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September 5, 2012

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DELIVERED BY COURIER

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

Dear Regional Hearing Clerk:

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

On behalf of Respondent, Liphatech, Inc., I enclose for filing an original and two copies of Respondent's Reply Brief.

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.

Yours very truly,

Michael H. Simpson

Encs.

cc Honorable Susan L. Biro (w/encs., by courier)
Ms. Nidhi K. O'Meara (*C-14J*) (w/encs., by First Class Mail)

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

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

RESPONDENT'S REPLY BRIEF

In accordance with the Chief Judge's April 16, 2012 Order Scheduling Post-Hearing Briefs, Liphatech, Inc. ("Respondent"), through its undersigned attorneys, respectfully submits the instant Respondent's Reply Brief, pursuant to section 22.26 of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation, Termination or Suspension of Permits ("Consolidated Rules"). 40 C.F.R. § 22.26.

I. 40 C.F.R. § 168.22 Is a Non-Binding Interpretive Rule That Is Not Applicable to this Proceeding

As set forth in Respondent's Post-Hearing Brief, 40 C.F.R. § 168.22 does not govern in the instant case because it is limited to five types of situations and pesticides, none of which are alleged in this proceeding. (Respt.'s Post-Hr'g. Br. 33-34). Even assuming *arguendo* that section 168.22 applies to Rozol,[1] it is an interpretive rule that is not binding on the Chief Judge and if interpreted in the manner suggested by

[1] Unless specifically noted otherwise, Respondent will use "Rozol Prairie Dog Bait" to refer generally to Rozol Prairie Dog Bait, EPA Reg. No. 7173-286, as well as the supplemental Special Local Needs registrations under FIFRA section 24(c). Respondent will use "Rozol Pocket Gopher Bait" to refer to Rozol Pocket Gopher Bait II (Alternate Name: Rozol Pocket Gopher Bait Burrow Builder Formula), EPA Reg. No. 7173-244. Finally, Respondent will use Rozol to refer to "Rozol Pocket Gopher Bait" and "Rozol Prairie Dog Bait," collectively.

Complainant, it would far exceed the statutory authority granted to the Environmental Protection Agency ("EPA") by Congress.

An interpretive rule describes the agency's view of the meaning of an existing statute or regulation. *Yale Broad. Co. v. F.C.C.*, 478 F.2d 594, 599 (D.C. Cir. 1973). Interpretive rules, as non-binding agency action, merely express an agency's interpretation and, as such, are not determinative of the issues or rights addressed. *Batterton v. Marshall*, 648 F.2d 694, 702 (D.C. Cir. 1980). "Unlike legislative rules, non-binding agency statements carry no more weight on judicial review than their inherent persuasiveness commands." *Id.* The validity of an interpretive rule stands or falls on the correctness of the agency's interpretation of the statute. *Metro. Sch. Dist. v. Davila*, 969 F.2d 485, 492 (7th Cir. 1992). Importantly, both legislative and interpretive rules are void if they go beyond the statutory authority granted to the agency. "Absent a claim of constitutional authority (and there is none here), executive agencies may exercise only the authority conferred by statute, and agencies may not transgress statutory limits on that authority." *EME Homer City Generation L.P. v. EPA*, No. 11-1302, 2012 WL 3570721, at *2 (D.C. Cir. Aug. 21, 2012).

The classification of 40 C.F.R. § 168.22 as an interpretive rule is confirmed by: (1) its location within Part 168 of the Code of Federal Regulations which is entitled "Statements of Enforcement Policies and Interpretations;" (2) the EPA's characterization of the proposed rule as a "proposed interpretive rule" and the final rule as a "final interpretive rule;" and (3) the fact that the provision does nothing more than offer the Agency's interpretation of the statute. *See* 40 C.F.R. Pt. 168; Pesticide Advertising, 51 Fed. Reg. 24393 (proposed July 3, 1986) (to be codified at 40 C.F.R. Pts. 153, 166);

Advertising of Unregistered Pesticides, Unregistered Uses of Registered Pesticides and FIFRA Section 24(c) Registrations, 54 Fed. Reg. 1122 (Jan. 11, 1989) (to be codified at 40 C.F.R. Pts. 166, 168).

