toXcel

Toxicology & Regulatory Affairs
P.O. Box 363
7140 Heritage Village Plaza
Gainesville, VA 20156
USA

Phone: (703) 335-5670 **Fax: (703) 310-6950**

Hand Delivered

August 8, 2007

Mr. Richard Gebken
Registration Division
Document Processing Desk (HSRB)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

ATTN: John Carley

RE: Submission of a Protocol for the Evaluation of Personal Insect Repellents Against Mosquitoes in the Laboratory for Consideration by the Human Studies Review Board

Dear Mr. Gebken and Mr. Carley:

On behalf of Avon Products, Inc. (Avon), we are submitting the enclosed protocol and its associated informed consent document for review and approval by the Human Studies Review Board (HSRB) at its upcoming meeting in October 2007. This protocol is intended to be used to substantiate the label claim of efficacy against West Nile Virus vector species on two EPA registered products – Avon Skin-So-Soft SSS Bug Guard Plus Picaridin Insect Repellent (EPA Reg. No. 806-29) and Avon Skin-So-Soft SSS Bug Guard Plus Picaridin Insect Repellent Spray (EPA Reg. No. 806-31).

The enclosed protocol and informed consent document have been reviewed and approved by the independent Essex Institutional Review Board. Supplemental documentation satisfying 40 CFR §26.1125 are also included with this package. Please note that the study protocol will be used for two test materials (806-29 and 806-31). If this protocol is approved, separate study reports will be submitted on each test material following completion of the studies.

If you have any questions, please feel free to contact Micah Reynolds or me by phone at (703) 335-5670 or by e-mail at micah@toxcel.com or alan@toxcel.com, respectively.

Sincerely,

Alan C. Katz, D.A.B.T.
Principal
toXcel, LLC
Authorized Representative for Avon Products, Inc.

Enclosures
Cc: A. Pechko (Avon)
E. Gilberti (Avon)
R. Labib (Avon)
C. Bartlett (Avon)
P. Quinn (The Accord Group)

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter (Registrant)

(EPA Company ID No. 806)

Avon Products, Inc.
1251 Avenue of Americas
New York, NY 10020

2. Regulatory Action for which this Package is Submitted:

Submission of a protocol for the evaluation of personal insect repellents against mosquitoes in the laboratory for review by the Human Studies Review Board (HSRB). The registrant intends to use this protocol to conduct laboratory efficacy studies for two currently registered products (EPA Reg. Nos. 806-29 and 806-31) in order to support a label claim of efficacy against West Nile Virus.

3. Transmittal Date

August 8, 2007

4. List of Submitted Documents

Volume 1 Protocol for the Evaluation of Personal Insect Repellents Against Mosquitoes in the Laboratory;
ICR Protocol ID: G0590607001A117

5. Company Contact

Company Name: Avon Products, Inc.

Authorized Representative: Alan C Katz 8/8/07
Alan C. Katz, D.A.B.T. DATE

toXcel, LLC
P.O. Box 363
7140 Heritage Village Plaza
Gainesville, VA 20155
email: alan@toxcel.com
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FAX: (703) 310-6950

Please read instructions on reverse side before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

EPA	United States Environmental Protection Agency Washington, DC 20460	☐ Registration ☐ Amendment ☒ Other	OPP Identifier Number

Application for Pesticide – Section 1

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
Avon Products, Inc./ 806-29 & 806-31	**Richard Gebken**	☒ None ☐ Restricted
4. Company/Product (Name) **Protocol ID: G0590607001A117**	PM# **10**	
5. Name And Address Of Applicant *(Include ZIP Code)* **Avon Products, Inc. 1251 Avenue of the Americas New York, NY 10020**	**6. Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section II

☐ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification – Explain below.
☐ Final Printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☒ Other – Explain Below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of a protocol for the evaluation of personal insect repellents against mosquitoes in the laboratory for review by the Human Studies Review Board (HSRB). The registrant intends to use this protocol to conduct laboratory efficacy studies for two currently registered products (EPA Reg. Nos. 806-29 and 806-31) in order to support a label claim of efficacy against West Nile Virus.

Section III

1. Material This Product Will Be Packaged In:

Child Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Unit Packaging wgt. / No. per Container	

3. Location of Net Contents Information	4. Size(S) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithographed ☐ Paper glued ☐ Stenciled ☐ Other _____

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Alan C. Katz, D.A.B.T. / *toXcel*, LLC	**Avon Authorized Representative**	**(703) 335-5670**

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received
Alan C Katz	**Avon Authorized Representative (*toXcel*, LLC)**	
4. Typed Name **Alan C. Katz, D.A.B.T.**	5. Date **August 8, 2007**	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete