



U.S. Food and Drug Administration

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CENTER FOR DRUG EVALUATION AND RESEARCH

Sunscreens Marketed Under the OTC Monograph System

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What is an OTC Drug Monograph?

- “Recipe book” for marketing an OTC drug
- To read OTC monograph documents:
 - <http://www.fda.gov/OTCrulemaking>
 - Final OTC monographs: 21 CFR parts 331-358
 - Final OTC sunscreen monograph: 21 CFR 352
 - Currently stayed (Not made effective)
- List of GRASE conditions
GRASE = Generally Recognized As Safe and Effective



What is included in an OTC Drug Monograph?

- **Active ingredients**
 - dosage strength
 - dosage form
- **Labeling requirements**
 - indications
 - warning & directions
- **Final formulation testing**

- **Label example**

Drug Facts	
Active ingredient	Purpose
Benzoyl peroxide 10%	Acne treatment cream
Uses ■ treats acne ■ dries up acne pimples ■ helps prevent new acne pimples	
Warnings	
For external use only	
Do not use ■ on broken skin ■ on large areas of the body	
When using this product	
■ apply to affected areas only ■ avoid unnecessary sun exposure and use a sunscreen	
■ do not use in or near the eyes ■ this product may bleach hair or dyed fabrics	
■ using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. Only one drug should be used unless directed by a doctor.	
Stop use and ask a doctor if too much skin irritation or sensitivity develops or increases	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
■ clean the skin thoroughly before applying ■ cover the entire affected area with a thin layer 1 to 3 times daily	
■ because too much drying of the skin may occur, start with 1 application daily, then gradually increase to 2 to 3 times daily if needed or as directed by a doctor	
■ if bothersome dryness or peeling occurs, reduce application to once a day or every other day	
■ if going outside, use a sunscreen. Allow benzoyl peroxide to dry, then follow directions in the sunscreen labeling.	
Other information store at 20-25°C (68-77°F)	
Inactive ingredients aluminum hydroxide gel, bentonite, carbomer-940, dimethicone, glyceryl stearate SE, isopropyl myristate, methylparaben, PEG-12, potassium hydroxide, propylene glycol, propylparaben, purified water	



How is an OTC Monograph Created?

- “The OTC Drug Review” (21 CFR 330), 1972 – present
- <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm106368.htm>
- Three-step rulemaking process

1. Advance Notice of Proposed Rulemaking

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Parts 330, 342, and 343
Notice of Proposed Rulemaking

OTC Drug Products for Over-the-Counter Human Use: Final Monograph

Summary: The Food and Drug Administration (FDA) is announcing a notice of proposed rulemaking (NPRM) to revise the OTC drug monograph for over-the-counter (OTC) drug products. The OTC drug monograph is a list of OTC drug products that are generally recognized as safe and effective (GRASE) for use without a prescription. The OTC drug monograph is published in the Federal Register of August 19, 1992 (57 FR 40141).

Background: The OTC drug monograph is a list of OTC drug products that are generally recognized as safe and effective (GRASE) for use without a prescription. The OTC drug monograph is published in the Federal Register of August 19, 1992 (57 FR 40141).

Comments: The OTC drug monograph is a list of OTC drug products that are generally recognized as safe and effective (GRASE) for use without a prescription. The OTC drug monograph is published in the Federal Register of August 19, 1992 (57 FR 40141).

FOR FURTHER INFORMATION CONTACT: Gerald M. Berkman, Center for Drug Evaluation and Research, 2020

2. Tentative Final Monograph (Proposed Rule)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Parts 330, 342, and 343
Notice of Proposed Rulemaking

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3. Final Monograph (Final Rule)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Parts 330, 342, and 343
Final Rule

OTC Drug Products for Over-the-Counter Human Use: Final Monograph

Summary: The Food and Drug Administration (FDA) is announcing a final rule to revise the OTC drug monograph for over-the-counter (OTC) drug products. The OTC drug monograph is a list of OTC drug products that are generally recognized as safe and effective (GRASE) for use without a prescription. The OTC drug monograph is published in the Federal Register of August 19, 1992 (57 FR 40141).

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1. Advance Notice of Proposed Rulemaking
2. Tentative Final Monograph (Proposed Rule)
3. Final Monograph (Final Rule)



FDA's Sunscreen Rulemaking History

- **1978 Advance Notice of Proposed Rulemaking**
- **1993 Proposed Rule**
- **1996 Proposed Rule: Avobenzone**
- **1998 Proposed Rule: Zinc oxide**
- **1999 Final Rule (requirements stayed in 2001)**
- **2007 Proposed Rule: UVA testing/labeling**

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/ucm072134.htm>



FDA's Sunscreen Rulemaking History (cont.)

