4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 310

[Docket No. FDA-1978-N-0018] (formerly Docket No. 1978N-0038)

RIN 0910-AF43

Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use; Delay of Compliance Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of compliance dates; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is delaying the compliance dates for the final rule for over-the-counter (OTC) sunscreen drug products that published in the Federal Register of June 17, 2011 (76 FR 35620). The final rule establishes labeling and effectiveness testing for certain OTC sunscreen products containing specified active ingredients and marketed without approved applications. It also amends labeling claims that are not currently supported by data and lifts the previously-published delay of implementation of the Drug Facts labeling requirements for OTC sunscreens. The 2011 final rule's compliance dates are being delayed because information received after publication of the 2011 final rule indicates that full implementation of the 2011 final rule's requirements for all affected products will require an additional 6 months. This final rule is part of FDA's ongoing review of OTC drug products.

DATES: Effective Date: This final rule is effective June 18, 2012. The final rule published at 76 FR 35620 on June 17, 2011, remains effective June 18, 2012.

Comment date: Submit written or electronic comments on the delay of compliance dates by [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Compliance Dates: The compliance dates for the final rule published at 76 FR 35620 on June 17, 2011, including the lifting of the delay of implementation date for 21 CFR 201.66 as published at 69 FR 53801, September 3, 2004, are delayed until December 17, 2013, for products with annual sales of less than $25,000, and until December 17, 2012 for all other products subject to the rule.

ADDRESSES: You may submit comments, identified by Docket No. FDA-1978-N-0018 (formerly Docket No. 1978N-0038) and RIN number 0910-AF43, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name, Docket No. FDA-1978-N-0018 (formerly Docket No. 1978N-0038), and RIN 0910-AF43 for this rulemaking. All

comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov, insert the docket numbers, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of June 17, 2011, a final rule was published for OTC sunscreen products (hereafter referred to as "2011 final rule"). The 2011 final rule established labeling and effectiveness testing requirements for certain OTC sunscreen products containing specified active ingredients and marketed without approved applications, to be codified in the Code of Federal Regulations (CFR) at § 201.327 (21 CFR 201.327) (which is effective June 18, 2012). It also amended § 310.545 (21 CFR 310.545) to classify as new drugs, requiring premarket

approval, sunscreens labeled with certain claims (claims for “instant protection” or protection immediately upon application, or claims for “all-day" protection or extended wear claims citing a specific number of hours of protection that is inconsistent with the directions for application in § 201.327). Finally, it lifted the delay of implementation of the Drug Facts regulation, § 201.66 (21 CFR 201.66), published at 69 FR 53801, September 3, 2004, requiring those products to comply with § 201.66 on the same date as they would be required to comply with § 201.327 (76 FR 35620 at 35629). The 2011 final rule had an effective date of June 18, 2012, which was 1 year following publication of the final rule. For OTC sunscreen products with annual sales of $25,000 or more, the 2011 final rule had a compliance date of June 18, 2012. For OTC sunscreen products with annual sales of less than $25,000, the 2011 final rule had a compliance date of June 17, 2013.

The 2011 final rule explains why these effective and compliance dates were chosen (76 FR 35620 at 35623 through 35624). The primary reason for a 1-year effective date and compliance date for the majority of products was that FDA chose a simpler and less expensive testing method to demonstrate broad spectrum activity than had been originally proposed. Because a simpler testing method was chosen, it was projected that most OTC sunscreen drug products could be brought into compliance with the new testing and labeling requirements within 1 year.

Following publication of the 2011 final rule, a request to extend the period for implementation of the 2011 final rule by 6 months was submitted to FDA by The Personal Care Products Council (PCPC) and The Consumer Healthcare Products Association (CHPA), which are trade associations for the cosmetic and personal care products industry and the OTC drug products industry, respectively, in the United States (Ref. 1). PCPC and CHPA consolidated

comments from its member companies in this submission. The submission provided several reasons, and supporting information, for requesting the additional time for implementation. Based on this submission, FDA is extending the compliance dates for the 2011 final rule, as explained in the paragraphs that follow.

