# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 5

In the Matter of:	) Docket No. FIFRA-05-2010-0016
Liphatech, Inc. Milwaukee, Wisconsin,	) ) MOTION OF RESPONDENT TO ) PARTIALLY DISMISS THE
Respondent.	) COMPLAINT OR IN THE ) ALTERNATIVE FOR PARTIAL
DECEIVEM	) ACCELERATED DECISION ON
REGEIVEIII	) AN ISSUE OF LIABILITY IN ) FAVOR OF RESPONDENT
SEP 17 2010	) WITH RESPECT TO THE
REGIONAL HEARING CLERK U.S. ENVIRONMENTAL PROTECTION AGENCY	) ALLEGED VIOLATIONS OF ) § 12(a)(1)(E) OF FIFRA )

Respondent, Liphatech, Inc. ("Respondent"), respectfully moves, pursuant to Sections 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, codified at 40 C.F.R. Part 22, for the Administrative Law Judge to partially dismiss the Complaint or in the alternative to render a partial accelerated decision on an issue of liability in favor of Respondent with respect to the alleged violations of § 12(a)(1)(E) of FIFRA set forth in the Complaint, as the Complaint fails to plead a *prima facie* case, there is no genuine issue as to any material fact and Respondent is entitled to judgment as a matter of law.

This Motion is supported by the attached Legal Memorandum of Respondent and Affidavit of Alan Smith.

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### Respectfully submitted this 16th day of September, 2010.

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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,	) ) LEGAL MEMORANDUM OF ) RESPONDENT IN SUPPORT OF
Respondent.  REP 1 7 2010	<ul> <li>ITS MOTION TO PARTIALLY</li> <li>DISMISS THE COMPLAINT OR</li> <li>IN THE ALTERNATIVE FOR</li> <li>PARTIAL ACCELERATED</li> <li>DECISION ON AN ISSUE OF</li> <li>LIABILITY IN FAVOR OF</li> </ul>
REGIONAL HEARING CLERK U.S. ENVIRONMENTAL PROTECTION AGENCY	<ul> <li>DIABILITY IN FAVOR OF</li> <li>RESPONDENT WITH RESPECT</li> <li>TO THE ALLEGED VIOLATIONS</li> <li>OF § 12(a)(1)(E) OF FIFRA</li> </ul>

#### Introduction

Demonstrating how a regulator can carry its zeal too far, Complainant seeks exorbitant penalties for nonexistent violations of the Federal Insecticide Fungicide and Rodenticide Act ("FIFRA"). Among other things, Complainant erroneously asserts that Respondent Liphatech, Inc. ("Liphatech") sold or distributed pesticides that were allegedly misbranded in violation of FIFRA §§ 12(a)(1)(E) and 2(q)(1)(A). A pesticide can only be misbranded under § 2(q)(1)(A) of FIFRA, however, if its <u>labeling</u> bears a statement which is false or misleading.

Nowhere in the 649 paragraph Complaint does the Complainant allege that any of the statements made by Liphatech in its advertising constitute "labeling" as

<sup>&</sup>lt;sup>1</sup> For ease of reference, these alleged violations are sometimes referred to herein as the "misbranding allegations."

that term is defined under FIFRA. As such, those portions of the Complaint asserting that Liphatech allegedly violated FIFRA § 12(a)(1)(E) are without proper foundation and should be dismissed as a matter of law.

These allegations cannot state a claim upon which relief can be granted, because Complainant has failed to plead all the material elements necessary to establish the alleged violations of FIFRA § 12(a)(1)(E). Early dismissal of these legally insufficient allegations will serve the interests of judicial economy and justice and will expedite this proceeding. For example, if it is determined that Liphatech's advertising materials are not "labeling," 87 full paragraphs and a portion of 44 paragraphs of the Complaint must be dismissed. See Exhibit A attached hereto for a complete list of the paragraphs of the Complaint and portions thereof that must be dismissed.

In the alternative, if it is determined that Complainant has met its burden to plead all of the elements necessary to establish its FIFRA § 12(a)(1)(E) prima facie case, then Liphatech respectfully requests a partial accelerated decision on the issue of liability in favor of Liphatech with respect to all alleged misbranding violations. As a matter of law, none of Liphatech's advertising materials constitutes "labeling" under FIFRA. Therefore, Liphatech's advertisements could not have caused its pesticide<sup>2</sup> to be misbranded. Prehearing dismissal of these

<sup>&</sup>lt;sup>2</sup> Complainant alleges in various portions of the Complaint that Liphatech's Rozol Pocket Gopher Bait II (Alternate Name: Rozol Pocket Gopher Bait Burrow Builder Formula), EPA Reg. No. 7173-244 and Rozol Prairie Dog Bait, EPA Reg. No. 7173-286, were misbranded. For purposes of this Motion, it is not necessary to differentiate between Rozol Pocket Gopher Bait II and Rozol Prairie Dog Bait. As a result,

fatally flawed allegations will streamline this case and conserve the resources of this tribunal and the parties by again eliminating numerous paragraphs from the Complaint.

#### **Background**

Liphatech is a pesticide manufacturer located in Milwaukee, Wisconsin. It is one of the many pesticide manufacturers that produce pesticides formulated to control rodents. Two of the rodenticides manufactured by Liphatech – Rozol Prairie Dog Bait and Rozol Poket Gopher Bait II – are the subject of the Complaint.

Liphatech sells its restricted use products to licensed pesticide distributors who in turn sell the products to other licensed dealers or directly to users that must, by law, also possess a valid Certified Applicator's license. Rozol Prairie Dog Bait and Rozol Pocket Gopher Bait II are restricted use pesticides that may only be sold to trained professionals who possess a Certified Applicators license. In Liphatech's case, the Certified Applicators who purchase and use these products are scattered throughout the western United States.

Like any business with a limited marketing budget in an extremely competitive industry, Liphatech identifies, educates and connects with its customer base through advertising. It targets its marketing effort by advertising on small radio networks and in niche trade journals. In addition, Liphatech invests in

Liphatech sometimes refers to Rozol Pocket Gopher Bait II and Rozol Prairie Dog Bait as the "pesticide" or "pesticides" in this Motion.

product research and efficacy studies to support the registration of its pesticides and enhance its promotional materials.

Among other things, Complainant erroneously asserts that Liphatech sold or distributed a misbranded pesticide because certain advertising literature for the pesticide, including radio broadcasts, print literature and literature posted on a website, was allegedly false and misleading. *See e.g.* Compl. at ¶¶ 148, 201, 208, 473. These allegations are incorrect, are legally insufficient and should be dismissed as a matter of law.

FIFRA prohibits distributing or selling to any person any pesticide that is misbranded. FIFRA § 12(a)(1)(E). A pesticide is misbranded if its <u>labeling</u> bears any statement, design or graphic representation relative thereto which is false or misleading. FIFRA § 2(q)(1)(A).

Section 2(p) of FIFRA defines labeling, subject to several exceptions that are irrelevant to this Motion, as follows:

### (p) Label and Labeling

- (1) Label. The term 'label' means the written printed or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.
- (2) Labeling. The term 'labeling' means all labels and all other written, printed, or graphic matter-
- (A) accompanying the pesticide or device at any time; or

(B) to which reference is made on the label or in literature accompanying the pesticide or device . . . . <sup>3</sup>

Advertising material, therefore, can only cause a pesticide to be misbranded under §§ 12(a)(1)(E) and 2(q)(1)(a) of FIFRA, as alleged by Complainant, if the advertising material (a) is either a "label" or "labeling" under FIFRA and (b) is false or misleading. However, nowhere in its 649 paragraph Complaint does the Complainant allege that Liphatech's advertising was either a "label" under section 2(p)(1) of FIFRA or "labeling" under section 2(p)(2) of FIFRA.

