EXHIBIT E

(Application Serial No. 87015660)

CFR - Code of Federal Regulations Title 21

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TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER D--DRUGS FOR HUMAN USE

PART 352 -- SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE [STAYED INDEFINITELY]

Subpart C--Labeling

Sec. 352.50 Principal display panel of all sunscreen drug products.

The active ingredient of the product consists of any of the following, within the concentration specified for each ingredient, and the finished product provides a minimum SPF value of not less than 2 as measured by the testing procedures established in subpart D of this part:

(a) Aminobenzoic acid (PABA) up to 15 percent.

(b) Avobenzone up to 3 percent.

(c) Cinoxate up to 3 percent.

(d) [Reserved]

(e) Dioxybenzone up to 3 percent.

(f) Homosalate up to 15 percent.

(g) [Reserved]

(h) Menthyl anthranilate up to 5 percent.

(i) Octocrylene up to 10 percent.

(j) Octyl methoxycinnamate up to 7.5 percent.

(k) Octyl salicylate up to 5 percent.

(l) Oxybenzone up to 6 percent.

(m) Padimate O up to 8 percent.

(n) Phenylbenzimidazole sulfonic acid up to 4 percent.

(o) Sulisobenzone up to 10 percent.

(p) Titanium dioxide up to 25 percent.

(q) Trolamine salicylate up to 12 percent.

(r) Zinc oxide up to 25 percent.

[64 FR 27687, May 21, 1999]

Effective Date Note:

At 67 FR 41823, June 20, 2002, 352.10 was amended by revising paragraphs (f) through (n), effective Sept. 1, 2002. This amendment could not be incorporated because at 66 FR 67485, Dec. 31, 2001, the effective date was stayed until further notice. For the convenience of the user, the revised text is set forth as follows:

(f) Ensulizole up to 4 percent.

(g) Homosalate up to 15 percent.

(h) [Reserved]

(i) Meradimate up to 5 percent.

(j) Octinoxate up to 7.5 percent.

(k) Octisalate up to 5 percent.

(l) Octocrylene up to 10 percent.

(m) Oxybenzone up to 6 percent.

(n) Padimate O up to 8 percent.

The SPF of any combination product is measured by the testing procedures established in subpart D of this part.

(a) *Combinations of sunscreen active ingredients.* (1) Two or more sunscreen active ingredients identified in 352.10(a), (c), (e), (f), and (h) through (r) may be combined with each other in a single product when used in the concentrations established for each ingredient in 352.10. The concentration of each active ingredient must be sufficient to contribute a minimum SPF of not less than 2 to the finished product. The finished product must have a minimum SPF of not less than the number of sunscreen active ingredients used in the combination multiplied by 2.

(2) Two or more sunscreen active ingredients identified in 352.10(b), (c), (e), (f), (i) through (l), (o), and (q) may be combined with each other in a single product when used in the concentrations established for each ingredient in 352.10. The concentration of each active ingredient must be sufficient to contribute a minimum SPF of not less than 2 to the finished product. The finished product must have a minimum SPF of not less than the number of sunscreen active ingredients used in the combination multiplied by 2.

(b) *Combinations of sunscreen and skin protectant active ingredients.* Any single sunscreen active ingredient or any permitted combination of sunscreen active ingredients when used in the concentrations established for each ingredient in 352.10 may be combined with one or more skin protectant active ingredients identified in 347.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r) of this chapter. The concentration of each sunscreen active ingredient must be sufficient to contribute a minimum SPF of not less that 2 to the finished product. The finished product must have a minimum SPF of not less than the number of sunscreen active ingredients used in the combination multiplied by 2, and the product must be labeled according to 352.60.

(c) [Reserved]

[64 FR 27687, May 21, 1999, as amended at 68 FR 33380, June 4, 2003]

At 67 FR 41823, June 20, 2002, 352.20 was amended by revising paragraphs (a)(1) through (a)(2), effective Sept. 1, 2002. This amendment could not be incorporated because at 66 FR 67485, Dec. 31, 2001 the effective date was stayed until further notice. For the convenience of the user, the text is set forth as follows:

(a) *Combinations of sunscreen active ingredients.* (1) Two or more sunscreen active ingredients identified in 352.10(a), (c), (e), (f), (g), and (i) through (r) may be combined with each other in a single product when used in the concentrations established for each ingredient in 352.10. The concentration of each active ingredient must be sufficient to contribute a

minimum SPF of not less than 2 to the finished product. The finished product must have a minimum SPF of not less than the number of sunscreen active ingredients used in the combination multiplied by 2.

(2) Two or more sunscreen active ingredients identified in 352.10(b), (c), (e), (g), (j) through (m), (o), and (q) may be combined with each other in a single product when used in the concentrations established for each ingredient in 352.10. The concentration of each active ingredient must be sufficient to contribute a minimum SPF of not less than 2 to the finished product. The finished product must have a minimum SPF of not less than the number of sunscreen active ingredients used in the combination multiplied by 2.

In addition to the statement of identity required in 352.52, the following labeling statements shall be prominently placed on the principal display panel:

(a) *For products that do not satisfy the water resistant or very water resistant sunscreen product testing procedures in 352.76* --(1) *For products with SPF values up to 30.* "SPF (insert tested SPF value of the product up to 30)."

(2) *For products with SPF values over 30.* "SPF 30" (select one of the following: "plus" or " + "). Any statement accompanying the marketed product that states a specific SPF value above 30 or similar language indicating a person can stay in the sun more than 30 times longer than without sunscreen will cause the product to be misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (the act).

(b) *For products that satisfy the water resistant sunscreen product testing procedures in 352.76.* (1) (Select one of the following: "Water," "Water/Sweat," or "Water/Perspiration") "Resistant."

(2) "SPF (insert SPF value of the product, as stated in paragraph (a)(1) or (a)(2) of this section, after it has been tested using the water resistant sunscreen product testing procedures in 352.76)."

(c) *For products that satisfy the very water resistant sunscreen product testing procedures in 352.76.* (1) "Very" (select one of the following: "Water," "Water/Sweat," or "Water/Perspiration") "Resistant."

(2) "SPF (insert SPF value of the product, as stated in paragraph (a)(1) or (a)(2) of this section, after it has been tested using the very water resistant sunscreen product testing procedures in 352.76)."

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