UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGIONS 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

REPLY TO THE ATTENTION OF:
C-14J

POUCH MAIL

DEC 20 2007

Honorable Barbara A. Gunning
Office of Administrative Law Judges
U.S. Environmental Protection Agency
Mail Code 1900L
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: *In the Matter of Behnke Lubricants, Inc.*
Docket No. FIFRA-05-2007-0025
Complainant's Supplemental Prehearing Exchange

Dear Judge Gunning:

Enclosed, please find a true, accurate and complete copy of Complainant's Supplemental Prehearing Exchange.

The original and one copy of the Complainant's Supplemental Prehearing Exchange, was filed with the Regional Hearing Clerk, Region 5, U.S. EPA, on December 20, 2007. A true, accurate copy of the Complainant's Supplemental Prehearing Exchange, was delivered to Respondent's counsel via U.S. Mail on December 20, 2007.

Please do not hesitate to contact me at (312) 886-0568 if the Court has any questions.

Sincerely,

Nidhi K. O'Meara
Associate Regional Counsel

cc: Mr. Bruce McIlnay, Esq.
McIlnay, Schmitt & Button, Ltd.
1150 Washington
Grafton, Wisconsin 53024
(*via U.S. Mail*)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:	)	
	)	
BEHNKE LUBRICANTS, INC.	)	**COMPLAINANT'S**
MENOMONEE FALLS, WISCONSIN	)	**SUPPLEMENTAL PREHEARING**
	)	**EXCHANGE**
	)	
Respondent.	)	
	)	**Docket No. FIFRA-05-2007-0025**

COMPLAINANT'S SUPPLEMENTAL PREHEARING EXCHANGE

Complainant, the Director, Land and Chemicals Division, Region 5, United States Environmental Protection Agency (U.S. EPA, Complainant or Agency), through her undersigned attorneys, hereby files the instant Complainant's Supplemental Prehearing Exchange pursuant to Section 22.19 of the *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation, Termination or Suspension of Permits* (Consolidated Rules), codified at 40 C.F.R. § 22.19.

I. Governing Legal Standard

The legal standard governing supplementation of prehearing exchanges is found at 40 C.F.R. § 22.19(f), which provides as follows:

> (f) Supplementing prior exchanges. A party who has made an information exchange under paragraph (a) of this section [22.19], ... shall promptly supplement or correct the exchange when the party learns that the information exchanged ... is incomplete, inaccurate or outdated, and the additional or corrective information has not otherwise been disclosed to the other party pursuant to this section.

The additional witness and documentary evidence submitted with this supplemental prehearing exchange is necessary to make the record in this proceeding

complete and accurate, and is relevant to the issues presented in U.S. EPA's Complaint and Respondent's Answer.

II. Additional Expert Witness

On November 15, 2007, Complainant filed its Complainant's Rebuttal Prehearing Exchange. In Section II of that filing, Complainant listed an additional expert witness and indicated that it would submit the specific name and curriculum vitae of that witness in a supplemental submission. The specific information is as follows:

Dr. Tajah L Blackburn, PhD
Lieutenant, Public health Service Commissioned Corps
Product Science Branch
Antimicrobials Division
Office of Pesticides Programs
U. S. Environmental Protection Services
United States Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20640

Dr. Blackburn is the Efficacy Evaluation Team Leader of the Products Science Branch of the Antimicrobials Division of the Office of Pesticide Programs at the U.S. EPA. She holds a PhD degree in Biomedical Sciences, Microbiology/Immunology. Her duties (which are set forth in greater detail in her curriculum vitae, attached hereto as Complainant's Exhibit 47) include reviewing efficacy data submitted by applicants seeking FIFRA registration of antimicrobial products; providing scientific expertise for a variety of emerging public health concerns; participating in external panels dedicated to scientific transparency; assisting in the Antimicrobial Testing Program to maintain and enforce government standards; and providing leadership to staff regarding efficacy reviews and protocol development and analyses.

Dr. Blackburn may be called as an expert witness to testify about her educational background (particularly in the areas of microbiology and related sciences,) her work experience, and her current role within the Product Science Branch of the Antimicrobial Division in the evaluation of antimicrobial products for which FIFRA registration is sought. She may testify about her experience in handling antimicrobial registration and testing of antimicrobial products coming in for registration.

Dr. Blackburn may also testify as an expert witness about the health hazards associated with pathogens such as Listeria (Listeria monocytogenes), E. coli (Escherichia coli) and Salmonella (Salmonella typhimurium) (the pathogens against which Behnke claims its MICRONOX technology is effective). She may respond to assertions made by Respondent's witnesses as to the "origin" of these pathogens. She may testify about the different ways by which such pathogens are spread to inanimate objects (such as plant equipment), and the potential for cross-contamination (i.e., the spreading of bacteria to inanimate objects, and the subsequent contamination of food or humans coming into contact with such objects).

