

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 352

[Docket No. 78N-0038]

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DMS

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Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph; Partial Stay; Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; partial stay.

SUMMARY: The Food and Drug Administration (FDA) is staying the final monograph for over-the-counter (OTC) sunscreen drug products that published in the **Federal Register** of May 21, 1999 (64 FR 27666). The final monograph established conditions under which OTC sunscreen drug products are generally recognized as safe and effective and not misbranded. This stay of effective date applies to all OTC sunscreen drug products that would be regulated under part 352 (21 CFR part 352). This action does not stay the effective date for products that would be regulated under parts 310 and 700 (21 CFR parts 310 and 700). This action is being taken because the agency will be amending part 352 to address formulation, labeling, and testing requirements for both ultraviolet A (UVA) radiation protection and ultraviolet B (UVB) radiation protection. This action is part of FDA's ongoing review of OTC drug products.

DATES: This rule is effective *[insert date 30 days after date of publication in the **Federal Register**]*. Part 352 added at 64 FR 27666 at 27687, is stayed until further notice. Written or electronic comments by *[insert date 90 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2307.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 21, 1999, FDA published a final rule in the form of a final monograph for OTC sunscreen drug products in part 352. The monograph included 16 active ingredients, required labeling for products that contain one or more of these active ingredients, a standardized test for measuring sun protection factor (SPF) values, and standard methods for measuring the water resistant properties of sunscreens. The labeling and test methods covered products intended to provide UVB radiation protection. The monograph did not, however, address active ingredients, labeling, and test methods for products intended to provide UVA protection. The final rule also included related nonmonograph conditions in § 310.545(a)(29) (21 CFR 310.545(a)(29)) and new § 700.35 (21 CFR 700.35), which addressed labeling for cosmetic products that contain sunscreen active ingredients for nontherapeutic, nonphysiologic uses (e.g., as a color additive or to protect the color of the product). The agency set a 2-year effective date (May 21, 2001) for part 352 and for 310.545(a)(29) and 700.35.

In the **Federal Register** of June 8, 2000 (65 FR 36319), the agency extended the effective date for all OTC sunscreen drug and cosmetic products that would be regulated under parts 310, 352, and 700 to December 31, 2002. The agency stated that this extension would be in the public interest as the agency developed a comprehensive sunscreen final monograph that addresses formulation, labeling, and testing requirements for both UVB and UVA radiation protection under part 352. The agency stated in this notice that it intended to move forward and publish a proposed

rule for a comprehensive final monograph, receive comments on that proposal, and issue a final rule by December 31, 2001. That final rule would then have a 1-year effective date of December 31, 2002.

II. Stay of Part 352

The June 8, 2000, extension of effective date also included a reopening of the administrative record to allow for comment on specific information the agency requested in that document. The comment period closed on September 6, 2000. Since that time, the agency has been developing a proposed amendment to part 352 that addresses both UVB and UVA radiation protection.

The agency expects to publish the proposal to amend part 352 next year. Following that publication, there will be a comment period and then the agency will prepare an amended final monograph for publication in a future issue of the **Federal Register**. Because the agency has not yet published the proposed amendment to part 352, it is not possible for manufacturers of OTC sunscreen drug products to relabel and test their products in accord with an amended final monograph by the current effective date of December 31, 2002.

Accordingly, the agency is staying part 352 until further notice is provided in a future issue of the **Federal Register**. The agency will propose a new effective date for part 352 within the proposed amendment. The agency anticipates that this new effective date will not be before January 1, 2005.

This stay of effective date does not apply to parts 310 or 700, because the amendment of the monograph in part 352 has no effect on the requirements in these parts. The agency has already extended the effective dates for parts 310 and 700 to December 31, 2002, and finds there is no reason to further extend that date.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. (553(b)(3)(A). Alternatively, the agency's implementation of this action without opportunity for public comment comes within the good cause exceptions in 5 U.S.C. 553(b)(3)(B) and (d)(3) in that obtaining public comment is impracticable,

unnecessary, and contrary to the public interest. The agency is staying part 352 because the agency has determined that it is not possible for manufacturers of OTC sunscreen drug products to relabel and test their products in accord with an amended final monograph by the current effective date of December 31, 2002. The agency intends to publish a proposal to amend part 352 next year in order to develop a comprehensive sunscreen monograph that addresses formulation, labeling, and testing requirements for both UVB and UVA radiation protection. This amendment will propose a new effective date for part 352. Thus, there will be an opportunity for public comment on the new effective date within the proposed amendment to part 352. In accordance with 21 CFR 10.40(e)(1), FDA is providing an opportunity for comment on whether this partial stay should be modified or revoked.

III. Analysis of Impacts

The economic impact of the final monograph was discussed in the final rule (64 FR 27666 at 27683). The economic impact of the extension of the effective date of the monograph until December 31, 2002, was discussed in the final rule extending that date (65 FR 36319 at 36323). This stay of the effective date provides additional time for companies to relabel and retest products, eliminates a second relabeling of sunscreen drug products when UVA labeling is included in the monograph, and reduces label obsolescence, as there will be additional time to use up more existing labeling. Thus, staying the effective date will significantly reduce the economic impact on industry.

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612), as amended by subtitle D of the Small Business Regulatory Fairness Act, and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze

regulatory options that would minimize any significant impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation).

The agency concludes that this final rule is consistent with the regulatory philosophy and principles set out in the Executive order and in these two statutes. The final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order. FDA has determined that the final rule does not have a significant economic impact on a substantial number of small entities. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed \$100 million adjusted for inflation.

The purpose of this final rule is to stay the effective date of the final monograph for OTC sunscreen drug products in part 352. This will provide additional time for manufacturers to relabel and retest products and to use up existing product labeling. The agency encourages manufacturers who use up their existing product labeling before the amended final monograph is issued to prepare new labeling in accord with the existing final monograph in part 352 in the format set forth in § 201.66 (21 CFR 201.66). Accordingly, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

IV. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Environmental Impact

The agency has determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

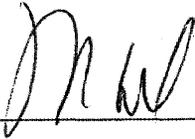
VII. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this rule by *[insert date 90 days after date of publication in the Federal Register]*. Three copies of all written comments are to be submitted. Individuals submitting written comments or anyone submitting electronic comments may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This final rule (partial stay) is issued under sections 201, 501, 502, 503, 505, 510, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, and 371) and under authority delegated to the Commissioner of Food and Drugs.

Dated: 12/21/01

December 21, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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