II. Discussion of Rationale for Delay

FDA is delaying the compliance dates of the 2011 final rule by 6 months, to December 17, 2012, for products with sales of $25,000 or more, and until December 17, 2013, for products with annual sales of less than $25,000. The 2011 final rule requirements are intended to ensure that OTC sunscreen products are used safely and effectively. Therefore, allowing adequate time for the 2011 final rule requirements to be fully implemented is in the interest of public health. Our reassessment of the time needed for full implementation of the 2011 final rule requirements supports delaying the compliance dates by 6 months.

FDA finds that the information provided by the PCPC/CHPA submission, describing the process for testing and relabeling sunscreen products, supports the requested extension of the time for compliance with the 2011 final rule. The submission included an operational timeline that detailed the numerous steps involved in implementation of the new labeling requirements for a given product, and included specific time estimates for the different stages of implementation (Ref. 1). The operational timeline's time estimates were calculated by taking the average of time estimates calculated by PCPC's and CHPA's member companies. The submission stated that complete implementation of new labeling could not be achieved by June 18, 2012, particularly for sunscreen products that: (1) Had complex label redesign issues and (2) required broad spectrum testing. Complex label redesign issues included contending with special production techniques to implement relabeling (e.g., glass or plastic bottles that require embossing),

incorporating complete Drug Facts panel labeling, and coordinating relabeling of product lines with many variants. The submission also estimated that because of the substantial number of existing or new formulations that would need to undergo broad spectrum testing and the limited capacity of testing facilities, it would require approximately 10 months for industry to complete the broad spectrum testing for all products. The overall operational timeline provided in the submission indicates that testing and other necessary label redesign issues could not be completed for all products in time for labeling consistent with those test results to be applied to products by June, 2012, the original compliance date for sunscreens with annual sales of $25,000 or more.

FDA concurs that the operational timeline included in the submission supports extending the implementation period by an additional 6 months. One of our primary objectives in the 2011 final rule is to provide labeling that will enable consumers to identify and select sunscreen products that provide broad spectrum protection as well as a minimum sun protection factor (SPF) of 15. These sunscreens are particularly important for the public health because, in addition to helping prevent sunburn, sunscreens with a broad spectrum SPF value of 15 or higher, if used as directed with other sun protection measures, decrease the risk of skin cancer and early skin aging caused by the sun. If the timeline for implementation discourages manufacturers from conducting broad spectrum testing, and instead prompts them to apply the labeling that the final rule establishes for products that have not been established to offer broad spectrum protection, a major public health goal of the rule will be undermined. For this reason, granting manufacturers additional time to complete testing and relabeling is in the public interest. Also, implementation of § 201.66, the general Drug Facts labeling requirements, has been intended to be coordinated with the implementation of the substantive labeling changes

necessitated by § 201.327, which provide the specific content for the Drug Facts panel for sunscreens. We therefore conclude that the implementation periods for these rules should remain coordinated.

We also conclude that extension of the compliance dates for § 310.545(a)(29)(ii) should likewise be extended because it is claims in labeling, and not formulation, that defines what sunscreens are subject to this provision of the 2011 final rule. The claims that would necessitate submission of a new drug application (NDA), as defined by that provision of the rule, are claims that would be in conflict with the labeling required by § 201.327. We believe that in many cases the relabeling of products to comply with § 201.327 will remove claims that would otherwise bring the sunscreen within § 310.545(a)(29)(ii). We therefore intend to revise the compliance dates to be codified in § 310.545(d)(40), so as to avoid requiring sunscreens that bear the indicated claims to be removed from the market before their relabeled replacements are ready.

We note that the PCPC/CHPA submission also stated that instituting a 6-month extension in the implementation period would be consistent with actions taken on previous FDA sunscreen rulemakings. The submission cited the 2007 sunscreen proposed rule (72 FR 49070 at 49073, August 27, 2007) and the 1999 sunscreen final rule (64 FR 27666 at 27686, May 21, 1999), where it was stated that complying with requirements in a sunscreen final monograph may require an implementation period of more than 1 year. The submission stated that FDA has delayed implementation of rules in the past when a delay is justified.