As such, the interpretive rule set forth at 40 C.F.R. § 168.22 is not binding on the Chief Judge in this proceeding. Moreover, even if applicable and binding, Complainant's strained interpretation of that section which suggests that all advertising constitutes an "offer for sale" extends well beyond the statutory grant of authority provided to EPA by Congress and is therefore void.

In order to avoid overstepping EPA's authority, as applied to the five situations and pesticides listed therein, 40 C.F.R. § 168.22 could reasonably be interpreted to mean that advertising in any medium, which *also* constitutes an offer for sale, may constitute a violation of FIFRA section 12(a)(1)(B) if it contains substantially different claims and the other elements of that section are met. For the reasons set forth in Respondent's Post-Hearing Brief and based upon the EAB's decision in *In re Tifa, Ltd.,* 9 E.A.D. 145, 2000 WL 739410 (EAB 2000), however, Respondent's website does not constitute an offer for sale and therefore Counts 2,184 through 2,231 of the Complaint must be dismissed. (Respt.'s Post-Hr'g. Br. 27-31).

II. The 1973 Office of General Counsel Memorandum Casts Doubt on EPA's Authority to Regulate Advertising

Complainant misconstrues Respondent's argument and mischaracterizes the reasons for which the 1973 Office of General Counsel ("OGC") memorandum was offered in this proceeding. As the OGC memorandum explains, as early as 1973, there was considerable doubt – even within the EPA – with respect to the scope of EPA's authority to regulate all pesticide advertising because Congress deliberately used the

words "distribution or sale" instead of the word "advertising" in section 12(a)(1)(B). Environmental Protection Agency ("EPA") Office of the General Counsel Memorandum, 1973 WL 21961, at *1-2 (July 1973) (EPA's authority to control advertising of pesticide products "rests upon a weak (or perhaps non-existent) reed"). Respondent offered the OGC memorandum simply to contrast its display of honest doubt regarding EPA's authority to regulate advertising with the Complainant's tactics in this case. Instead of requesting that Congress clarify the EPA's authority, almost 40 years after the OGC memorandum was written, Complainant is attempting to obtain its desired result by singling out Respondent for an unprecedented penalty.

In addition, the EAB's single reference to 40 C.F.R. § 168.22 in a footnote in *Microban II* has absolutely no impact on the issues presented in this case. *See In re Microban Prods. Co. ("Microban II")*, 11 E.A.D. 425, 444 n. 26, 2004 WL 1658591 (EAB 2009). First, the EAB was responding to a unit of violation argument raised by the respondent in that case which was rejected over 13 years earlier by the EAB in *In re Sporicidin International*, 3 E.A.D. 589 1991 WL 155255 (EAB 1991). Second, the reference to 40 C.F.R. § 168.22 in *Microban II* was only made to show that EPA's interpretation of the scope of FIFRA section 12(a)(1)(B) was extended to some advertisements that rise to the level of an offer for sale under certain circumstances.

Moreover, Complainant incorrectly states that Respondent relies on the OGC memorandum to support the position "that EPA does not have authority to police substantially different claims made in advertisements." (Complainant's Reply Br. 2). In doing so, Complainant has misconstrued Respondent's position. Respondent has never contended that EPA does not have authority to police substantially different claims made

as part of the sale or distribution of a registered pesticide as set forth in FIFRA section 12(a)(1)(B). Not all advertisements, however, fall within this scope.

III. Complainant Has Failed to Demonstrate the Requisite Nexus Between Any Substantially Different Claim and Any Sale or Distribution of Rozol

While the statutory scheme set forth in FIFRA does not create a single test to determine whether a claim has been made as part of the sale or distribution of a pesticide, the EAB in *Microban II* confirmed that, at a minimum, the Complainant must show that each person who received a shipment of Rozol must have also received product information for the product at issue (which contained a differing claim) prior to the time the shipment was made in order for a violation of FIFRA section 12(a)(1)(B) to be found. *Microban II*, 2004 WL 1658591, 15 ("shipments made prior to Microban's furnishing these documents to Hasbro obviously cannot be considered as linked to the unapproved claims in the two documents").