June 17, 2011 documents

- **2011 Final Rule: Testing & Labeling Requirements**
- **2011 Proposed Rule: Maximum Labeled "SPF 50+"**
- **2011 Advance Notice of Proposed Rulemaking: Dosage Forms**
- **2011 Draft Guidance: FDA Enforcement Policy**

www.fda.gov/sunscreen



2011 Final Rule: Testing & Labeling Requirements

- **21 CFR 201.327**
(Not 21 CFR 352, designated part for OTC sunscreen monograph)
- **Effective date: June 18, 2012**



2011 Final Rule: SPF Testing

- **in vivo MED (minimum erythematol dose) test**
- **10-13 human subjects; ≥ 10 valid results**
- **Updated solar simulator specifications**

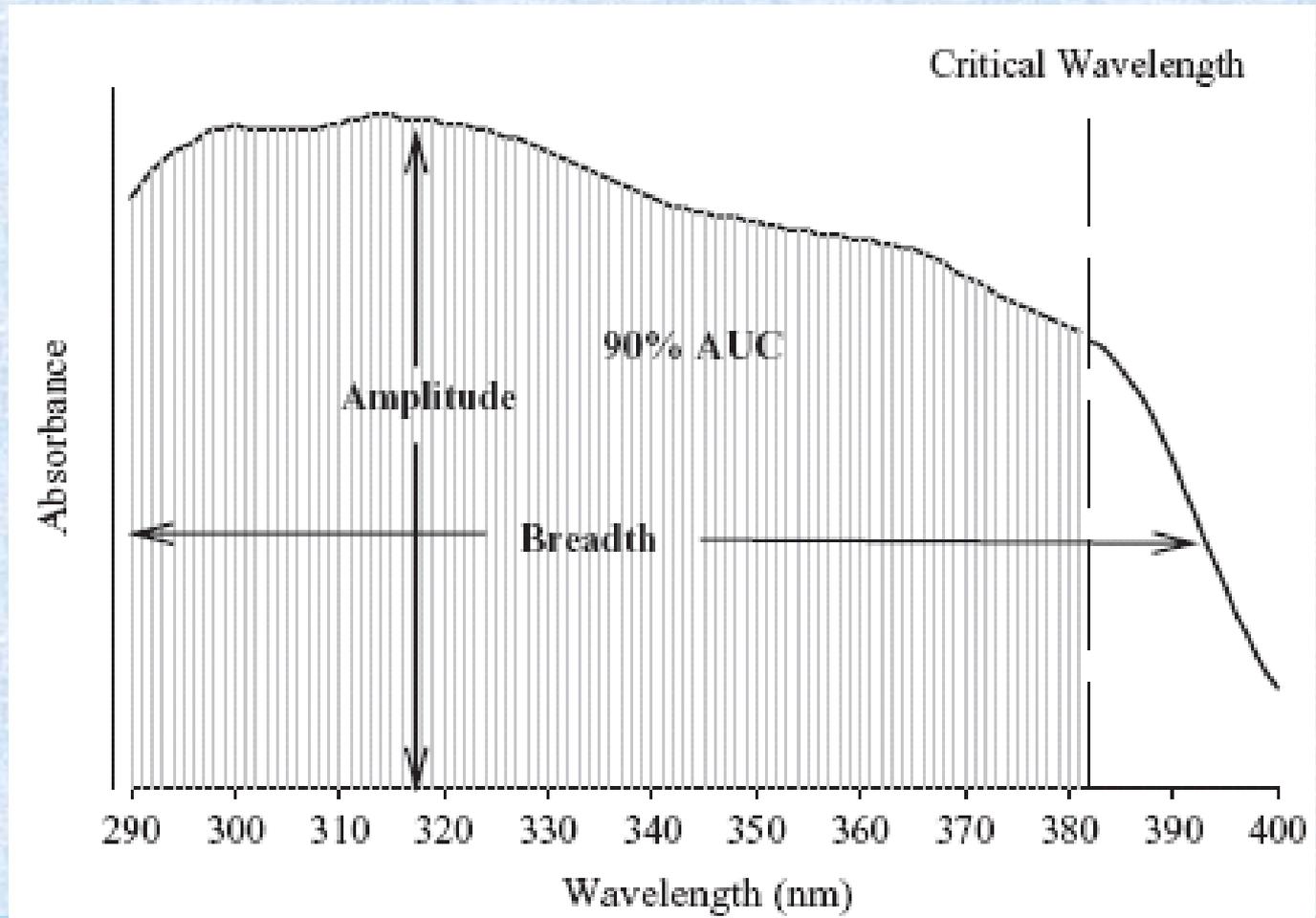


2011 Final Rule: Broad Spectrum Testing

- **in vitro test; pass/fail (critical wavelength > 370 nm)**
- **Accurate, reproducible**
- **Simple to perform**
- **Experience with use**