Dr. Blackburn may also testify about the requirements of efficacy testing for certain pesticides, including those pesticides for which public health claims are made (such as claims that the product is effective against certain bacteria or other microorganisms that present risks to human health) at the time of the registration of such pesticides pursuant to FIFRA. She may testify that, in the FIFRA registration process, her office will review an antimicrobial pesticide for which public health claims are made to determine (among other things) whether the applicant has provided sufficient efficacy data to prove that the product has the specific antimicrobial effect claimed on the

product's labeling or in associated product literature. Dr. Blackburn may testify about specific requirements applicable to such data and the analytical work used to produce the data, including the requirement to comply with the standards for Good Laboratory Practices codified at 40 C.F.R. Part 160. She may testify about the different levels of efficacy which an applicant may claim for a particular product (i.e., an applicant may claim that its antimicrobial product is a sterilant, disinfectant, sanitizer or otherwise), and that the requirements of efficacy data will be more demanding when an applicant makes stronger claims of efficacy. Dr. Blackburn may further testify as to the importance of reliable efficacy data, particularly when the product at issue is claimed to mitigate or destroy diseases that affect human health (i.e., public health claims). She may testify about the potential danger that users of such products may forego other sanitation practices in reliance on the antimicrobial public health claims made in connection with such products.

Dr. Blackburn may also testify about the analyses used to determine the toxicity of pesticides, including antimicrobial pesticides.

Dr. Blackburn may also testify to EPA's historical interpretation of the term "processed food" as it is used in FIFRA and it s regulations. She may also testify to the importance of proper labeling of antimicrobial pesticides through the registration process, including ensuring that the label includes (but is not limited to) mandatory and advisory statements, precautionary statements, physical and chemical hazards, directions for use (which could include mixing, application and cleaning), ingredient statements, use classification, environmental hazards, worker protection labeling, directions for use including how long a pesticide must be applied to effectively kill or mitigate a microbe

and storage and disposal information (which could include temperature requirements to ensure efficacy).

Dr. Blackburn may offer her expert opinion as to whether, based on the label and literature claims made by Behnke in connection with the lubricants identified in this matter and the intended use of such lubricants, such lubricants are pesticides that must be registered with the U.S. EPA under FIFRA.

Finally, she may testify to additional subjects as necessary to respond to assertions or arguments raised by Respondent. Dr. Blackburn may also refer to a number of U.S. EPA guidance and reference documents during her testimony. See Complainant's Exhibits 47 through 61. To the extent deemed necessary by the Court, Dr. Blackburn will provide testimony sufficient to authenticate the documents that she refers to during her testimony at the hearing.

III. Additional Exhibits

CX 47 Curriculum Vitae of Dr. Tajah Blackburn

CX 48 Guidance for Pre-Application Meetings on New Active Ingredients, Major New Uses and Other Registration Actions.

CX 49 Consumer Products Treated with Pesticides

CX 50 EPA Label Review Manual, 3rd Edition

CX 51 Series 91: Product Performance/Efficacy Test Guidelines; Subseries 91A: Public Health Use Antimicrobial Agent Product Performance Test Guidelines

CX 52 Subdivision H: Labeling Guidelines for Pesticide Use Directions

CX 53 Antimicrobial Policy & Guidance Documents

CX 54 Antimicrobial Science Polices, Disinfectant Technical Section (DIS/TSS)

CX 55 The Efficacy Evaluation Team of the Antimicrobial Division SOP

CX 56 AOAC Official Method 955.11, Testing Disinfectants against Salmonella typhl

CX 57 July 25, 1986 letter to Registrants of Antimicrobial Products Used as Food Contact Surface Substances.

CX 58 Pesticide Registration Kit

CX 59 Registration Service Fees; Pesticide Registration Improvement Renewal Act

CX 60 Regulatory Action Fact Sheets with Antimicrobial Pesticide Products attached.

CX 61 Pesticide Registration (PR) Notices Relating to Antimicrobials listed with PR Notice 2002-X and PR Notice 2000-5 attached.

IV. Reservation of Rights

Complainant respectfully reserves the right to supplement its list of witnesses and/or its list of exhibits upon reasonable notice to Respondent, or by order of this Honorable Court.

Complainant's Supplemental Prehearing Exchange for *In the Matter of Behnke Lubricants, Inc.*, is hereby respectfully submitted.

Respectfully Submitted,

Nidhi K. O'Meara — Date: 12/19/07

James J. Cha — Date: 12/19/07

Associate Regional Counsels
U.S. EPA, Region 5

In the Matter of Behnke Lubricants, Inc.
Docket No. FIFRA-05-2007-0025

CERTIFICATE OF SERVICE

I hereby certify that the original and one true, accurate and complete copy of Complainant's Supplemental Prehearing Exchange, together with true, accurate and complete copies of Complainant's Exhibits 47 through 61, were filed with the Regional Hearing Clerk, U.S. EPA, Region 5, on the date indicated below, and that true, accurate and complete copies of Complainant's Supplemental Prehearing Exchange and Complainant's Exhibits 47 through 61, were served on the Honorable Barbara Gunning, Administrative Law Judge (service by Pouch Mail), and Mr. Bruce McIlnay, Esq., Counsel for Respondent Behnke Lubricants, Inc. (service by Federal Express), on the date indicated below:

Dated in Chicago, Illinois, this 20th day of December, 2007.

Patricia Jeffries-Harwell
Legal Technician