Liphatech's advertising materials were not and could never have been a "label" under § 2(p)(1) of FIFRA, because these materials were never attached to the pesticide or any of its containers or wrappers. The Affidavit of Alan Smith, Liphatech's Business Director, Agricultural Division, attached hereto as Exhibit B, establishes that the advertising materials in question were never attached to the pesticides. Smith Aff., ¶ 4.

Complainant does not allege the predicate facts necessary to show that Liphatech's advertising materials are "labeling" under § 2(p)(2) of FIFRA, nor does it ever assert the legal conclusion that these materials are "labeling." For example, there is no assertion in the Complaint that the advertising materials in question ever accompanied the pesticide or were referenced on the pesticide label or in literature accompanying the pesticide. Apart from this, Liphatech's

<sup>&</sup>lt;sup>3</sup> Complainant has paraphrased the definition of "labeling" in the Complaint in an inaccurate manner. Complainant suggests that labeling is defined, in pertinent part, as all labels and all other written printed or graphic matter. Compl. at ¶ 17; Answer To Compl. at ¶ 17. Any such suggestion is mistaken.

advertising materials cannot be "labeling" under the statutory definition for the following reasons:

- (a) Complainant bases some of the alleged misbranding violations on Liphatech's radio ads. This advertising cannot be "labeling" because a radio advertisement is not "written, printed, or graphic matter" as required under § 2(p)(2) of FIFRA.
- (b) The other advertising on which Complainant bases its misbranding violation allegations is written material; however, this material
- (i) did not "accompany" the pesticides at any time, as required by § 2(p)(2)(A) of FIFRA, and
- (ii) was not referenced on the label or in the literature accompanying the pesticide, as required by § 2(p)(2)(B) of FIFRA.

As a result, the Complainant's "labeling" allegations against Liphatech are legally insufficient, fail to state a claim upon which relief can be granted and must be dismissed as a matter of law.

#### Argument

I. As the Complaint fails to allege that Liphatech's radio spots, print literature and website literature are labels or labeling under FIFRA, those portions of the Complaint alleging misbranding violations fail to state a claim upon which relief can be granted and must be dismissed as a matter of law.

The Complaint fails to allege a critical element of a claim for relief for misbranding: that Respondent's radio spots, print literature and website are "labels" or "labeling" under FIFRA.

Section 22.20(a) of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (the "Consolidated Rules") states in pertinent part that:

The Presiding Officer, upon motion of the respondent, may at any time dismiss a proceeding without further hearing or upon such limited additional evidence as he requires, on the basis of failure to establish a prima facie case or other grounds which show no right to relief on the part of the complainant.

40 C.F.R. § 22.20(a).

Motions to dismiss under Section 22.20(a) of the Consolidated Rules are analogous to motions to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure ("FRCP"). *In re Bug Bam Prod., LLC v. Flash Sales, Inc.*, Docket No. FIFRA-09-2009-0013, 2010 WL 1816755, at \*2 (ALJ Apr. 23, 2010). Dismissal is warranted for failure to state a claim when the plaintiff fails to lay out allegations respecting all the material elements necessary to sustain recovery under its legal theory. *Id.* (citing *Bell Atl. Corp v. Twombly*, 550 U.S. 544, 562 (2007)).

For purposes of a motion to dismiss, the allegations contained in the Complaint are assumed to be true. Conclusory allegations and unwarranted deductions of fact, however, are not admitted as true. *Id.* (citing *Associated Builders, Inc. v. Ala. Power Co.*, 505 F.2d 97, 100 (5th Cir. 1974)).

In this case, even assuming that all of the alleged facts asserted in the Complaint are true, such assumed facts still do not establish a misbranding violation. This is because Complainant has not alleged facts sufficient to show

that Liphatech's radio broadcasts, print literature and website literature are either "labels" or "labeling" under FIFRA.

Complainant does not allege that Liphatech's advertising materials are part of the product label. Complainant does not allege that Liphatech's advertising materials were attached to the product. Complainant does not allege that the advertising materials accompanied the pesticide. Complainant does not allege that the advertising materials are referenced on the product label or in literature accompanying the pesticide.

