of Pesticide Programs (OPP), U.S. Environmental Protection Agency ("EPA"). From 1974 through 1991, I served as a product manager reporting directly to the Herbicide-Fungicide Branch Chief in Registration Division and as a senior staff member in EFED/OPP of EPA on the review and evaluation of pesticide chemicals and registration packages. Since 1997, I have been employed as a pesticide registration consultant, most recently with The Acta Group, L.L.C., where I provide advice and support regarding pesticide registration matters and applications to U.S. EPA.

4. All capitalized terms not defined below shall have the meaning ascribed to them in the Complaint and/or Complainant's Motion for Accelerated Decision on Liability for Counts 2,141 through 2,183 of the Complaint.

5. Section 12(a)(1)(B) of FIFRA states that it is unlawful for any person to distribute or sell to any person "any registered pesticide if any claims made for it as part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 3."

6. The "statement" required in connection with a pesticide's registration under Section 3 of FIFRA includes all of the studies, documents and data that a registrant generates and submits to the U.S. EPA as part of the registration process; the "statement" is not limited to the accepted product label.

7. The Notice of Pesticide Registration and accepted label for Rozol and the associated SLNs for Rozol identify the claims that Respondent could make on the product label regarding its pesticide product; these documents do not identify what claims Respondent may or may not make in advertising its pesticide product.

8. All "labeling" for a pesticide is reviewed and approved by U.S. EPA as part of the FIFRA pesticide registration process.

9. FIFRA does not require U.S. EPA to review "advertising" material as part of the pesticide registration process and U.S. EPA does not routinely review "advertising" material as part of the pesticide registration process.

10. The statements 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 and belief.

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

Executed on December 1, 2010.

Henry M. Jacoby

REINHART\5380156

EXHIBIT B

See Attached Declaration of Thomas Schmit

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:	)	**Docket No. FIFRA-05-2010-0016**
	)	
Liphatech, Inc.	)	
Milwaukee, Wisconsin,	)	
	)	
Respondent.	)	
	)	
	)	

DECLARATION OF THOMAS SCHMIT

State of Wisconsin
County of Milwaukee

I, Thomas Schmit, declare and state as follows:

1. The statements I make in this declaration are based on my personal knowledge and belief.

2. I am and have been the Manager of Regulatory Affairs of Liphatech, Inc. ("Liphatech") since 2002, and have been employed at Liphatech since 2000.

3. All capitalized terms not defined below shall have the meaning ascribed to them in the Complaint.

4. None of the claims for Rozol set forth in Complainant's Motion for Accelerated Decision on Liability for Counts 2,141 through 2,183 of the Complaint are substantially different from the statement required as part of the registration for Rozol.

5. The single application effectiveness of Rozol is supported by efficacy studies, including, but not limited to, a study by Charles D. Lee and Scott E. Hygnstrom entitled *Field Efficacy and Hazards of Rozol Bait for Controlling Black Tailed Prairie Dogs* (the "Lee Study"). *See* Respondent's Exhibit ("RX") 10. The single application effectiveness of Rozol was acknowledged by the EPA in the IRB Efficacy Review of Rozol Prairie Dog Bait included as RX 29. *See* RX __001880 stating: "The efficacy report by Lee and Hyngstrom . . . suggests that

single applications of 1/4 cup of bait effectively controlled black tailed prairie dogs . . . the trials were adequate to support the fundamental label claim."

6. The low primary poisoning potential of Rozol is supported by a document published by William Erickson and Douglas Urban entitled "Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals" (the "EPA Report"). *See* RX 12.

7. The formulation of Rozol is set forth on the approved product labels for Rozol, which indicate that they include chlorophacinone in a concentration of 50 parts per million.

8. The Lee Study concludes that black tailed prairie dogs normally expire underground and are therefore not available to predators on the soil surface. *See* RX 10.

9. The Lee Study concludes that Rozol provided 95% average population reduction when measured by the "plugged burrow" census method and 94% average population reduction when measured by the "visual count" census method. *See* RX 10.

10. The EPA Report supports Liphatech's statements regarding the toxicity profile of Rozol and its toxicity to dogs, mice and other nontargets. *See* RX 12.

11. The observations and statements 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 and belief.

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

Executed on December 3, 2010.

