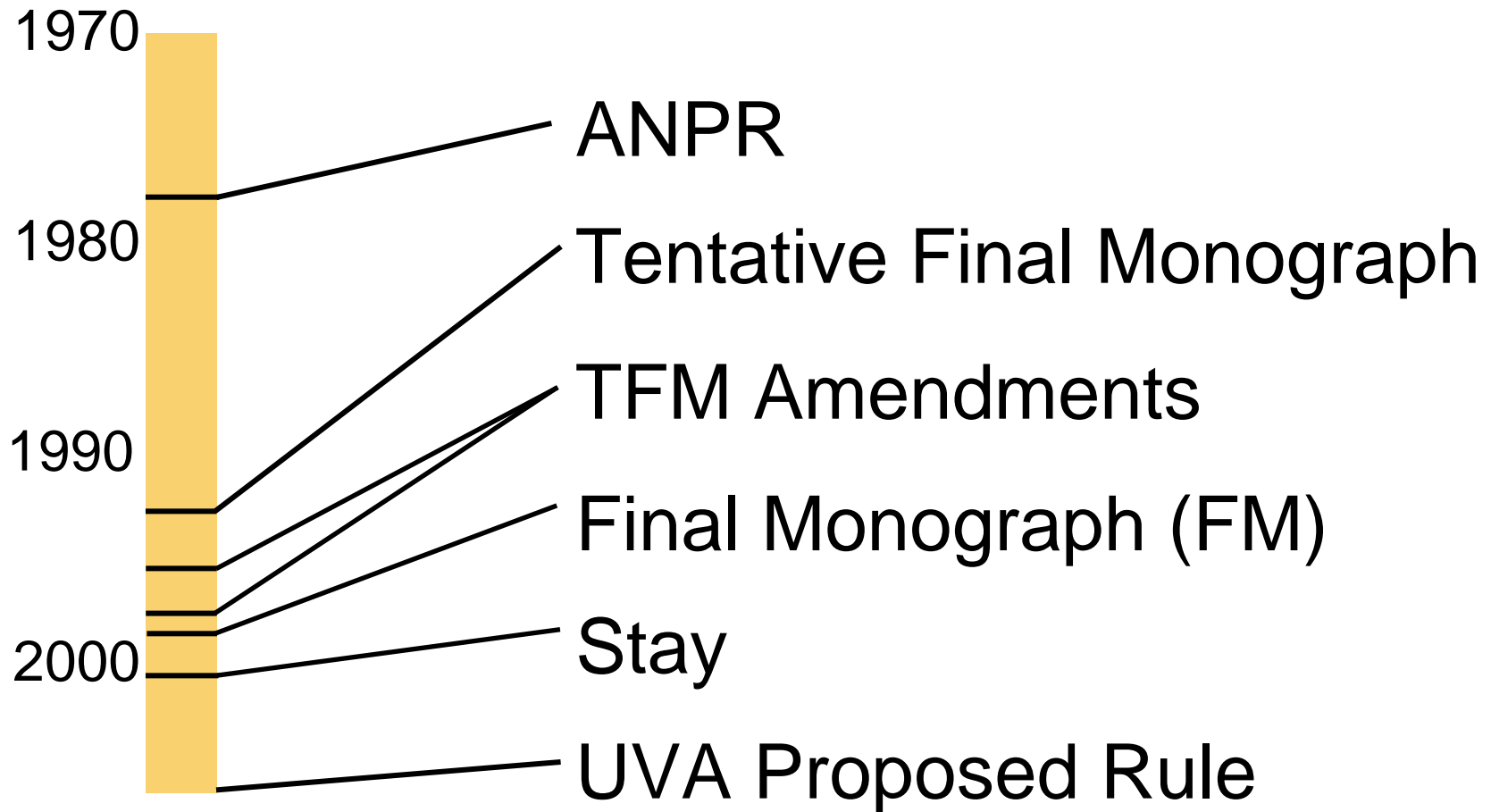


# Current Status

A final monograph was published in 1999, but is not in effect. The effective date, originally set as May 21, 2001, has been stayed indefinitely so that FDA can address sunscreen protection against both UVA and UVB radiation. Sunscreen manufacturers are encouraged, but not required, to adhere to the regulations set forth in the 1999 final monograph.

# Monograph History



# ANPR

## Advance Notice of Proposed Rulemaking (1978)

Report of the Advisory Review Panel  
considering which sunscreen ingredients  
could be considered safe and effective.

- Labeling
- SPF Testing

# TFM

## Tentative Final Monograph (1993)

FDA's position on the safety and effectiveness of sunscreen ingredients based, in part, on comments received from the public since the ANPR published.

# TFM Amendment

(1996)

This amendment to the 1993 TFM added the UVA filter avobenzone to the list of ingredients considered safe and effective sunscreens.

# TFM Amendment

(1998)

This amendment to the TFM added zinc oxide to the list of ingredients considered safe and effective sunscreens.

# Final Monograph

(1999)

The final monograph established conditions under which OTC sunscreen drug products are considered safe and effective. The document set labeling and testing standards for OTC sunscreens providing UVB protection.

# Stay of Final Monograph

(2001)

This action delayed the effective date of the final monograph until FDA could address formulation, labeling and testing requirements for sunscreens providing UVA protection. FDA also anticipated making changes to the requirements for sunscreens providing UVB protection.



# UVA Proposed Rule

(2006)

This document proposes to amend the final monograph to include formulation, labeling and testing requirements for sunscreens providing UVA protection. FDA also proposes changes to the requirements for sunscreens providing UVB protection.