2011 Final Rule: Broad Spectrum Testing (cont.)





2011 Final Rule: Labeling Principal Display Panels





2011 Final Rule: Drug Facts Labeling

For Broad Spectrum SPF 15 or higher:

Use(s)

- helps prevent sunburn
- if used as directed with other sun protection measures (see *Directions*), decreases the risk of skin cancer and early skin aging caused by the sun

Directions

Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m. - 2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses

For non-Broad Spectrum or SPF<15:

Use(s)

- helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging



2011 Final Rule: Drug Facts Labeling (cont.)

- For water resistant products:

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
 - after 40 [or 80] minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- children under 6 months: Ask a doctor

- For non-water resistant products:

Directions

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: Ask a doctor

- Sunscreen-cosmetic products: Inactive ingredients should be listed in order of decreasing concentration in the product



2011 Final Rule: Unallowed Label Claims

- **“sunblock”**
- **“sweatproof”**
- **“waterproof”**
- **“all-day” or extended wear claims**
- **instant protection**



Sunscreen Active Ingredients

- **The only currently permitted sunscreen active ingredients are the 16 listed in the 1999 sunscreen final rule.**
 - 21 CFR 352.10 Sunscreen active ingredients
- **FDA is continuing to evaluate sunscreen active ingredients.**
- **FDA is continuing to evaluate time & extent applications for new sunscreen active ingredients not previously marketed in the U.S.**



Sunscreen Active Ingredient Combinations

- **The only currently permitted combinations are those listed in the 1999 sunscreen final rule.**
 - 21 CFR 352.20 Permitted combinations of active ingredients
- **Certain avobenzone combinations are permitted.**
 - 1997 Announcement of Enforcement Policy (Federal Register, Vol. 62, No. 83; April 30, 1997)
 - Avobenzone + Ensulizole is not currently allowed.



Drug Registration & Listing

- **21 CFR 207.20: All establishments that manufacture, prepare, propagate, compound or process a drug must register and list commercially distributed products.**
- **<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm084014.htm>**



Expiration Dates

- **21 CFR 211.166(b): cGMPs, “Stability testing”**
 - All drugs must be tested to determine an appropriate expiration date.
- **21 CFR 201.17: Expiration date must appear on immediate container and outer package**
- **21 CFR 211.137(h): Exemption from expiration dating for OTC drugs that have:**
 - Data demonstrating ≥ 3 years stability; no dosing limitations
 - “Pending consideration”
- **USP monographs contain packing & storage requirements**



2011 Proposed Rule: Maximum Labeled “SPF 50+”

- 1978 ANPR: “SPF 15”
- 1993 Proposed Rule: “SPF 30”
- 1999 Final Rule: “SPF 30+”
- 2007 Proposed Rule: “SPF 50+”
- 2011 Proposed Rule: “SPF 50+”



2011 Proposed Rule: Maximum Labeled “SPF 50+”

- **Request data demonstrating SPF>50 product provides additional benefit**
- **SPF test accuracy & reproducibility acceptable for products up to SPF 80**



2011 Advance Notice of Proposed Rulemaking: Dosage Forms

- **Oils, creams, lotions, gels, butters, pastes, ointments, sticks, and sprays eligible for inclusion in the OTC sunscreen monograph**
- **Wipes, towelettes, powders, body washes, shampoos not eligible**



2011 Advance Notice of Proposed Rulemaking: Dosage Forms (cont.)

Sprays

- **Eligible for inclusion in final OTC sunscreen monograph**
- **Remaining effectiveness & safety concerns**
 - No information on how sprays are applied
 - Potential safety concern with inhalation



2011 Draft guidance: FDA Enforcement Policy

- **Broad spectrum test not required (Certain labeling claims reserved for “Broad Spectrum” products)**
- **SPF values over 50 allowed during pendency of 2011 Proposed Rule**
- **Oils, creams, lotions, gels, butters, pastes, ointments, sticks, and sprays are not subject to regulatory action if they comply with 2011 Final Rule & Draft Guidance**
- **Sunscreen-insect repellent combinations: Comply with EPA and FDA requirements as closely as possible**



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Thank You

www.fda.gov/sunscreen