Reinhart
Attorneys at Law

Reinhart Boerner Van Deuren s.c.
P.O. Box 2965
Milwaukee, WI 53201-2965

1000 North Water Street
Suite 1700
Milwaukee, WI 53202

Telephone: 414-298-1000
Fax: 414-298-8097
Toll Free: 800-553-6215
reinhartlaw.com

February 11, 2011

Michael H. Simpson
Direct Dial: 414-298-8124
msimpson@reinhartlaw.com

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 First Amended 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

Michael H. Simpson

REINHART\6045823

Encs.

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

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 First Amended Complaint, to the persons designated below, by depositing it with a commercial delivery service, postage prepaid, at Milwaukee, Wisconsin, in envelopes addressed to:

Honorable Susan L. Biro
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 Memorandum of Respondent Opposing Motion of Complainant For Accelerated Decision on Liability for Counts 2,141 Through 2,183 of The First Amended Complaint 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 11th day of February, 2011.

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

REINHART\6045431LNR:JES 02/10/11

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

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

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

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INTRODUCTION

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 deny, in its entirety, Complainant's Motion for Accelerated Decision on Liability for Counts 2,184 through 2,231 of the First Amended Complaint, which was filed on January 27, 2011 ("Motion").

This is the second motion by Complainant for accelerated decision relating to Respondent's alleged violations of FIFRA § 12(a)(1)(B), 7 U.S.C. § 136j(a)(1)(B). The first motion was filed by Complainant on November 18, 2010 and involved Counts 2,141 through 2,183 of the First Amended Complaint ("Complainant's First Motion"). The allegations in Complainant's First Motion involved events occurring during 2007 and 2008.

This Motion involves events occurring during the period from November 2009 through February 2010. These allegations, like the allegations in Complainant's First Motion, do not involve any alleged product misbranding or any alleged unlawful use or application of Rozol. Rather, they simply involve words used by Respondent in "advertising," allegedly in violation of FIFRA section 12(a)(1)(B). However, the legal theory used by Complainant to substantiate the alleged violations in this Motion is different from the legal theories used in Complainant's First Motion.

Complainant's First Motion alleged that Respondent violated section 12(a)(1)(B) as a result of "differing claims" allegedly made in connection with physical sales and distributions of Rozol. In the instant Motion, Complainant alleges that Respondent's website, which is available to the general public and pesticide users, constitutes an "offer for sale" and that certain portions of Respondent's website contained claims that were

substantially different from claims made for the product as part of the statement required in connection with the registration of Rozol.[1] As a result, Complainant concludes that Respondent violated FIFRA section 12(a)(1)(B).

Complainant, however, has introduced no evidence that (a) the literature on Respondent's website to which Complainant objects was ever sent to the parties Complainant alleges it was sent to; (b) Rozol was sold or distributed to the parties to whom Complainant asserts the allegedly offending literature was distributed; or (c) anyone other than Complainant, much less the 48 distributors, ever viewed the web pages allegedly containing differing claims.[2]

Complainant's Motion is an attempt to establish broad agency authority to regulate pesticide advertising under FIFRA. This attempt by Complainant goes far beyond the limited statutory authority that Congress gave the U.S. Environmental Protection Agency ("EPA") to regulate "differing claims" when it enacted section 12(a)(1)(B). In addition,

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[1] The arguments advanced by Complainant to support its "differing claims" theory are no different from the arguments that it advanced in its First Motion and accompanying reply to Respondent's Response to Complainant's First Motion that was filed on December 13, 2010 ("Complainant's First Reply").

[2] Complainant asserts that the Presiding Officer can infer that the 48 companies that received a letter from Liphatech directing that they destroy certain literature (if such literature was in their possession) in response to a SSURO which EPA issued to Respondent, establishes that the 48 companies were sent hard copies of the literature found on Respondent's website which Complainant alleges contain differing claims. *See* Mot. 9. Liphatech's response to the SSURO, however, was taken in an abundance of caution in a good faith effort to comply with Complainant's request that the letters be sent. Nothing in the First Amended Complaint, pre-hearing exchange or Motion establishes that any of the 48 distributors received "hard copies" of the materials that are the subject of this Motion. In addition, Complainant's assertion that Respondent admits sending the literature directly to the 48 distributors that were contacted by Respondent following the SSURO is misleading. *Compare* Mot., 9 (stating the Presiding Officer can infer the literature was sent in hard copy) *to* Mot., 11-12 ("it is undisputed that Respondent sent 48 distributors the Advertisements"). Contrary to Complainant's assertion (Mot. 11), Complainant's Exhibit 54 is not an admission that the material was sent to anyone. Further, there is no allegation in the Motion that anyone other than Complainant ever viewed Respondent's website. If the Presiding Officer determines that the relevant portions of Respondent's website constitute an "offer for sale" and therefore a "distribution or sale" occurred, this distinction becomes important in determining to whom the offers were made and therefore how many violations of section 12(a)(1)(B) could have occurred.

Complainant's position even goes beyond the limited regulatory authority which the EPA has asserted for itself under 40 C.F.R. § 168.22.