Thomas Schmit

REINHART\5405879

EXHIBIT C

See Attached Declaration of Alan Smith

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:	)	**Docket No. FIFRA-05-2010-0016**
	)	
Liphatech, Inc.	)	
Milwaukee, Wisconsin,	)	
	)	
Respondent.	)	
	)	
	)	

DECLARATION OF ALAN SMITH

State of Wisconsin
County of Milwaukee

I, Alan Smith, declare and state as follows:

1. The statements I make in this declaration are based on my personal knowledge and belief.

2. I am and have been the Business Director, Agricultural Division of Liphatech, Inc. ("Liphatech") since 2007 and have been employed by Liphatech since 1998.

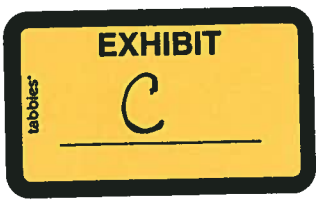
3. All capitalized terms not defined below shall have the meaning ascribed to them in the Complaint.

4. Mr. Jim Knuth was an employee of Liphatech on October 29, 2007.

5. Mr. Mark Newman was an employee of Liphatech on April 18, 2008.

6. The Direct Mail Packages, including the Research Bulletin, were not available to the general public prior to October 31, 2007.

7. The date located on the back of the Research Bulletin, 10/17/07, is the date the final art work for the Research bulletin was approved, not the print date or the date on which the Research Bulletin was made available to the public.



8. The observations and statements 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 and belief.

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

Executed on Dec. 3, 2010.

Alan Smith

Alan Smith

REINHART\5405873.

EXHIBIT D

See Attached Declaration of Carl Tanner

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:	)	**Docket No. FIFRA-05-2010-0016**
	)	
Liphatech, Inc.	)	
Milwaukee, Wisconsin,	)	
	)	
Respondent.	)	
	)	
	)	

DECLARATION OF CARL TANNER

State of Wisconsin
County of Milwaukee

I, Carl Tanner, declare and state as follows:

1. The statements I make in this declaration are based on my personal knowledge and belief.

2. I am and have been the Chief Executive Officer of Liphatech, Inc. ("Liphatech") since December, 2003.

3. All capitalized terms not defined below shall have the meaning ascribed to them in the Complaint.

4. Liphatech provides product literature to its distributors and/or dealers, such as the Research Bulletin, to inform and educate the distributors and/or dealers about Liphatech's products—not to induce sales or distribution of the product.

5. When provided to distributors, the Research Bulletin was not accompanied by a price list or order form for Rozol or any other terms and conditions of sale.

6. Liphatech does not sell Rozol directly to end users. Instead, Liphatech sells Rozol to distributors and/or dealers that in turn sell the product to end users. The demand for the purchase of Rozol by distributors is driven by end users of the product. Therefore, providing literature to distributors cannot induce the sale of Rozol. Rather, sales of Rozol are induced by

advertising directly to potential users of the product, not by providing product information to distributors and/or dealers.

7. The statements 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 and belief.

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

Executed on Dec 3, 2010.

Carl Tanner

REINHART\5405872

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

CERTIFICATE OF SERVICE

I, Michael H. Simpson, one of the attorneys for the Respondent, Liphatech, Inc., hereby certify that I delivered one copy of the foregoing Memorandum of Respondent Opposing Motion of Complainant for Accelerated Decision on Liability for Counts 2,141 Through 2,183 of the Complaint ("Respondent's Memorandum"), to the persons designated below, by depositing it with a commercial delivery service, postage prepaid, at Milwaukee, Wisconsin, in envelopes addressed to:

Honorable Barbara A. Gunning
Office of the Administrative Law Judges
Franklin Court Building
1099 14th Street, NW, Suite 350
Washington, D.C. 20005; and

Ms. Nidhi K. O'Meara (C-14J)
Office of Regional Counsel
U.S. EPA, Region 5
77 West Jackson Boulevard
Chicago, IL 60604

I further certify that I filed the original and one copy of the Respondent's Memorandum and the original of this Certificate of Service in the Office of the Regional Hearing Clerk, U.S. EPA, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, by depositing them with a commercial delivery service, postage prepaid, at Milwaukee, Wisconsin, on the date below.

Dated this 3rd day of December, 2010.

Michael H. Simpson
One of the Attorneys for Respondent
Liphatech, Inc.

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