While one may examine surrounding facts and circumstances to make a determination that the requisite nexus exists, Complainant has failed to meet its burden in this regard. While Complainant argues "that Respondent made substantially different claims as part of a targeted 'sales promotion' and 'advertising' campaign," Complainant has failed to present ANY evidence to show that any of the persons that received shipments of Rozol EVER actually received any product information that contained a substantially different claim. (*See* Compl.'s Reply Br. 4).

Complainant contends that: "twenty-one of the shipments of Rozol that are at issue in Counts 2,141 through 2,183 were preceded by the receipt of Respondent's Research Bulletin." (Complainant's Reply Br. 4 (emphasis added)). Complainant then cites to CX 17, EPA 378, which is a list of "companies that distribute Liphatech's Rozol

Prairie Dog Bait SLNs." Complainant's assertion that the document set forth at CX 17, EPA 378 provides a list of companies that received Respondent's Research Bulletin is contrary to the record at best, and disingenuous at worst.

Complainant goes on to assert an even more tenuous nexus by arguing that the remaining shipments of Rozol "were to different locations of Respondent's authorized and existing distributors during Respondent's targeted radio and print advertising campaign." (Complainant's Reply Br. 4). Again, Complainant has presented absolutely no evidence that any persons that received a shipment of the product ever received product information or listened to a radio advertisement that contained a differing claim prior to the time he or she received a shipment of Rozol.

With respect to Counts 2,184 through 2,231 which are based solely on allegedly differing claims found on Respondent's website, Complainant asserts that the "offers for sale" were received by the 48 distributors without providing any evidence that any of the 48 distributors ever accessed Respondent's website. (*Id.* at 5). Instead, Complainant cites to CX 53, EPA 994 which is Respondent's proposed response to the second stop sale, use or removal order and a list of distributors that were advised to destroy certain advertising material if in their possession, regardless of whether they ever received it.

Complainant concludes its nexus argument in summary fashion by grouping together the various product information and Counts at issue in this case. By doing so, Complainant disregards the factual inquiry that is necessary to find a violation of FIFRA section 12(a)(1)(B). As an example, Complainant alleges in Count 2,172 that McCoy Farms located at HC 72 Box 1, Crookston, Nebraska 69212 received a shipment of Rozol on March 24, 2008. In order for a violation of FIFRA section 12(a)(1)(B) to be found

based upon the shipment to McCoy Farms, Complainant, at a minimum, must show that McCoy Farms received the material containing the substantially different claim prior to March 24, 2008 and that the material was an integral part of the shipment. As set forth in more detail in Respondent's Post-Hearing Brief, the record is devoid of any such evidence. Similarly, with respect to Counts 2,184 through 2,231 which are based on allegations that Respondent's website contained differing claims (*see e.g.* Compl. ¶ 275) (referencing a Product Information sheet on www.liphatech.com)), Complainant must, at a minimum, show that the 48 distributors upon which these counts are based each individually accessed Respondent's website and that the website constituted an "offer for sale." The record is devoid of any such evidence.

IV. Complainant Misconstrues the Reason for Which the United States Sentencing Guidelines Were Offered

Respondent's Post-Hearing Brief made it clear that the United States Sentencing Guidelines ("Sentencing Guidelines") were offered by Respondent as a means to contrast Complainant's unit of violation analysis. (Respt.'s Post-Hr'g. Br. 84-85). The Sentencing Guidelines remain instructive for grouping of counts in the context of the unit of violation, particularly when EPA has routinely grouped multiple-count violations in the past. *See In re Rhee Bros.,* No. FIFRA-03-2005-0028, 2006 WL 2847398 at 26 (ALJ Sept. 19, 2006) ("regardless of what the statute, ERP or the EAB directs, the Agency frequently does not assess FIFRA violations on a per sale or per shipment basis, as it did here, resulting in lack of consistency in assessing penalties").

V. Complainant Has Failed to Respond to Numerous Arguments Raised by Respondent in Its Post-Hearing Brief

Complainant's Reply ignores many of the arguments raised in Respondent's Post-Hearing Brief. For example:

1. Complainant failed to respond to the fact that, at a minimum, Complainant must show that a person that received a shipment of Rozol must have received product information containing a differing claim prior to receiving a shipment of the product in order for a violation of FIFRA section 12(a)(1)(B) to be found. (Respt.'s Post-Hr'g Br. 39).