A careful examination of the Motion shows that Complainant must convince the Presiding Officer that it has correctly interpreted FIFRA with respect to four legal issues, all of which are questions of first impression, in order to prevail. These include:

(a) What is "advertising" under 40 C.F.R. § 168.22;

(b) Whether "advertising" constitutes an "offer for sale;"[3]

(c) What is the statement required in connection with the registration of a pesticide product; and

(d) When is a claim "substantially different" from claims made as part of Respondent's registration statement?[4]

In addition, the Presiding Officer will be required to examine the effect of Complainant's expansive interpretation of FIFRA § 12(a)(1)(B), which, in turn, is based on its interpretation of 40 C.F.R. § 168.22, on Respondent's constitutional right to commercial free speech. Importantly, Respondent is not asserting that FIFRA § 12(a)(1)(B) is unconstitutional, but that Complainant's broad interpretation of this statute, if accepted, would impermissibly impinge on Respondent's right to commercial free speech. Moreover, as a general rule, statutes that impose a penalty must be strictly construed against the party seeking a penalty. *Ivan Allen Co. v. United States,* 422 U.S. 617, 626-27 (1975). Tying these canons of statutory interpretation together, it becomes clear that the

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[3] Complainant suggests that this must be an issue of first impression because in footnote 10 of its Motion it attempts to distinguish and dismiss the relevance of the decision of the Environmental Appeals Board in *In re: Tifa Ltd.*, 9 E.A.D. 145, 158, 2000 WL 739401 (EAB 2000).

[4] Respondent acknowledges that some case law has applied section 12(a)(1)(B), but its counsel is not aware of any such case law where the presiding officer was required to define the limits of "differing claims."

Presiding Officer should narrowly construe EPA's limited authority under section 12(a)(1)(B).

This memorandum explains Respondent's position on these issues in more detail. For the reasons set forth below, Respondent respectfully requests that the Presiding Officer deny Complainant's Motion in its entirety.

I. Standard of Review for Motions for Accelerated Decision.

The standard of review for a motion for accelerated decision under section 22.20(a) of the Consolidated Rules is 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 a motion for accelerated decision. *See In re: CWM Chem. Serv., Inc.*, 6 E.A.D. 1, 1995 WL 302356 (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 (1986).

Summary judgment is inappropriate where contradictory inferences may be drawn from the evidence. *Rogers Corp. v. E.P.A.*, 275 F.3d 1096, 1103 (D.C. Cir. 2002).[5] 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

[5] Notably, Complainant asserts: "The receipt of Respondent's Advertisements by those 48 distributors, which this Tribunal can infer from Respondent's request to these distributors to destroy the Advertisements, is the basis for the final 48 counts of the Complaint." Mot., 9 (emphasis added). Such inferences are not permitted when ruling on motions for accelerated decisions.

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, a movant'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. Cmty. Technical Colls.*, No. 3:05 CV 957, 2007 WL 963178 (D. Conn. Mar. 30, 2007). As discussed in greater detail below, Complainant has failed to establish that undisputed material facts support its Motion.

If, however, the Presiding Officer determines that there are no genuine issues of material fact, then, for the reasons set forth below, Complainant's Motion must be denied as a matter of law.

II. 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).

To prevail on its Motion, Complainant must show that Respondent distributed or sold a registered pesticide with claims made for it as part of its distribution or sale that substantially differ from any claims made for it as part of the statement required in connection with its registration under section 136a. *Id.* In ruling on the Motion, the

Presiding Officer will be required to interpret the meaning of each of these four statutory phrases.

III. Based on the Facts Alleged and Legal Theories Advanced By Complainant, Respondent Did Not Offer Rozol for Sale Between November 2009 and February 2010.

A. Introduction.

FIFRA defines "to distribute or sell" to mean "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." FIFRA § 2(gg), 7 U.S.C. § 136(gg) (emphasis added).

The only allegation in Complainant's Motion regarding the distribution or sale of Rozol between November 2009 and February 2010 is that Respondent made an "offer for sale" of Rozol. *See* Mot., 11.[6] Therefore, to prevail on its Motion, Complainant must establish that there was an "offer for sale" of Rozol during this period.

This issue is critical because if the Presiding Officer concludes that Respondent did not "offer [Rozol] for sale," no violation of section 12(a)(1)(B) can be found. As stated by the EAB:

> Clearly if the additional elements of paragraph (B) are met, but no [offer for sale] . . . of a registered pesticide occurred, Pesticide Enforcement could not prove a violation and a presiding officer could not conclude that the section had been violated.

See In re Microban Prods. Co., 9 E.A.D. 674, 2001 WL 221611, at *10 (EAB 2001).

[6] Complainant has not alleged that Respondent sold or distributed Rozol during this period in violation of FIFRA, that Respondent held Rozol for sale or distribution during this period in violation of FIFRA, that Respondent shipped, held, delivered or released Rozol for shipment during this period in violation of FIFRA or that Respondent received, delivered or offered to deliver Rozol during this period in violation of FIFRA.

There is no evidence in the record and no viable legal theory upon which an "offer for sale" occurred during this period. For this reason alone, the Presiding Officer should dismiss Complainant's Motion.

B. *Tifa* Defines "Offer for Sale" Under FIFRA § 12(a)(1)(B).

Complainant admits in its Motion that the term "offer for sale" has not been defined in FIFRA nor in any regulation promulgated by EPA under FIFRA and that no relevant legislative history exists. Mot., 11; *see also Tifa*, 2000 WL 739401, at *9. Complainant dismisses *Tifa* as irrelevant to aid the Presiding Officer in determining the meaning of the term "offer for sale" as used in FIFRA. However, Complainant's characterization and dismissal of the EAB discussion of "offer for sale" in *Tifa* is misplaced and the EAB's discussion of this term is particularly relevant – and controlling – in this case.

