Johnson & Johnson
CONSUMER & PERSONAL PRODUCTS WORLDWIDE
Division of Johnson & Johnson Consumer Companies, Inc.

Energizer
Personal Care

February 1, 2012
Ms. Lydia Velazquez
Sr. Supervisor Regulatory
Division of Health and Human Services, Food and Drug Administration
10903 New Hampshire Avenue
Mail Stop HFD-560
Room WO22
Silver Springs, MD 20993

Re: Docket No. FDA-1978-N-0018, RIN number 0910-AF43

Revised Effectiveness Determination; Sunscreen Drug Products for Over-the-Counter Human Use: Proposed rule

Dear Ms. Velazquez,

On June 17, 2011, the Food and Drug Administration ("FDA" or "the Agency") published a proposed rule that would limit the Sun Protection Factor (SPF) label declaration to a maximum value of SPF 50+ for sunscreen drug products marketed under the authority of the over-the-counter (OTC) monograph for drug products containing sunscreen active ingredients. FDA based this proposal on its conclusion that products with SPF values above 50 had not been shown to provide additional clinical benefit.

In the proposed rule, FDA discussed a study by Russak et. al., which was intended to demonstrate the superiority of a SPF 85 sunscreen product over a SPF 50 product. The Russak study was a double-blind, split-face study of subjects at a high altitude ski resort using a SPF 50 product on one side of the face and a SPF 85 product on the other side of the face. In its evaluation of this study, FDA cited inadequacies in the reporting of the following:

- Amount of ultraviolet (UV) exposure for individual test subjects;
- Amount of sunscreen product applied by individual test subjects; and,
- Time of day of the UV exposure.

In addition, the Agency noted that after the initial application of each sunscreen product, the test subjects had been instructed explicitly not to reapply the sunscreen products during the UV exposure period.

In the proposed rule, the Agency stressed that it is important that any such studies be well-designed so that they could draw conclusions from them. The Agency recommended that any party interested in conducting these studies contact FDA prior to beginning the study.

The study design proposed in this protocol is intended to address the deficiencies of the Russak study, as cited by FDA. In addition, the study is intended to respond to FDA's request for demonstration of additional clinical benefit in more typical situations of sunlight exposure, such as exposure at outdoor festivals.

The proposed study repeats the essential elements of the Russak study design but will also gather the additional information that was found lacking in the original study. Individual subject exposure data will be gathered with time of day and UV exposure measurements. Product usage for each individual will be determined from test product weights prior to and after application. Based on available consumer data which indicates that as many as 58% of sunscreen users do not re-apply sunscreen, test subjects will be instructed to read product use instructions which contain the re-application instructions. There will be no instructions to the test subjects to prohibit re-application of the product, but rather instructions to use the product "as they normally would." The study is designed to determine whether under actual use conditions, sunscreen products with SPF greater than 50 offer a clinical benefit above that provided by sunscreen products with SPF 50.

Johnson & Johnson Consumer and Personal Products Worldwide Division of Johnson & Johnson Consumer Companies, Inc (JJCPPW) and Energizer Personal Care are seeking the Agency's comments and agreement for the proposed clinical plans to support sunscreen products with SPF values greater than 50. If you have any questions regarding the attached protocol, please do not hesitate to contact me at (908)-904-3717.

Sincerely,

Nadine M. Harrison
Director, Regulatory Affairs
Johnson & Johnson Consumer& Personal Products Worldwide

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