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*APPLICATION NUMBER:*

**22-009**

**PHARMACOLOGY REVIEW(S)**

## PHARMACOLOGY/TOXICOLOGY REVIEW

### NDA 22-009 Helioblock SX Sunscreen Cream (SPF) L'Oreal USA

Background: L'Oreal is submitting a 505(b)(1) for Helioblock SX sunscreen cream in an attempt to provide a product that absorbs UV radiation across a broad spectrum of light.

Helioblock SX contains 4 UVA/UVB filters: Ecamsule (USAN) (3% Mexoryl SX, a UVA filter, proprietary to L'Oreal), 2% avobenzone USP, 10% octocrylene USP and 5% titanium oxide USP. While the first 3 ingredients (ecamsule, avobenzone and octocrylene act as sunscreens that absorb light at different wavelengths titanium oxide acts to reflect, scatter, and possibly absorb UV and visible wavelengths of light.

While avobenzone, octocrylene and titanium oxide are all monograph OTC approved products, Ecamsule has been approved for use in the USA under NDAs 21-471, 21-501 & 21-502. Helioblock, which consists of all 4 products, has been studied in the USA under IND 57,850. Another NDA, 21-471, for Helioblock SX (also known as \_\_\_\_\_ SPF 20 water resistance) sunscreen lotion has been approved since 2005 and marketed by the same sponsor, L'Oreal Inc. b(4)

The sponsor has requested a partial exemption from PREA testing requirements for infants 6 months and younger. Sponsor supplied data for infants 6 months and older, up to 18 years of age.

#### Nonclinical safety issues relevant to clinical use:

Sponsor refers to the pharmacology/toxicology studies conducted and reviewed under IND 59,126 and the approved NDAs 21-471 \_\_\_\_\_ SPF 20 water resistant sunscreen lotion, WRSL), 21-501 ( \_\_\_\_\_ SPF 15 WRSL) and 21-502 \_\_\_\_\_ SPF 15 sunscreen moisturizing lotion) as well as IND 57,870 for the approvable NDA 21-469 (Helioblock SX cream, \_\_\_\_\_ cream). b(4)

Overall conclusions: No pharm/tox issues are pending. The reviewer relied on previous Agency's findings from already approved NDAs containing the same sunscreen ingredients included in this NDA. b(4)

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