A variation of the term "distribute or sell" is used in at least four different places in FIFRA § 12(a)(1).[7] The relevant language of FIFRA § 12(a)(1) follows:

> (1) . . . It shall be unlawful for any person in any State to **distribute or sell** to any person –
>
> > (A) any pesticide that is not registered . . . or whose registration has been cancelled or suspended, except to the extent that **distribution or sale** otherwise has been authorized by the Administrator under this subchapter;
> >
> > (B) 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 . . .;

[7] EPA's regulatory definition ensures that grammatical variations are included within the definition of to "distribute and sell." 40 C.F.R. § 152.3.

> (C) any registered pesticide the composition of which differs at the time of its **distribution or sale** from its composition as described in the statement required in connection with its registration . . .

FIFRA § 12(a)(1) (emphasis added).

Tifa examined the meaning of the term "distribution or sale" under FIFRA § 12(a)(1)(A). *Tifa*, 2000 WL 739401, at *4. This term "distribution or sale" is identical to the term that is used in the other three places in FIFRA § 12(a)(1), including FIFRA § 12(a)(1)(B), which is the section Complainant alleges that Respondent violated.

When Congress uses the same term in multiple places in the same section of a statute, a court must conclude that Congress intended to ascribe the same meaning to that term throughout that section. *Arnett Comm'r.*, 473 F.3d 790, 798 (7th Cir. 2007) (absent evidence of Congress's intent to the contrary, courts assume that Congress intended the same words used close together in a statute to have the same meaning); *Kinney ex rel N.L.R.B. v. Int'l Union of Operating Eng'rs*, 994 F.2d 1271, 1276 (7th Cir. 1993) ("we may logically assume that when Congress used the same key phrase in two provisions of one statute, lawmakers intended the words to have the same meaning"). Since the term "offer for sale" is a subset of "distribution or sale," the same meaning should be ascribed to the term "offer for sale" throughout FIFRA § 12(a)(1).

The EAB's decision in *Tifa* is the only judicial interpretation of which Respondent is aware that discusses the meaning of the term "offer for sale." Since the term "offer for sale" that was discussed in *Tifa* is the same as that used in the statutory section that Complainant alleges Respondent violated, the discussion of "offer for sale" by the EAB in *Tifa* is relevant to the case at hand.

In *Tifa*, the EAB was asked to determine if a pesticide manufacturer and distributor violated an EPA suspension order by offering its pesticide product for sale when it sent a facsimile to a potential customer stating the following: "Reference your telephone inquiry of yesterday afternoon regarding Rotenone. We are pleased to confirm our prices as follows." *Tifa*, 2000 WL 739401, at *8-9. In addition, the facsimile stated, "Prices are all delivered Missouri. Material in stock available prompt shipment." *Id.* at *9.

In effect, the complainant in *Tifa* alleged that submitting a price list to a prospective customer and stating that the product was available in response to the prospective customer's request for information about the pesticide constituted an "offer for sale."

Following an extensive analysis of contract law, including a discussion of cases and treatises, the EAB concluded in *Tifa* that "an offer must be definite and certain, and must be made under circumstances evidencing the express or implied intent of the offerer or that its acceptance shall constitute a binding contract." *Id.* (Internal citation omitted.)

According to the EAB in *Tifa,* an offer to sell must be sufficiently certain such that all the recipient needs to do is accept in order to create a binding contract. While prices are a fundamental component of an offer to sell, under the circumstances of that case, the EAB concluded that sending a published price list to a potential purchaser of the product and stating the product was available did not constitute an offer for sale and therefore no violation of FIFRA could have occurred. *Id.*

In order to determine whether certain material on Respondent's website rises to the level of an offer to sell, the Presiding Officer must examine the subject material in light of the EAB's interpretation in *Tifa*. Under the EAB's holding in *Tifa*, in order for an offer to sell to occur, a prospective buyer and seller must interact and exchange information at a

level of detail which only requires the prospective buyer to say "yes" in order to accept and form the contract. Careful analysis of Complainant's allegations in this case shows that the specific product information available on Liphatech's website that is referenced in the First Amended Complaint does not constitute an "offer to sell." S*ee generally*, CX 28, EPA 512-13; CX 28, EPA 522-32; CX 31, EPA 596. As a result, no sale or distribution of Rozol occurred as alleged in the First Amended Complaint, and no violation of FIFRA § 12(a)(1)(B) can be found. Therefore, the Motion should be denied.

Complainant alleges that the product information included on Liphatech's website, which consisted of a "Product Information Sheet" for Rozol Prairie Dog Bait, a brochure entitled "Control Range Rodents" and a "Product Information Sheet" for Rozol Pocket Gopher Bait, constituted an "offer for sale." None of this information includes any prices for the product or any other relevant terms of sale. *See generally*, CX 28, EPA512-13; CX 28, EPA522-32; CX31, EPA596. Clearly, product information without prices or other relevant terms of sale cannot constitute an "offer for sale."

