PM -15

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# 22 FEB 1995

Geri L. Vander Leest S.C. Johnson & Son, Inc. 1525 Howe Street Racine, Wisconsin 53403-5011

Dear Ms. Vander Leest:

Subject: Additional Label Claims For:
OFF! Lotion Formula II
EPA Registration No. 4822-362
Application dated April 14, 1994

The proposed amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended is acceptable subject to the comment listed below. Astamped copy of the draft label is enclosede for your records.

Delete the statement, "Pediatrician recommended".

Submit five copies of the finished printed label corrected in accordance with the comment listed above before the product is released for shipment under this revised label.

A copy of the review of the Efficacy data is enclosed for your records. This review covers registrations 4822-362,4822-373,4822-368, and 4822-395.

Sincerely,

Rebecca S. Cool

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Acting Product Manager 10 Insecticide & Rodenticide Branch Registration Division (7505C) <label 4822-362 amendment to EPA 4/94 to standardize and add claims, CHANGES ARE IN ITALICS>

## S. C. Johnson wax

# OFF! Lotion Formula II

New

Insect repellent

Provides protection from mosquitoes, biting flies, ticks (including ticks that cause Lyme Disease), gnats, no-see-

ums and fleas

Repels insects

Pediatrician recommended

Light, pleasant scent

Clean fresh scent

Raby powder fresh scent

\_otion

Non-greasy

Leaves your skin feeling smooth and natural

With aloe vera

Moisturizes with aloe vera

Feels so good you'll forget you've got it on!

OFF! Insect screen lotion

Insect screen lotion

Low DEET formula

# **ACTIVE INGREDIENTS**

 ACCEPTED
with COMMENTS
in EPA Letter Detail

22 FEB 1995

Under the Federal Insecticide, Funcicide, and Rodouticide Ast an amended, for the presticide registered under EPA Reg. No.

Keep out of reach of children
WARNING
See additional precautions on back panel

Net 0.4 - 12 fl. oz.

OFF! Lotion Formula II is a pleasant (baby powder fresh) smelling lotion specially formulated to expel mosquitoes, biting flies, ticks (including ticks that cause Lyme Disease), gnats, no-sec-unis and fleas for up to two hours. OFF! Lotion Formula II also moisturizes your skin. It contains aloe vera to leave skin feeling smooth and natural, never sticky or greasy. Keeping insects away never felt so good.

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to u e this product in a manner inconsistent with its labeling. Read all directions before using this product.

For best results, spread evenly and completely over all exposed skin. Apply to hand for application to face and neck and rub on. Do not apply to eyes and mouth and do not apply to hands of young children. Use just enough repellent to cover exposed skin. Avoid overexposure. Frequent reapplication and saturation are unnecessary. Do not keep product on any longer than necessary. After returning indoors, wash treated skin with soap and water. Do not apply under clothing.

Do not apply on or near: acetate, rayon, spandex, dynel fabrics or other synthetics (other than nylon), furniture, plastics, leather, watch crystals and painted or varnished surfaces including automobiles.

#### PRECAUTIONARY STATEMENTS

Hazards to Humans - Warning: Harmful if swallowed. May cause eye injury. Use sparingly on small children. Do not allow use by small children without close adult supervision. Do not apply to excessively sunburned or damaged skin. May cause skin reaction in rare cases.

## STATEMENT OF PRACTICAL TREATMENT

If in eyes: Flush with plenty of water. If irritation persists, get medical treatment. If swallowed: Call a physician or poison control center. Get medical attention. If you suspect that you or your child is reacting to this product, wash treated skin and call your doctor.

STORAGE: Store away from heat or flame in an area inaccessible to children. DISPOSAL: Do not reuse empty container. Wrap container and put in trash.

Questions? Comments? Call 800-558-5252 weekdays, 9-9 Eastern Time or Write Helen Johnson ©1991 S. C. Johnson & Son, Inc. Racine, WI 53403-2236 U.S.A. All Rights Reserved

Contents: Deionized water, N,N-Diethyl-toluamide, Distearyldimonium Chloride, Petrolatum USP, Glycerin USP, Isopropyl Palmitate, Cetylalcohol, Aloe, Dimethicone, Titanium Dioxide USP, Methyl Paraben, Propyl Paraben, Sodium Chloride, Fragrance

If this product is sold in individual pouches, the following additional labeling may be added to the container: Single use pouches

## Directions for use:

- 1) Cut (tear) corner where indicated at top of pouch.
- 2) Apply lotion to hand for application to face and neck.
- 3) Spread evenly and completely over all exposed skin.
- 4) Wrap empty container and dispose in trash.]

EPA Reg. No. 4822-362 EPA Est. No. 4822-WI-1