In order to establish that material is either a "label" or "labeling" under FIFRA, Complainant must allege sufficient facts in the Complaint to establish these legal conclusions. Absent these predicate facts, the Complaint fails to plead elements necessary to obtain relief. Therefore, Complainant has not met its burden to plead a prima facie case with respect to the alleged misbranding violations of FIFRA. As a result, those paragraphs or portions of paragraphs in the Complaint that allege misbranding violations must be dismissed as a matter of law. (Please see the attached Exhibit A for a list of the relevant paragraphs.)

II. Alternatively, if Complainant is determined to have alleged sufficient facts to withstand Respondent's Motion to Partially Dismiss the Complaint, the alleged misbranding violations must still be dismissed as a matter of law.

Section 22.20(a) of the Consolidated Rules authorizes the Administrative Law Judge to "render an accelerated decision in favor of a party as to any or all parts of the proceeding, without further hearing or upon such limited additional

evidence, such as affidavits, as he may require, if no genuine issue of material fact exists and a party is entitled to judgment as a matter of law." 40 C.F.R. § 22.20(a).

Motions for accelerated decision under Section 22.20(a) of the Consolidated Rules are treated as motions for summary judgment under Rule 56 of the FRCP. See In re Behnke Lubricants, Inc., No. FIFRA-05-2007-0025, 2008 WL 711033 (ALJ Mar. 5, 2008). A party moving for accelerated decision must establish the absence of genuine issues of material fact and that it is entitled to judgment as a matter of law by a preponderance of the evidence. Id. at \*18. "[A] party opposing a properly supported motion for accelerated decision must demonstrate the existence of a genuine issue of material fact by proffering significant probative evidence from which a reasonable presiding officer could find in that party's favor by a preponderance of the evidence." Id.

As set forth above, FIFRA prohibits distributing or selling a pesticide if its "label" or "labeling" bears any statement that is false or misleading. FIFRA  $\S\S 12(a)(1)(E)$ , 2(q)(1)(A). Written material can be a "label" only if it is attached to the pesticide or any of its containers or wrappers. None of Liphatech's written material meets this standard. Smith Aff.,  $\P 4$ .

Written material may be considered "labeling" under FIFRA only if: (1) it accompanies the product at any time; or (2) it is referenced on the label or in literature accompanying the label. FIFRA § 2(p)(2).

Therefore, Liphatech's advertising material can only qualify as "labeling" if it is written, printed or graphic matter and it either (i) accompanied the pesticide

or (ii) is referenced on the label or in material accompanying the label. A portion of the advertising material upon which Complainant bases its misbranding allegations was not written, printed or graphic material and therefore cannot be labeling. The remaining advertising material that was in a written form is not labeling because it did not accompany the pesticide and was not referenced on the product label approved by EPA.

A. <u>Broadcast advertisements are not written, printed or graphic matter and therefore cannot be labeling under FIFRA</u>.

Complainant asserts in paragraphs 201 and 204 of the Complaint that Liphatech's spoken radio broadcasts caused the pesticide to be misbranded. The definition of labeling in FIFRA § 2(p), however, clearly states that only written, printed or graphic matter can be labeling. An oral broadcast advertisement could never satisfy this definition because a radio broadcast is not written, printed, or graphic matter.

Complainant's assertion that spoken radio advertisements could cause a pesticide to be misbranded is clearly contrary to FIFRA. Therefore, paragraphs 201 and 204 must be stricken from the Complaint as a matter of law.

B. <u>Because Liphatech's print advertisements and website</u>
<u>literature did not "accompany" the pesticide and were not referenced on the label,</u>
<u>they cannot constitute labeling under FIFRA.</u>

Liphatech's written advertising material and website literature that is the subject of the Complaint could only be "labeling" under FIFRA if the advertising material "accompanied" the pesticide, or if the advertising material is referenced

on the label. None of the advertising material at issue in this proceeding is referenced on the EPA-approved label for Rozol or Rozol Prairie Dog Bait. Smith Aff.,  $\P$  6. The only remaining inquiry is whether the advertising material ever "accompanied" the pesticide within the meaning of FIFRA § 2(p)(2)(a).

In *Sporicidin International*, the Environmental Appeals Board stated that "the term 'labeling' refers to written, printed or graphic material that <u>physically</u> accompanies but is not attached to the pesticide or its wrapping." *In re Sporicidin In'l*, 3 E.A.D. 589, 1991 WL 155255, at \*1 n.2 (EAB June 4, 1991) (emphasis added). EPA has previously taken the position that promotional material distributed to the public apart from the pesticide is not considered labeling. In a letter dated May 18, 1984, Ms. Juanita Wills, then Chief of the Disinfectants Branch in EPA's Office of Pesticide Programs, stated:

First it should be noted that the Agency does not regulate advertising per se. Advertising of a pesticide product becomes subject to FIFRA only if the advertisement comes within the meaning of labeling because it accompanies the product as it is sold or distributed ... Promotional material distributed to the public apart from the pesticide product, is not considered labeling..."

In re Sporicidin Int'l, No. 88-H-02 1988 WL 236319 \*14 n. 31(ALJ Nov. 1, 1988) aff'd 3 E.A.D. 589.

Liphatech's advertising material was distributed to the general public apart from the product and did not physically accompany the pesticide through distribution. Smith Aff ¶¶ 4, 5 and 8. As such, Liphatech's advertising material is

not labeling under FIFRA and, therefore, could not have caused the pesticide to be misbranded.

Several federal court decisions evaluating the potential federal preemption of state law by FIFRA have interpreted the definition of "labeling" to include written material that does not physically accompany a pesticide when the written material is an essential supplement to or explanation of the product label that is designed to be read and followed by the end user. See Indian Brand Farms, Inc. v. Novartis Crop Prot. Inc., ---F.3d---, 2010 WL 3122815, at \*5 (3d Cir. 2010); Lowe's Home Ctrs., Inc. v. Olin Corp., 313 F.3d 1307 (11th Cir. 2002); Chem. Specialties Mfrs. Ass'n, Inc. v. Allenby, 958 F.2d 941 (9th Cir. 1992); NY State Pesticide Coal., Inc. v. Jorling, 874 F.2d 115 (2d Cir. 1989). Although these federal preemption decisions have no binding effect in this proceeding, even under the inclusive definition of "labeling" adopted in these cases, Liphatech's advertising materials are not "labeling" and, therefore, could not have caused the pesticide to be misbranded.

FIFRA provides that states may regulate the sale and use of registered pesticides, but states may not impose any requirement on pesticide "labeling" in addition to or different from that required by FIFRA. FIFRA § 24. Accordingly, FIFRA preempts state law if the state law imposes a labeling requirement different from or in addition to that required under FIFRA.

Each of these FIFRA preemption cases rely to some degree on the U.S. Supreme Court decision in *Kordel v. United States*, 335 U.S. 345 (1948), in

which the Supreme Court held that under the Federal Food, Drug and Cosmetic Act ("FFDC Act") written information could be "labeling" even if it did not physically accompany the product. The FFDC Act prohibits introducing misbranded products into interstate commerce. A product is misbranded under the FFDC Act if its labeling is false and misleading. The term "labeling" under the FFDC Act includes all written material "accompanying" the product.

The unique facts in the *Kordel* case led the Supreme Court to its decision. In that case, a manufacturer distributed a product, but its packaging contained no directions on how to use the product. *Id.* at 348. Separate from the distribution of the product, the manufacturer distributed literature that contained directions for use that were false and misleading. *Id.* at 347-49. The Supreme Court was concerned that if this separate literature was determined not to be labeling, it would create a wide loophole under the FFDC Act because then

drugs would be misbranded if the literature had been shipped in the same container but not misbranded if the literature left in the next or in the preceding mail.... Accordingly, we conclude the phrase 'accompanying such article' is not restricted to labels that are on or in the article or package that is transported."