In addition, Respondent's website, which is a passive website, cannot constitute an "offer for sale." The Sixth Circuit Court of Appeals has observed: "There are generally three levels of interactivity of websites, including: (1) passive sites that only offer information for the user to access; (2) active sites that clearly transact business and/or form contracts; and (3) hybrid or interactive sites that allow users to exchange information with the host computer." *See, Inc. v. Imago Eyewear Pty, Ltd.*, 167 F. App'x. 518, 522 (6th Cir. 2006) (internal citation omitted). A passive website cannot create a binding contract and therefore cannot constitute an "offer to sell."

According to the Declaration of Alan Smith of Liphatech attached hereto and incorporated herein by reference as Exhibit A, Liphatech's website is passive: website users cannot exchange information through the website, Rozol cannot be purchased on the website and the website does not include product pricing or other relevant terms of sale. Based on this fact, it is clear that Respondent's website is not an offer to sell under FIFRA. Therefore, no violation of FIFRA could have occurred even if the website material contained "differing claims."[8]

C. Complainant Misinterprets the Meaning and Scope of 40 C.F.R. § 168.22.

Having erroneously dismissed the relevance of *Tifa*, Complainant then asserts that the relevant analysis and definition of "offer for sale" is found within the language of 40 C.F.R. § 168.22(a). This section reads:

> (a) FIFRA §§ 12(a)(1)(A) and (B) make it unlawful for any person to "offer for sale" any pesticide if it is unregistered, or if claims made for it is part of its distribution or sale differ substantially from any claim made for it as part of the statement required in connection with its registration under FIFRA § 3. EPA interprets **these** provisions as extending to advertisements in any advertising medium to which pesticide users or the general public have access.

40 C.F.R. § 168.22(a) (emphasis added).

In effect, Complainant is taking the position that advertisements to which pesticide users or the general public have access automatically, without further analysis or thought, constitute an "offer for sale" under FIFRA § 12(a)(1)(B) regardless of what the statutory term "offer for sale" means. If this position prevails, Complainant will have successfully substituted a

[8] Assuming the EAB interprets the term "offer for sale" today in the same manner that it did in 2000, the EAB would conclude that an advertisement, which does not contain a price list and does not otherwise contain any of the essential elements that are necessary to create an offer, would not constitute an "offer for sale." The literature to which Complainant objects is significantly less of an "offer for sale" than was the exchange of information that occurred in *Tifa*.

word selected by the agency – "advertising" – for a statutorily mandated term – "offer for sale." Respondent does not believe that is what Congress intended.

While the Complainant dismisses *Tifa* as irrelevant because it discusses a violation alleged under § 12(a)(1)(A), the regulation which Complainant references to support its case applies to both FIFRA §§ 12(a)(1)(A) and (B). Complainant's attempt to distinguish *Tifa* is illogical based on the wording of 40 C.F.R. § 168.22(a), which was in existence prior to the EAB's decision in *Tifa*.

As mentioned above, under its expansive construction of 40 C.F.R. § 168.22(a), Complainant simply substitutes the word "advertising" for the term "offer for sale" in FIFRA § 12(a)(1)(B). This substitution of words conflicts with the intent of Congress regarding the limited scope of section 12(a)(1)(B). The precursor to section 12(a)(1)(B) was adopted by Congress in 1947 and its substance has essentially remained unchanged to this day. *See* FIFRA, P.L. 80-104, 61 Stat. 163, 166 (1947). On the other hand, when Congress amended FIFRA in 1974, it added § 12(a)(2)(E) which provides that:

> It shall be unlawful for any person . . . (E) who is a registrant . . . to **advertise** a product registered under this subchapter for restricted use without giving the classification of the product assigned to it . . . . (Emphasis added.)

FIFRA § 12(a)(2)(E) (emphasis added).

When Congress amended FIFRA in 1974 to give EPA limited authority to regulate advertising as set forth in FIFRA § 12(a)(2)(E), Congress elected not to expand the scope of section 12(a)(1)(B) to encompass advertising. Therefore, one can only assume that Congress intended EPA's regulatory control over "advertising" to be limited to those circumstances in which the "advertising" actually constitutes an "offer for sale."

In contrast to FIFRA, when Congress has intended elsewhere to grant an agency authority to regulate advertising, Congress has explicitly referenced the term "advertising." For example, in the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1331-1341., Congress states its purpose as "to deal with cigarette labeling and advertising . . . ." 15 U.S.C. § 1331. In addition, in the Federal Alcohol Administration Act, Congress states specific actions with regard to "labeling" and other actions with regard to "advertising" that are prohibited. 27 U.S.C. § 205. FIFRA is a labeling, not an advertising, statute.

In fact, when EPA promulgated 40 C.F.R. § 168.22(a), the regulation upon which Complainant relies in this case, EPA acknowledged that "FIFRA does not grant EPA plenary authority to regulate advertising and it is arguable that there can be advertising that is separate from and not a part of the distribution of a pesticide." Advertising of Unregistered Pesticides, Unregistered Uses of Registered Pesticides and FIFRA Section 24(c) Registrations, 54 Fed. Reg. 1122, 1124 (Jan. 11, 1989).

Any attempt by EPA to extend its authority beyond the statutory limits is void. *Skelly Oil Co. v. Fed. Energy Admin.*, 448 F. Supp. 16 (N.D. Okla. 1977) ("It is well settled that the authority of an administrative agency to promulgate regulations is limited by the statute authorizing the regulations, and that regulations which exceed Congressional authority are void."). By substituting the word "advertising" for the term "offer for sale," as Complainant attempts to do in its Motion, Complainant is rendering the statutory term "offer for sale" meaningless. Under Complainant's flawed reasoning, any document or information which it deems to be an "advertisement" constitutes an "offer for sale"

regardless of the breadth or scope of the term "offer for sale" as defined by any court. This cannot be the type of statutory interpretation that Congress intended.

Importantly, a basic canon of statutory construction is that "a statute should be construed so no part will be void or insignificant . . . ." *Corley v. United States*, 129 S. Ct. 1558, 1566 (2009). Moreover, an agency's interpretive rule is not binding on the Presiding Officer. *Durable Mfg. Co. v. U.S. Dept. of Labor*, 584 F. Supp. 2d 1092 (N.D. Ill. 2008) (regulations adopted pursuant to interpretive authority are not binding on the court). If EPA's interpretive rule set forth in 40 C.F.R. § 168.22(a) is given any weight by the Presiding Officer, the impact of the interpretation should be to provide public notice that advertising, in any medium, that constitutes an "offer for sale" (as that term is used in FIFRA) may constitute a violation of section 12(a)(1)(B) if the advertising contains "differing claims."

Complainant also overinflates the scope of 40 C.F.R. § 168.22. The history of this regulatory section is set forth in a proposed and final rule in the Federal Registers attached hereto as Exhibits B and C, respectively. It is clear that the intent of this section was to provide EPA's interpretation of its narrow authority to regulate advertising in five distinct and limited areas. 40 C.F.R. § 168.22(b). These narrow areas are:

1. Advertising the use of a pesticide authorized under a FIFRA Section 5 experimental use permit;

2. Advertising a pesticide for use authorized under a FIFRA Section 18 emergency exemption;

3. Advertising any pesticide for use authorized only by a FIFRA Section 24(c) special local need registration;

4. Advertising any unregistered pesticide, except in circumstances not relevant here; and

5. Advertising any registered pesticide product for an unregistered use unless the advertisement is otherwise permitted by section 2(ee).[9]

As one reviews the proposed rule published in 1986 and the final rule published in 1989, it becomes clear that the focus of this rule was to control advertising in the five narrow areas listed above. The regulation does not discuss the legal rationale as to why an "advertisement" constitutes an "offer for sale." Also, one cannot find any discussion of how Complainant reaches the conclusion that an advertisement is an "offer for sale." Just because a regulatory agency interprets an "advertisement" to be an "offer for sale," that interpretation is not binding on the Presiding Officer. *Durable Mfg. Co.*, 584 F. Supp. 2d at 1097-98.

IV. Product Information Available on Respondent's Website Did Not Make Claims For Rozol As Part of Its Sale and Distribution That Are Substantially Different Than the Statement Required in Connection With the Registration of Rozol.

If the Presiding Officer determines that Respondent "offered [Rozol] for sale" by way of certain product information appearing on its website, the Presiding Officer will need to determine if the product information available on Respondent's Website made claims for Rozol as part of the sale and distribution of Rozol that are substantially different than those submitted as part of the registration of Rozol. In order to make this determination, the Presiding Officer must answer the following legal questions:

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[9] This is further illustrated by the title of 40 C.F.R. § 168.22 which states:

> Advertising of unregistered pesticides, unregistered uses of registered pesticides and FIFRA § 24(c) registrations.

1. What is the "statement" required in connection with the registration of Rozol?

2. When does a claim "substantially differ" from claims made as part of the statement required in connection with the registration of Rozol?

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

A. <u>What is the "statement" that is required in connection with the registration for Rozol</u>?

Complainant asserts erroneously that in order for it to establish that Respondent made a claim for Rozol that is substantially different than the statement submitted as part of the registration for Rozol, one must only compare Respondent's website material with what has been "approved" by the EPA. Mot., 19. Under Complainant's construction of this statutory term, a violation would occur whenever any claim is made that has not been specifically approved by EPA for the product. Presumably, if Complainant is correct, a registrant would even be prohibited from stating the color of its product in advertising if EPA had not previously approved the claim. This severe construction of section 12(a)(1)(B) of FIFRA is: (1) not supported by the literal language of FIFRA; (2) not supported by any of the precedents cited by Complainant; and (3) is inconsistent with the text and legislative history of FIFRA.

Importantly, section 12(a)(1)(B) makes no reference to information that has been "approved" by EPA for use on the product label or in an additional statement of claims. Rather, this statutory provision simply states that claims made as part of the sale and distribution of the pesticide cannot be substantially different than the claims made for it "as part of the statement required in connection with its registration under section 136(a) of this title." FIFRA § 12(a)(1)(B). In determining whether advertising claims substantially differ from those made in "the registration statement," the materials to be considered

include, but are not limited to, the EPA approved labeling. *See Lescs v. William R. Hughes, Inc.*, No. 97-2278, 1999 U.S. App. LEXIS 475, at 28 (4th Cir. 1999).

Section 3(c)(1) of FIFRA defines the statement required to be submitted in connection with the registration of a pesticide 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 . . . .[10]

FIFRA § 3(c)(1) (emphasis added). 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 a pesticide product as part of its sale or distribution are substantially different. The registration statement required by FIFRA

[10] 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.

section 3(c)(1) must include "a full description of the tests made and the results thereof . . . or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator. . . . " FIFRA § 3(c)(1)(F), 7 U.S.C. § 136a(c)(1)(F).

Complainant's interpretation of section 12(a)(1)(B) of FIFRA is illogical because, for the vast majority of pesticide products, EPA has waived the requirement that registrants submit efficacy data. Nevertheless, Congress expected that pesticide manufacturers would continue to inform their distributors and purchasers and users of their pesticides about the efficacy of their products. *See, e.g.*, S. Rep. No. 95-334, at 65 (1977) (indicating EPA's expectation that efficacy information would continue to be used in advertising despite the waiver regarding efficacy data).[11]

Even if Congress granted EPA authority to regulate some "advertising" material, that grant of authority falls far short of controlling the type of literature that is the subject of the Motion. While the literature described in Counts 2,184 through 2,231 of the First

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[11] EPA utilized its discretion under FIFRA section 3(c)(5) to waive any requirement to submit efficacy data for most pesticide products. 40 C.F.R. § 158.400(e)(1) states:

> The Agency has waived the requirement to submit product performance data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user. However, each registrant must ensure through testing that his product is efficacious when used in accordance with the label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration.

Legislative history also explains Congress's rationale in waiving the efficacy data requirement:

> Because of the large amounts of efficacy data which are on file, considerable resources would have to be dedicated to complete validation of those tests. EPA believes that except for public health and disinfectant type products, the user community can best judge a product's efficacy, based on local conditions and pest resistance. Because of this and because a manufacturer would not find it in his best interests to go to the expense of registering a product which did not work, public resources can be most effectively put to use in hazard rather than efficacy evaluation of products other than public health/disinfectant uses.

S. Rep. No. 95-334 at 47 (1977).

Amended Complaint is "advertising" in a general sense, the literature is not the type of advertising that is subject to 40 C.F.R. § 168.22.

As discussed in the December 3, 2010 Declaration of Carl Tanner, information provided on Liphatech's website is intended to educate and inform individuals about Liphatech's products, not to induce or create sales or distribution of the product. A previous court concluded that such material distributed to a company's distributors to aid them in educating salespersons to solicit purchase orders for the company's product is not advertising. *See Int'l Ins. Co. v. Florists' Mut. Ins. Co.,* 559 N.E.2d 7, 10 (Ill. App. Ct. 1990).

Moreover, if Complainant's interpretation of section 12(a)(1)(B) that all advertisements must be approved by the EPA is upheld, every pesticide registrant in the United States would be required to supply EPA with its efficacy data along with a detailed statement of the claims based on the efficacy data for approval by the EPA.[12] This is not the way the EPA operates. As explained in the Declaration of James Aidala attached hereto and incorporated herein by reference as Exhibit D, at the time that Congress adopted the 1978 amendments to FIFRA which authorized the waiver of filing efficacy data, Congress was concerned about the slow pace of the re-registration and the waiver allowed EPA staff to devote more time to critical matters. EPA's interpretation of section 12(a)(1)(B), if adopted, would result in an avalanche of submissions to EPA of advertising for approval. *See* James Aidala Decl., attached hereto as Exhibit D.

Indeed, EPA does not operate today the way Complainant suggests. As set forth on the Declaration of Henry M. Jacoby attached hereto and incorporated herein by reference

[12] Such a requirement would inundate EPA with advertising material and supporting data and essentially negate EPA's waiver regarding efficacy data.

as Exhibit E, EPA does not routinely review or approve advertising claims for pesticides. Complainant's assertion that some registrants include alternative marketing claims for use on the product label (Mot., 18) does little to support its position on EPA's authority to regulate advertising.

Complainant's incorrect interpretation of section 12(a)(1)(B) can also be illustrated by reviewing FIFRA § 2(ee), 7 U.S.C. § 136(ee), which allows the use of a registered pesticide "against any target pest not specified on the labeling" unless otherwise restricted by EPA. 40 C.F.R. § 168.22(b)(5) specifically permits this use to be advertised as long as the advertisement is one permitted by 40 C.F.R. § 168.22(b)(2) or (3) and is not an antimicrobial pesticide targeted against human pathogens. 40 C.F.R. § 168.22(b)(5) states as follows:

> (b) EPA regards it as unlawful . . . to plan or sponsor advertisements which recommend or suggest the purchase or use of:
>
> (5) A registered pesticide product for an unregistered use, unless the advertisement is one permitted by paragraph (b)(2) or (3) of this section. However, 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.

40 C.F.R. § 168.22(b)(5).

Thus, under Complainant's expansive interpretation of FIFRA § 12(a)(1)(B), a pesticide manufacturer cannot make any claim for the use of a pesticide in advertising that is permitted by FIFRA § 2(ee) unless it submitted the advertising claim on that use along with supporting data to the EPA for approval. This interpretation is directly contrary to the specific wording of 40 C.F.R. § 168.22(b)(5) and further illustrates the illogic of Complainant's position.

Moreover, it would be illogical for Complainant to argue that a use that is not specified on the label can be advertised pursuant to 40 C.F.R. § 168.22(b)(5) without EPA approval, yet any claim made for a product, such as a claim that Rozol is effective in a single application,[13] cannot be made unless it is approved by the EPA. Such an assertion is absurd.