2. Complainant failed to address the fact that during the years 2007 and 2008, Rozol Pocket Gopher Bait Burrow Builder Formula, EPA Reg. No. 7173-244, could be sold for use on pocket gophers pursuant to its "parent" label or could be sold with an accompanying FIFRA section 24(c) special local needs label and be used to control black-tailed prairie dog populations. If Respondent made a substantially different claim about the prairie dog bait product (pursuant to the SLN), such a differing claim could not be an integral part of the sale of the product for use on pocket gophers. As a result, in order to find a violation during the 2007 and 2008 time frame, Complainant would need to show that a person received product information related to the prairie dog bait SLN which contained a differing claim and that there was a subsequent shipment of the product for use on black-tailed prairie dogs pursuant to the supplemental SLN label. (*Id.* at 40-41).

3. Complainant did not rebut the fact that Respondent's website is completely passive, that Rozol cannot be purchased on the website, that the website did not contain product pricing information, that the website did not contain any other relevant terms of sale and therefore Respondent's website cannot constitute an offer for sale. Furthermore, Complainant did not rebut the fact that an "offer for sale" is a subset of advertising. (*Id.* at 27-30, 32).

4. Complainant did not respond to the extensive chart prepared by Respondent that showed support for each of the claims made by it. (*Id.* at Exhibit A).

5. Complainant did not address the fact that it continues to mix the "false and misleading" standard applicable to pesticide labeling with the "substantially different" standard applicable to certain claims made in connection with the sale or distribution of the pesticide. (*Id.* at 54-56).

6. Complainant failed to address the fact that much of its case is based upon speculation and conjecture that fails to satisfy its burden as set forth in 40 C.F.R. § 22.24. (*Id.* at 17-21).

7. Complainant did not dispute that the violations alleged in the Complaint did not result in any actual harm to human health or the environment. (*Id.* at 70).

8. Complainant did not dispute that there is no evidence in the record that any of the alleged violations resulted in confusion in the marketplace or potential harm to human health or the environment. (*Id.* at 74).

9. Complainant failed to address the fact that Respondent did not profit from the alleged violations and no economic benefit was received by it as a result of the alleged violations. (*Id.* at 66-67).

10. Complainant provided no response to the fact the agency's Enforcement Response Policy compresses violators and violations into a few select categories and its application in this case fails to capture the low gravity of any violation that may have occurred. (*Id.*).

The only inference that can be drawn from such silence is that Complainant has no meritorious response and, as a result, the Chief Judge should adopt the arguments raised by Respondent. As case law makes clear, in many cases the failure to respond to an argument results in waiver. *Bonte v. U.S. Bank*, 624 F.3d 461, 466 (7th Cir. 2010) (citing *United States v. Farris*, 532 F.3d 615, 619 (7th Cir. 2008)). In this case, the Chief Judge should infer that no reply was provided because Complainant was simply unable to rebut these arguments effectively.

VI. Conclusion

For the reasons set forth above and in Respondent's Post-Hearing Brief, Respondent respectfully requests that the Chief Judge enter an initial decision finding that Respondent did not violate FIFRA section 12(a)(1)(B) as alleged in Counts 2,141-2,231 of the Complaint and levy a fair and reasonable penalty, if any, for the unintentional violation of FIFRA section 12(a)(2)(E) based on the totality of circumstances, including the lack of any actual or potential harm to human health and environment resulting from such violations.

Dated this 5th day of September, 2012.

Respectfully submitted,

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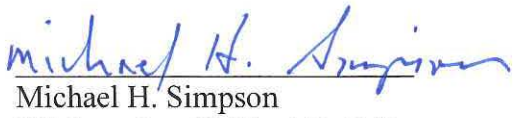

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8944304

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 Respondent's Reply Brief, to the persons designated below, by depositing it with a commercial delivery service or First Class Mail, 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 Respondent's Reply Brief 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 5th day of September, 2012.

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