We acknowledge that implementation periods of more than 1 year were allowed for previous OTC sunscreen rulemakings and concur with the requested delay of implementation in light of the specific information submitted after the publication of the final rule, detailing specific reasons why additional time is required for all sunscreen drug products to achieve

compliance. Because we cannot determine which particular products would be unable to comply, we are extending the compliance dates generally, but we nonetheless encourage manufacturers to act with diligence to bring products into compliance as soon as possible, so as to provide the public with the benefits of the new labeling. We have not altered the effective date of the regulation, and encourage manufacturers to introduce individual products bearing the new labeling as it becomes available, even in advance of the revised compliance date.

We find that there is adequate rationale to delay the compliance dates for the 2011 final rule. We are issuing this rule directly, without issuing a notice of proposed rulemaking or taking comments on this action, for good cause. Because manufacturers' plans depend on the date by which compliance is expected, and the original compliance date for most products is now imminent, we find that issuing notice and taking comments are impracticable, unnecessary, and contrary to the public interest with respect to this action. As already noted, without this extension of the time for implementation, manufacturers who do not anticipate being able to comply by the original compliance dates expressed in the final rule would be faced either with discontinuing distribution, or potentially confining themselves to the labeling for products that have not been established to be broad spectrum. This means that consumers would be deprived of the additional information to make informed choices regarding their sun protection options. With regard to § 310.545, in particular, we also find it is in the public interest to extend the compliance date prior to the effective date, to avoid the confusion that would likely ensue if the codified had already been incorporated into the CFR with the earlier compliance dates. Accordingly, 5 U.S.C. 553(b) and § 10.40(e)(1) (21 CFR 10.40(e)(1)) provide a statutory and regulatory basis for not issuing notice or taking comment prior to implementing the delay of the compliance dates for the 2011 final rule. In accordance with § 10.40(e)(1), however, interested

parties may submit comments on whether the extension of compliance dates set forth in this document should subsequently be modified or revoked.

III. Submission of Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Analysis of Impacts

The 2011 final rule includes a comprehensive examination of the economic impact of the 2011 final rule (76 FR 35620 at 35654 through 35657). A 6-month delay of the compliance dates for the 2011 final rule is unlikely to significantly affect the time or cost estimates made in that economic impact analysis. The 6-month delay allows additional time for testing and relabeling. However, the economic impact analysis in the 2011 final rule presumed that testing and relabeling could be fully implemented without the additional 6 months. Therefore, delaying the compliance dates by 6 months should not increase the time and cost estimates in the 2011 final rule.

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct 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). We have determined that this final rule is not a significant regulatory action under Executive Order 12866. Consistent with Executive Order 13563, the approach taken here maintains "flexibility and freedom of choice for the public," above all by providing "information for the public in a form that is clear and intelligible."

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. We concluded that the 2011 final rule would have a significant economic impact on a substantial number of small entities. Our analysis of this economic impact is discussed at 76 FR 35620 at 35657. However, delaying the compliance dates of the 2011 final rule does not affect any of the numerical estimates made in our analysis.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. It is not expected that this final rule will result in any 1-year expenditure that would meet or exceed this amount.

The purpose of this final rule is to delay the compliance dates for the 2011 final rule by 6 months. The delay of the compliance dates is based upon information received after publication of the 2011 final rule that indicates that full implementation of the 2011 final rule's requirements for all affected products will require an additional 6 months.

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. References

The following reference has been placed on display in the Division of Dockets Management (see ADDRESSES), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.)

1. "Personal Care Products Council--Comment, FDA-2011-N-0449-0003, 10/06/2011," http://www.regulations.gov.

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310 is amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b-360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b-263n.

2. Section 310.545 is amended by revising paragraph (d)(40) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

* * * * *

(d) * * *

(40) December 17, 2012, for products subject to paragraph (a)(29)(ii) of this section. December 17, 2013, for products with annual sales less than $25,000.

Dated: May 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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