In construing section 12(a)(1)(B), the Presiding Officer must read FIFRA as a whole and avoid interpretations that would produce absurd results. *Compton Unified Sch. Dist. v. Addison*, 598 F.3d 1181 (9th Cir. 2010) ("In construing a statute, courts read the statute as a whole and avoid interpretations that would produce absurd results"). Clearly, Congress could not have intended the absurd result that would occur if Complainant's aggressive position is upheld.

B. When is a claim "substantially different" than the statement required as part of the product's registration?

If the Presiding Officer concludes that Respondent offered Rozol for sale on its website despite the fact that the website did not contain the price of Rozol or any other pertinent terms of sale, and despite the fact that Respondent's website is passive (i.e., Rozol cannot be purchased on the website), the Presiding Officer will be required to determine if any statements made by Respondent on its website are "substantially different" than the statement required in connection with the registration of Rozol. FIFRA, EPA's regulations and the pertinent legislative history do not provide meaningful guidance on when a claim is "substantially different."

[13] Assuming this claim is supported by research studies submitted to the EPA that support its single application effectiveness, EPA's review and support of those studies and the approved directions for use for Rozol, *see* generally RX 1-11, Exhibit F attached hereto.

The only legal support Complainant cites for its broad interpretation of FIFRA section 12(a)(1)(B) is an order issued *In re: Microban Products Company*, No. FIFRA-98-H-01, 1998 EPA ALJ LEXIS 9, at *17 (ALJ Apr. 3, 1998) ("*Microban*"). 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."

Microban at 17-18.

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

Microban involved a product that had been registered "as . . . effective only against non-health related organisms. . . ." *Id.* at *4. In fact, EPA alerted the respondent in *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 *Microban*, the complainant showed that the respondent 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.

These types of health-related claims are specifically the type of claims prohibited by 40 C.F.R. § 168.22(b)(5). In addition, as mentioned above, prior to bringing the enforcement action against the respondent in *Microban*, the EPA had sent a letter to the company warning it that these claims were not permitted. Therefore, it was easy for the presiding officer in *Microban* to refer to the notice of pesticide registration as the "base line" from which to judge violations of section 12(a)(1)(B). This is because in *Microban*,

the respondent was making claims that its pesticide was effective against a pest for which use of the product was not allowed.

While the company in *Microban* made claims about its product for use against an unapproved pest, Respondent's statements that are the subject of the Motion regarding Rozol involved the characteristics of Rozol when used to control the pest which EPA approved it to control. According to Henry Jacoby, a long-time former EPA employee and pesticide registration expert, the appropriate standard that the EPA uses for judging advertising material is the entire registration statement. This statement includes all of the studies, documents and data generated for the product, not simply the "accepted label," as erroneously asserted by Complainant. *See* Jacoby Decl., attached hereto and incorporated herein by reference as Exhibit E.

As discussed above, Complainant has offered an 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 because Complainant has incorrectly interpreted the scope of the word "statement." On this basis alone, the Motion should be denied.

1. Respondent's Website Did Not Contain "Substantially Different" Claims.

If the Presiding Officer does not deny the Motion on the basis of Complainant's application of an incorrect legal standard, none of the statements made by Respondent on its website were "substantially different" than that submitted as part of the registration statement.[14] Therefore, the Motion should be denied.

[14] The term "substantially different" has not been defined in FIFRA or in any regulation promulgated by EPA under FIFRA or by any court or tribunal.

When a statute, regulations, legislative history and existing case law do not define a term, courts typically refer to the plain meaning of the word. *In re Bil-Dry Corp.*, 9 E.A.D. 575, 595, 2001 WL 59296 (EAB 2001). According to the Merriam-Webster dictionary, "substantially" means "being largely but not wholly that which is specified." Merriam-Webster Dictionary, Definition of Substantial, link http://www.merriam-webster.com/dictionary/substantial (last visited Feb. 11, 2011). "Different" is defined by the same dictionary to mean "partly or totally unlike in nature, form, or quality....different may imply little more than separateness but it may also imply contrast or contrariness" Merriam-Webster Dictionary, Definition of Different, link http://www.merriam-webster.com/dictionary/different (last visited Feb. 11, 2011). Therefore, in order to be substantially different, the material must be largely or totally unlike (or contradictory to) the material submitted as part of the registration for Rozol.

As shown on the spreadsheet attached hereto and incorporated herein by reference as Exhibit F, all of the allegedly violative statements found on Respondent's website that are the subject of the Motion are supported by Liphatech's registration materials and other publicly available information and are therefore not substantially different or false or misleading.

In addition, EPA's own documents support the statements regarding Rozol made by Respondent. For example, the EPA's Response to the World Wildlife Fund Petition attached hereto and incorporated herein by reference as Exhibit G discusses the benefits of Rozol in comparison to zinc phosphide as well as the reduced labor requirements associated with applying Rozol. Similarly, the document entitled "Benefits Assessment for Chlorophacinone Used to Control Black-Tailed Prairie Dogs" attached hereto and

incorporated herein by reference as Exhibit H discusses the relative costs, benefits and toxicity profile of Rozol. [15]

2. EPA's Authority Under § 12(a)(1)(B) Should Be Interpreted Narrowly.

Importantly, if there are any questions regarding the interpretation of section 12(a)(1)(B) of FIFRA, a narrow interpretation should be adopted to avoid a construction that would violate the First Amendment. A broad interpretation of the statute would infringe substantially on the right of pesticide registrants, distributors and retailers to constitutionally-protected commercial speech. *See United States ex rel. Attorney Gen. v. Delaware & 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.").

