FDA OTC REVIEW PROCESS

• August 25, 1978
  – Proposed Monograph (ANPR)
• May 12, 1993
  – Tentative Final Monograph
• May 21, 1999
  – Final Monograph
  – Legal status for manufacturers
    • 2 years
    • 3 years for cosmetic warnings
    • *Put on hold until 2005*
ULTRAVIOLET RADIATION

• UVB (290-320 nm; Sunburn Radiation)
  – Erythema (sunburn)
  – Vitamin D$_3$ synthesis
  – Skin cancer
  – Peak levels reach surface > 10:00 am - 3:00 pm
ULTRAVIOLET RADIATION

- **UVA (320 - 400 nm)**
  - Negligible erythema
  - Penetrates deeper into skin than UVB
    - Vascular and other tissue damage
    - Affects immune system (photoimmunology)
    - Greater effect on dermis than UVB
  - Augments the cancer-producing effects of UVB.
  - Produces photosensitivity (primarily)
ULTRAVIOLET RADIATION

• UVA (320 - 400 nm)
  – 2 Sub-bands
    • UVA II: 320-340 nm
      – Less epidermal skin damage than UVB
    • UVA I: 340-400 nm
      – Higher incidence of photosensitivity than UVA II
LONG-TERM HAZARDS

• Malignant Changes
  – Premature Actinic Keratoses
    • Develop into SCC
  – Basal Cell Carcinoma (BCC)
    • 800,000 new cases in 2002 (ACS)
    • mortality rate < 0.5%
  – Squamous Cell Carcinoma (SCC)
    • 160,000 new cases in 2002 (ACS)
    • Deaths are rare
LONG-TERM HAZARDS

• Malignant Changes
  – Melanoma
  • 53,600 new cases in 2002 (ACS Cancer Facts & Figures 2002 – American Cancer Society)
  • 7,400 deaths (mortality rate = 14%)

American Academy of Dermatology: Skin Cancer Facts
LONG-TERM HAZARDS

• Premature Aging
  – Elastosis
  – Drying/Thinning/Wrinkling
  – Telangectasia
    • spider vessels
  – Ecchymoses
    • subcutaneous hemorrhagic lesions
  – Others
USES (INDICATIONS) FOR SUNSCREENS

• PHOTOSENSITIVITY (mainly UVA)
  – Photoallergy
    • 5% of cases
    • Immunologic response to radiation
    • Urticaria, bullae, exaggerated sunburn
  – Phototoxicity
    • 95% of cases
    • Non-immunologic response to radiation
    • Exaggerated sunburn
USES (INDICATIONS) FOR SUNSCREENS

- Phototoxicity
  - anticancer drugs
  - antidepressants
  - antihistamines
  - antimicrobials
  - diuretics
  - hypoglycemics
  - NSAIDS
  - Antipsychotic agents
USES (INDICATIONS) FOR SUNSCREENS

• Phototoxicity
  – Sunscreens
    • Benzophenones
      – oxybenzone*, dioxybenzone, sulisobenzone
    • Cinnamates
      – cinoxate, diethanolamine methoxycinnamate, octyl methoxycinnamate, octocrylene
    • Aminobenzoic acid & derivatives
      – Padimate O
      – Ethyl 4-[bis(hydroxypropyl)] aminobenzoate (No)
      – Glyceryl aminobenzoate (No)
USES (INDICATIONS) FOR SUNSCREENS

- PHOTODERMATOSES (more than 40)
  - Induced by UVR
    - Polymorphic Light Eruption (PMLE)
  - Exacerbated by UVA
    - Systemic Lupus Erythematosus (SLE)
INDICATIONS FOR SUNSCREENS

• 1. Helps prevent sunburn
• 2. Provides protection against tanning
• Old statements from TFM:
  – *Helps prevent lip damage*
  – *Helps prevent skin damage*
  – *Helps prevent freckling*
  – *Helps prevent uneven coloration*
  – *Permits tanning*
• “Anti-aging” - unapproved new drug
USES (INDICATIONS) FOR SUNSCREENS

• FDA allows an optional “sun alert” on the label: “Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.”
MEASURES OF PROTECTION

• Minimal Erythema Dose (MED)
• Sun Protection Factor (SPF)
• UVA protection factor
  – No approved method as yet
  – Should appear in the final monograph
  – Claims of UVA protection: product spectrum must extend to at least 360 nm. (will be addressed with all UVA issues at a later date.)
PRODUCT INFORMATION

• 16 Agents are safe and effective
  – 14 chemical agents
  – 2 physical agents
• Strengths - only maximum strengths listed due to role of formulation
• Dihydroxyacetone (DHA) - cosmetic
PRODUCT INFORMATION

• Avobenzone - dibenzoylmethane derivative
• Currently found in two products
• Shade UVAGUARD SPF–15 (Schering-Plough)
  – Avobenzone 3%
  – Oxybenzone 3%
  – Octyl Methoxycinnamate 7.5%
• PreSun Ultra SPF-30
  – Same formula as above plus…
  – Octyl Salicylate 5%
PRODUCT INFORMATION

• Rationale for this formula:
  – Octyl methoxycinnamate > 290-320 nm (310)
  – Oxybenzone >>>>>>>>>> 270-350 nm (290)
  – Avobenzone >>>>>>>>>> 320-400 nm (360)
  – Octyl Salicylate >>>>>>>> 280-320 nm (305)
PRODUCT SELECTION

• SPF Protection
  – Maximum SPF 30 (SPF 30+ or 30plus)
    • Increased potential for adverse effects
    • Increased cost
  – Amount of UVB protection based on SPF
    • SPF 15 blocks 93.0% of UVB
    • SPF 30 blocks 96.7% of UVB
    • SPF 40 blocks 97.5% of UVB
    • SPF 70 blocks 98.6% of UVB
  – As SPF goes up, so does UVA protection.*
PRODUCT SELECTION

• Broad Spectrum
  – Sunscreen product that extends up to at least 360 nm, and
  – Contains sunscreen agent which absorbs/reflects in UVB range.

• Provides more UVA protection than a product that is not broad spectrum. (It is NOT necessarily “full spectrum” coverage)
PRODUCT SELECTION

• UVA vs. UVB
  – Photosensitizing drugs - UVA protection
    • Broad spectrum product
    • Avobenzone produce
  – Photodermatoses - UVA protection
    • Broad spectrum product
    • Shade UVAGUARD
  – Until UVA protection factor approved, use high SPF (30+)
  – Sunburn - use highest SPF product
PRODUCT SELECTION

– ALLERGY TO SUNSCREEN
(avoid these?!)

• Benzophenones
  – oxybenzone*, dioxybenzone, sulisobenzone

• Cinnamates
  – cinoxate, octyl methoxycinnamate, octocrylene

• Aminobenzoic acid & derivatives
  – Padimate O
PRODUCT SELECTION

• Substantivity - ability of product to adhere to the skin.
• The more substantive, the longer the protection.
  – water resistant: retains its sun protection for at least 40 minutes in the water.
  – very water resistant: retains its sun protection for at least 80 minutes in the water.
• “Waterproof” - not allowed
PATIENT COUNSELING

• SPF use
  – Protection
    • use high SPF product
    • avoid 10 am - 3 pm
  – Tanning
    • Start with SPF appropriate for skin type
    • Taper SPF as tan develops
PATIENT COUNSELING

• Substantivity
  – The more substantive, the better.
  – The more substantive, the more expensive.
  – Follow label directions for re-application.
PATIENT COUNSELING

• Photosensitivity
  – Wear protective clothing.
  – Wear hat.
  – Apply sunscreen (UVA type) to exposed areas of skin.
PATIENT COUNSELING

• UV exposure (amount of penetration)
  – Clouds       >>  90%
  – Clothing, wet >>  50%
  – Swimming     >>  90%
  – Sand (white, higher) >>  4%
  – Snow (reflects up) >>  90%
  – Window glass
    • UVA       >>  100%
    • UVB       >>  0%
PATIENT COUNSELING

- Application (22.5 mL)
  - Face & Neck 1/2 tsp
  - Arm & Shoulder 1/2 tsp to each side
  - Torso 1/2 tsp to front & to back
  - Leg & top of foot 1 tsp to each side

- Question: How long have you had your current bottle of sunscreen?
LABELING

- Waiting period between application and exposure - up to the manufacturer to determine if needed and the wording.
- “All Day Protection” & similar wording is considered nonmonograph.
- “Keep out of eyes. Rinse with water to remove.”
- “Children under 6 months of age: ask a doctor.”
- “Sunblock” - not allowed
QUESTIONS?
LEARNING OBJECTIVES

The student will be able to….

• COMPARE and CONTRAST the types of radiation.
• DESCRIBE briefly the short- and long-term hazards of UVR.
• LIST/SELECT and DESCRIBE briefly the approved and unapproved indications for sunscreens.
• DESCRIBE briefly each of the following:
  – MED
  – SPF
  – UVA protection
• LIST/SELECT those agents that are safe and effective.
• DESCRIBE briefly the term substantivity.
• COMPARE and CONTRAST tanning beds and booths to solar radiation and DESCRIBE briefly the associated hazards.
• DESCRIBE briefly the role of sunglasses in eye protection.
LEARNING OBJECTIVES
The student will be able to….

• DESCRIBE briefly each of the following:
  – Pigmenting agents
  – Oral agents
  – Tan accelerators

• DESCRIBE briefly the proposed changes in the TFM.

• LIST/SELECT and DESCRIBE briefly the criteria for drug product selection for patients of all ages and medical conditions.

• LIST/SELECT and DESCRIBE briefly all appropriate patient counseling on how to prevent injury and long-term damage from UVR.

• LIST/SELECT and DESCRIBE briefly all appropriate patient counseling for the proper use of sunscreen agents.

• Given a patient situation, SELECT the appropriate product and counsel the patient on its use.