Technology Sciences Group Inc.

712 Fifth St., Suite A
Davis, CA 95616
Direct dial: (202) 684-2784
Fax: (530) 757-1299
E-Mail: aroberts@tsgusa.com

Amy Plato Roberts
Senior Regulatory Consultant

Linda Hollis, Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs, EPA
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

October 15, 2013

RE: BullFrog® Mosquito Coast® Twilight; EPA Reg. No. 89523-2
NOTIFICATION to add marketing text and optional label claims

Dear Ms. Hollis:

Enclosed with this letter you will find the following in support of a label NOTIFICATION to add marketing text and optional label claims, as follows:

1) 8570-1 Notification form;
2) One (1) copy of the label with all changes highlighted in red.

Marketing text and optional label claims added are in line with text and claims already on the EPA approved label for this product. Please do not hesitate to let me know if you have any questions or comments.

Sincerely,

Amy Plato Roberts
Sr. Regulatory Consultant
(202) 684-2784; aroberts@tsgusa.com

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 I

1. Company/Product Number **89523-2**	2. EPA Product Manager **Linda Hollis**	3. Proposed Classification ☒ None ☐ Restricted
4. Company/Product (Name) **BullFrog® Mosquito Coast® Twilight**	PM# **91/Biochemical/BPPD**	
5. Name And Address Of Applicant *(Include ZIP Code)* **Sun & Skin Care Research, LLC 851 Greensboro Rd. Cocoa, FL32926** ☐ *Check if this is a new address*	**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.)

Notification to add marketing text and optional label claims. See cover letter dated October 15, 2013 for details.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

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 ☐ Pager 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)
Amy Plato Roberts, Technology Sciences Group, Inc.	**Regulatory Consultant; aroberts@tsgusa.com**	**(202) 684-2784**

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.

6. Date Application Received **(Stamped)**

2. Signature	3. Title
	Regulatory Consultant
4. Typed Name **Amy Plato Roberts**	5. Date **October 15, 2013**

(Front Panel)

BullFrog® Mosquito Coast® Twilight

Alternate Brand Names:
"BullFrog® Mosquito Coast® Insect Repellent"
"Fresh Rain BullFrog® Mosquito Coast®"
"Cool Aloe BullFrog® Mosquito Coast®"
"Unscented BullFrog® Mosquito Coast®"

ACTIVE INGREDIENT:
3-((N-butyl-N-acetyl)amino)
propionic acid ethyl ester* 20.0%
OTHER INGREDIENTS: 80.0%
TOTAL: 100.0%
*IR3535® Insect Repellent

KEEP OUT OF REACH OF CHILDREN
CAUTION

NET CONTENTS: 4.7 fl. oz. (139 mL); 6 fl. oz. (177 mL)

(Back Panel)

(BullFrog® Mosquito Coast® Twilight formula repels mosquitoes for up to eight hours. Gentle formula does not need to be washed off when returning from the outdoors. Pleasant fragrance.)

(BullFrog® Mosquito Coast® Twilight is the perfect choice when the sun goes down and the bugs come out. With a splash of cool aloe, this non-greasy formula goes on clear and dries instantly. It helps to keep skin looking and feeling good – moisturizes and cools sun-drenched skin while keeping biting insects away.

IR3535® Insect Repellent in this product provides long lasting protection and is suitable for the entire family to use. Plus, this gentle formula does not need to be washed off when returning from the outdoors. BullFrog® Mosquito Coast® Twilight…Enjoy being outdoors even longer!)

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. An adult must apply this product to children under 10. Do not exceed 3 applications per day for children. **To apply to skin:** Apply liberally and evenly over dry, exposed skin. **To apply to face:** Do not spray directly on face. Spray on palm of hand and apply to face by patting. For continued protection from mosquitoes, reapply after 8 hours, not to exceed 4 applications per day for adults.

For liquid spray packaging:
STORAGE: Store in a cool, dry place in tightly closed container.
DISPOSAL: If empty: Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

For pressurized packaging:
STORAGE: Store in a cool, dry place. Avoid long term storage above 104°F (40°C). Do not store at temperatures above 120°F (49°C).
DISPOSAL: If empty: Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions.

PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS: CAUTION. For external use only. Causes moderate eye irritation. Do not get in eyes. Do not use on children under 6 months of age unless with the advice of a physician.

For liquid spray packaging:
PHYSICAL OR CHEMICAL HAZARDS: **Flammable.** Keep away from heat and open flame. Contains alcohol. Avoid contacts with plastics.

For pressurized packaging:
PHYSICAL OR CHEMICAL HAZARDS: **Flammable.** Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. Avoid contact with plastics.

FIRST AID	
If in eyes:	♦ Hold eye open and rinse slowly and gently with water for 15-20 minutes. ♦ Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye. ♦ Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.	

Distributed (and) (Manufactured) By:
Sun & Skin Care Research, LLC
851 Greensboro Rd.
Cocoa, FL 32962
(website)
800-715-3485

EPA Reg. No.: 89523-2
EPA Est. No.: 89523-FL-001

(Julian Day Lot Code Number with Exp. Month / Year) Not for sale or use after expiration date.

(IR3535® is a registered trademark of Merck KgaA.)

(U.S. Patent No. 7,037,515)

OPTIONAL LABEL CLAIMS:

General Claims:

- New Fragrance *["New Fragrance" claim would be valid for 6 months from the date of the first product shipment with new fragrance alternate formulation.]*
- (Fragrance Free) (Unscented) (- New) *["New" claim would be valid for 6 months from the date of the first product shipment with new alternate formulation.]*
- Repels (mosquitoes) (for) up to 8 hours.
- Contains 20% IR3535® Insect Repellent.
- DEET-Free
- Contains Aloe and Vitamin E to soothe and naturally moisturize skin.
- Dries Instantly – no greasy residue.
- Non-Greasy
- Easy to use spray formula for no hassle application.
- Light spray gel won't drip – or cause your grip to slip.
- Goes on clear
- With cooling aloe.
- Pleasant fragrance (Cool Aloe) (Fresh Rain).
- Pleasant, (Cool Aloe) (Fresh Rain) fragrance.
- DEET-Free so no unpleasant odor.
- Suitable for the entire family.
- Ideal for family use.
- Doesn't require washing off of skin upon return to indoors.
- Gentle formula does not need to be washed off when returning from the outdoors.
- Repels mosquitoes (up to 8 hours) that may (carry) (transmit) (the) West Nile virus (encephalitis) (diseases).
- Provides effective, dependable, and long lasting repellency for up to 8 hours against mosquitoes.
- Made in the USA

Claims specific to the pressurized packaging:

- NEW (claim would be valid for 6 months from the date of the first product shipment with pressurized packaging)
- Continuous spray
- No Rubbing Required
- One Touch Pump
- Fine Mist Spray
- Easy Application
- No Mess
- Convenient, no mess, no rub protection
- Sprays Upside Down