*Id.* at 349. The Supreme Court concluded that the literature and product were interdependent and stated:

One article or thing is accompanied by another when it supplements or explains it . . . No physical attachment one to the other is necessary. It is the textual relationship that is significant. *Id.* at 350.

The applicability of the *Kordel* decision to pesticide products registered under FIFRA is questionable, because the label on the product packaging in that

case contained no directions for use. EPA may only register a pesticide product if it determines that the "labeling and other material required to be submitted comply with the requirements of [FIFRA]," FIFRA § 3(c)(5)(B), and product labeling is violative of FIFRA if it "does not contain directions for use which are necessary for effecting the purpose for which the product is intended." FIFRA § 2(q)(1)(f). Nevertheless, several federal courts have considered the interpretation of "accompany" under the FFDC Act in *Kordel* as part of their construction of the word "accompany" under FIFRA.

In *Jorling*, for example, the U.S. Court of Appeals for the Second Circuit was asked to decide whether a state law that required pesticide applicators to place notification materials in locations where pesticides are being applied imposed a "labeling" requirement that was preempted by FIFRA because the materials "accompanied" the pesticide under § 2(p)(2)(A) of FIFRA. *Jorling*, 874 F.2d 115. The federal preemption question turned on whether the state-mandated notification materials were "labeling" under FIFRA because the materials were coincidentally present in the same location as the pesticide and therefore "accompanied" the pesticide. Following the reasoning in *Kordel*, the court in *Jorling* said that the term "labeling" is better understood by its relationship, rather than proximity to the product. *Id.* at 119. The court concluded that written material aimed at the general public that was not designed to be read and followed by the end user of the product was not "labeling." *Id.* The *Jorling* court stated:

FIFRA "labeling" is designed to be read and followed by the end user. Generally, it is conceived as being attached to the immediate container of the product in such a way as it can be expected to remain affixed during the period of use. *Id*.

The court in *Jorling* also reviewed a letter from the EPA which stated that interpreting the word "accompanies" in terms of physical presence would result in clearly extraneous material being considered labeling and stated that

"[L]abeling" comprises those materials designed to accompany the product through the stream of commerce to the end user, but not those designed to notify purchasers of services or the general public. *Id.* at 120.

Another federal court, the U.S. Court of Appeals for the Ninth Circuit, also found that warnings that a manufacturer was required to give under California's Proposition 65 did not constitute "labeling" under FIFRA. *Chem. Specialties Mfrs. Ass'n, Inc.*, 958 F.2d 941. The court relied heavily on the reasoning in the *Jorling* case to reach its decision. This court also distinguished the U.S. Supreme Court's decision in *Kordel* stating that (i) the literature involved in *Kordel* was aimed at the ultimate user of the product, (ii) the literature contained directions for use that were required to be on the label, but were not and (iii) the context of the manufacturer's mailings in [the *Kordel*] case suggested that the manufacturer was attempting to circumvent the [FFDC] Act rather than supplement it. *Id.* at 946-47.

The U.S. Court of Appeals for the Third Circuit recently held in another federal preemption case that a marketing brochure distributed to retailers was not "labeling" under FIFRA because the brochure did not contain essential directions for using the product. *Indian Brand Farms*, 2010 WL 3122815.

In Lowe's Home Centers, Inc., the U.S. Court of Appeals for the Eleventh Circuit found certain "guidelines" that the product manufacturer sent only to its retail merchandisers to be "labeling" even though it was sent to those merchandisers separate and apart from the product. Lowe's Home Ctrs., Inc., 313 F.3d 1307. The "guideline" was not made available to the general public and included specific directions for the handling, storage and hazards of the product. Id. at 1312.

The facts of the *Lowe's* case are very different from the facts involved in Liphatech's case. The guidance to retailers in the *Lowe's* case was an integral part of the safe distribution of the product through channels of trade, while the advertising material at issue in this case was made available to the general public in order to educate potential customers about the benefits of the pesticides.

Importantly, each of these federal preemption cases recognize that even if the term "accompany" can be interpreted to include material that does not physically accompany the pesticide product, it must still be interpreted narrowly because "[t]he labeling provisions of FIFRA were . . . clearly not intended to regulate sales literature generally. . ." *Indian Brand Farms*, 2010 WL 3122815, at \*8.

In addition, the definition of "labeling" under FIFRA should be construed narrowly in order to avoid infringing on the First Amendment commercial 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 reasonably susceptible of two interpretations. . . it is our plain duty to adopt that construction which will save the statute from constitutionally 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"). Interpreting Liphatech's advertising materials to be labeling under FIFRA would unnecessarily restrict Liphatech's right of commercial free speech under the First Amendment.

Complainant has not alleged that Liphatech's advertising materials are considered "labeling" under any definition. As established by the affidavit of Alan Smith of Liphatech:

- (i) The advertising material was made available to the general public through Liphatech's website, its radio broadcasts and/or print ads and was intended to educate potential customers about the benefits of the pesticides.
- (ii) The advertising material was not referenced on the approved label for the affected products.
- (iii) The advertising material did not include directions for use that were in any way intended to augment or supplement the label.
- (iv) There was no intent on the part of Liphatech to circumvent FIFRA, especially because its pesticides had EPA-approved labels which included detailed directions for use.
- (iv) There was no intent on the part of Liphatech that the advertising material that Complainant alleges is false and misleading in the Complaint ever accompany the product user into the field during application.

Smith Aff. at ¶¶ 6, 8-11. As such, Liphatech's advertisements do not constitute "labeling" under any definition.

There is no genuine issue of any material fact with respect to the misbranding allegations. Liphatech is entitled to partial judgment in its favor on this liability issue as a matter of law because Liphatech's radio broadcasts, print literature, and website literature are not labeling under FIFRA and, therefore, they could not have caused the pesticide to be misbranded.

As a result, Respondent respectfully requests that the Administrative Law Judge render an accelerated decision on liability in favor of Liphatech with respect to all of the allegations that Liphatech's products were misbranded and all of the alleged violations of FIFRA § 12(a)(1)(E) set forth in the Complaint.

III. <u>If this tribunal determines that the existence of material factual issues precludes an accelerated decision in favor of Liphatech with respect to the alleged misbranding violations, Liphatech respectfully requests an accelerated hearing on the disputed facts.</u>

If this tribunal determines that the existence of issues of material fact precludes it from rendering a partial accelerated decision on the issue of liability in favor of Liphatech with respect to the alleged misbranding violations, then Liphatech respectfully requests an accelerated hearing on the relevant disputed factual issues, if any. A separate hearing on the relevant disputed facts, if any, would simplify this case and conserve the resources of this tribunal and the parties.

#### Conclusion

Complainant has failed to plead all of the predicate facts necessary to prove its alleged misbranding case. In the alternative, because Liphatech is entitled to judgment in its favor as a matter of law holding its advertising materials are not labeling under FIFRA and could not have caused the pesticide to be misbranded. For these reasons, Liphatech respectfully requests that its motion be granted and that all of the alleged misbranding violations asserted in the Complaint (as itemized in the attached Exhibit A) be dismissed.

Dated this \_\_\_\_\_ day of September, 2010.

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#### **EXHIBIT A**

# LIST OF PARAGRAPHS REFERENCING ALLEGED MISBRANDING THAT MUST BE DISMISSED IN WHOLE OR IN PART

I. The following paragraphs of the Complaint referring to alleged misbranding must be dismissed in whole:

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7, 12, 16, 148, 151, 154, 157, 160, 163, 166, 169, 172, 175, 178, 181, 184, 187, 190, 193, 196, 201, 204, 208, 277, 280, 283, 286, 289, 292, 295, 298, 301, 304, 307, 310, 313, 316, 319, 322, 325, 328, 337, 473, 477, 481, 485, 489, 493, 497, 501, 505, 509, 513, 517, 521, 525, 529, 533, 537, 541, 545, 549, 553, 557, 561, 565, 569, 573, 577, 581, 585, 589, 593, 597, 601, 605, 609, 613, 617, 621, 625, 629, 633, 637, 641, 645, 647
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II. That portion of the following paragraphs referring to alleged misbranding must be dismissed:

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474, 478, 482, 486, 490, 494, 498, 502, 506, 510, 514, 518, 522, 526, 530, 534, 538, 542, 546, 550, 554, 558, 562, 566, 570, 574, 578, 582, 586, 590, 594, 598, 602, 606, 610, 614, 618, 622, 626, 630, 634, 638, 642, 648
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## **EXHIBIT B**

## [SEE ATTACHED AFFIDAVIT 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.	) )
	)

AFFIDAVIT OF ALAN SMITH OF RESPONDENT LIPHATECH, INC. IN SUPPORT OF MOTION TO PARTIALLY DISMISS THE COMPLAINT OR IN THE ALTERNATIVE FOR PARTIAL ACCELERATED DECISION ON AN ISSUE OF LIABILITY IN FAVOR OF RESPONDENT

State of Wisconsin	)
	: <b>SS</b>
Milwaukee County	)

. .

Alan Smith, being first duly sworn on oath, deposes and says:

- 1. I am and have been the Business Director, Agricultural Division of Liphatech, Inc. ("Liphatech") since September 2007 and have been employed by Liphatech since November 1998.
- 2. All capitalized terms not defined below shall have the meaning ascribed to them in the Complaint.
  - 3. I have personal knowledge of the following facts.
- 4. The advertising material that is the subject of the Complaint was not attached to Rozol or Rozol Prairie Dog Bait.
- 5. To the best of my recollection and belief, the advertising material that is the subject of the Complaint was not distributed with and never physically accompanied Rozol or Rozol Prairie Dog Bait.

- 6. The advertising material that is the subject of the Complaint was not referenced on the label for Rozol or Rozol Prairie Dog Bait.
- 7. To the best of my recollection and belief, the advertising material that is the subject of the Complaint was not referenced in literature accompanying Rozol or Rozol Prairie Dog Bait.
- 8. The advertising material that is the subject of the Complaint was made available to the general public through Liphatech's website, radio broadcasts and print ads and was intended to educate potential customers about the benefits of Rozol and Rozol Prairie Dog Bait.
- 9. The advertising material that is the subject of the Complaint did not contain directions for use that were in any way intended to augment or supplement the label.
- 10. There was no intent on the part of Liphatech to circumvent FIFRA, especially because Liphatech's pesticides had EPA-approved labels which included detailed directions for use.
- 11. The advertising material that is the subject of the Complaint was not intended to accompany the product user into the field during application.

Subscribed and sworn to before me by Han Smith this le day of

Notary Public, State of Wisconsin

My commission expires on

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U.S. ENVIRONMENTAL PROTECTION AGENCY A W

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

#### CERTIFICATE OF SERVICE

I, Jeffrey P. Clark, one of the attorneys for the Respondent, Liphatech, Inc., hereby certify that I delivered one copy of the foregoing Motion of Respondent for Partial Accelerated Decision on an Issue of Liability in Favor of Respondent with Respect to the Alleged Violations of § 12(a)(2)(E) of FIFRA Set Forth in Counts 1-2,117 of the Complaint and Legal Memorandum in support thereof and Motion of Respondent to Partially Dismiss the Complaint or in the Alternative for Partial Accelerated Decision on an Issue of Liability in Favor of Respondent with Respect to the Alleged Violations of § 12(a)(1)(E) of FIFRA and Legal Memorandum and Affidavit of Alan Smith in support thereof, 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 Administrative Law Judge Office of the Administrative Law Judges U.S. Environmental Protection Agency Mail Code 1900L 1200 Pennsylvania Avenue, NW Washington, D.C. 20460-2001; 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 originals of the aforementioned documents and 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 16th day of September, 2010.

ed et

Jeffrey P. Clark

One of the Attorneys for Respondent

Liphatech, Inc.