By seeking to restrain and sanction truthful educational material, Complainant offers a construction of FIFRA that is more expansive than necessary to serve the governmental interest. *See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 566 (1980). EPA has also acknowledged that its regulation is subject to scrutiny under the First Amendment. Pesticide Advertising, 51 Fed. Reg. 24393at 24395 (proposed July 3, 1986). The Presiding Officer may reasonably adopt a construction of FIFRA that is supported by its legislative history which will not infringe on

[15] Because the material attached hereto as Exhibit G and Exhibit H was not in Respondent's possession at the time Respondent filed its pre-hearing exchange, Respondent intends to file a first supplemental pre-hearing exchange including these materials.

the First Amendment rights of pesticide manufacturers to truthfully advertise their products.

A plausible interpretation of section 12(a)(1)(B) would not prohibit truthful claims from being made in advertising if such claims do not inherently conflict with the product label.

3. EPA's Regulations Regarding Pesticide Misbranding Are Not Relevant to This Motion.

In addition, as an apparent attempt to bolster its position, or confuse the Presiding Officer, Complainant repeatedly references regulations promulgated by EPA to determine if a pesticide is misbranded and erroneously asserts that these regulations have a bearing on FIFRA § 12(a)(1)(B). *See, e.g.,* Mot. 19-20 (citing 40 C.F.R. § 156.10(a)(5)). These references, however, are only Complainant's attempt to equate "advertising" with "labeling." The Presiding Officer has already granted Complainant leave to amend the Complaint to remove all allegations in the Complaint that Rozol was misbranded – the only statutory section to which 40 C.F.R. § 156.10(a)(5) applies.

C. Were claims made as part of the sale and distribution of Rozol?

If the Presiding Officer finds that Respondent's website material constitutes an offer for sale that contained differing claims, then the Presiding Officer must determine whether the differing claims were made as part of the distribution or sale of Rozol. A nexus must exist between the unapproved claims and the distribution or sale of the pesticide, particularly in determining the number of violations. *Microban Prods. Co.*, 9 E.A.D. at 688.

Complainant attempts to circumvent this requirement by asserting erroneously that advertising constitutes an offer for sale under FIFRA and since an offer for sale is defined as a sale or distribution of the product, no further nexus must be shown. *See* Mot., 15-16.

Complainant, however, has not established any link between the website and any of Respondent's 48 distributors. Complainant asks the Presiding Officer to infer that these distributors received the material because Respondent sent letters to them requesting that whatever product literature was in their possession be destroyed following EPA's issuance of a SSURO to Liphatech. Complainant has shown no connection between the literature available on Respondent's website and the 48 distributors. There is no evidence in the record that supports Complainant's inference and Complainant has not even alleged that any of the 48 distributors ever looked at Respondent's website, much less the specific pages of the website that are alleged to have violated section 12(a)(1)(B) of FIFRA.

Judgment for Complainant where contradictory inferences may be drawn from the evidence and where Complainant has cited absolutely no support for its assertion of 48 violations of section 12(a)(1)(B) would be inappropriate. *Rogers Corp.*, 275 F.3d at 1103.

V. **Conclusion.**

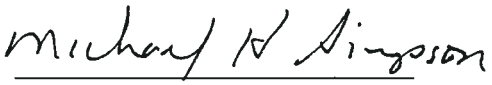
Based on the pleadings, evidence submitted and testimonial declarations on file, the Motion must be denied. For several of Complainant's conclusory statements and erroneous assertions that are discussed above, Complainant has not introduced any supporting admissible evidence. In addition, genuine issues 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 all of these reasons, the Motion should be denied in its entirety.

Dated this 11th day of February, 2011.

Respectfully submitted,

Reinhart Boerner Van Deuren s.c.
1000 North Water Street, Suite 1700
Milwaukee, WI 53202
Telephone: 414-298-1000
Facsimile: 414-298-8097

Mailing Address:
P.O. Box 2965
Milwaukee, WI 53201-2965



Michael H. Simpson
WI State Bar ID No. 1014363
msimpson@reinhartlaw.com
Jeffrey P. Clark
WI State Bar ID No. 1009316
jclark@reinhartlaw.com
Lucas N. Roe
WI State Bar ID No. 1069233
lroe@reinhartlaw.com
Attorneys for Respondent Liphatech, Inc.

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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, information 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 First Amended Complaint.

4. For all time periods relevant to the First Amended Complaint, Liphatech's website has been and is a passive website that only offers educational information to visitors to the site. Rozol can not be purchased on the website and the website can not be used to transact business. The website does not allow users of the site to exchange information with the host computer.

5. Liphatech's website does not contain an electronic price list for Rozol or other relevant terms of sale for Rozol.

6. The observations and statements I make in this declaration are truthful.

7. 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, information and belief.

[SIGNATURE PAGE FOLLOWS]

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

Executed on February 10, 2011.

Alan Smith

Alan Smith

REINHART\6039789