SPF Labeling and Testing Requirements for OTC Sunscreen Products with SPF Values Greater Than 50

0910-AF43

Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration's (FDA) legal authority to modify and simplify the manner in which certain information is presented in over-the-counter (OTC) drug product labeling derives from sections 201, 502, 503, 505, and 701 of the Federal Food, Drug, and Cosmetics Act (The Act). Regulating the order, appearance, and format of OTC drug product labeling is consistent with FDA's authority to ensure that drug labeling conveys all material information to the consumer (sections 201(n) and 502(a) of the act), and that labeling communicates this information in a manner that is ''likely to be read and understood by the ordinary individual under customary conditions of purchase and use'' (section 502(c) of the act).

Proposed regulations (proposed 21 CFR 201.327(a)(1)) currently being reviewed by OMB would require sunscreen products determined to have SPF values higher than 50, according to testing in 21 CFR 201.327(i), to be labeled as "SPF 50+" or "SPF 50 plus."

This collection of information is not related to the American Recovery and Reinvestment Act of 2009.

2. Purpose and Use of the Information Collection

Under current 21 CFR 201.327(a)(1), sunscreen products are allowed to label with the numerical SPF value determined by the SPF test procedure in 21 CFR 201.327(i). Consumers may be led to believe that increasingly higher numerical SPF values indicate increasingly greater protection against skin damage from sun exposure. However, FDA currently lacks data demonstrating that products with SPF values higher than 50 provide additional clinical benefit compared to products with SPF values of 50. Therefore, the labeling of products with SPF values higher than 50 may be misleading. Under proposed 21 CFR 201.327(a)(1), sunscreen products determined to have SPF values higher than 50 would be required to be labeled as "SPF 50+" or "SPF 50 plus." This proposed regulation to prohibit the labeling of sunscreen products with SPF values higher than 50 thereby prevents consumers from being misinformed about the effectiveness of sunscreen products.

The labeling information that would be required under proposed § 201.327(a)(1) is a one-time burden for manufacturers of OTC sunscreen drug products determined to have SPF

values higher than 50 according to testing in 21 CFR 201.327(i). These manufacturers would need to replace current labeled numerical SPF values with "SPF 50+" or "SPF 50 plus." These manufacturers are not required to comply with these proposed regulations but could become subject to these requirements when a final rule becomes effective.

3. Use of Improved Information Technology and Burden Reduction

The process of determining an SPF value depends on a subjective assessment of reddening of the skin is a time consuming process. Currently available software and hardware will greatly simplify the process of integrating SPF values into product labeling.

4. Efforts to Identify Duplication and Use of Similar Information

The SPF value for a sunscreen drug product depends on the number and concentration of active ingredients as well as the final formulation and, therefore, is unique for each sunscreen product.

5. Impact on Small Businesses or Other Small Entities

Although FDA must apply the statutory and regulatory requirements equally to all enterprises, the agency does provide special help to small businesses. The Center for Drug Evaluation and Research (CDER) Office of Communication, Division of Drug Information, will provide assistance to small businesses or small entities.

6. Consequences of Collecting the Information Less Frequently

The collection of information for purpose of public disclosure will be a one-time burden for sunscreen products determined to have SPF values higher than 50 according to testing in 21 CFR 201.327(i).

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

This proposed rule is being issued after reviewing data and information FDA received on the safety and effectiveness of OTC sunscreen drug products after publication of the 2007 proposed rule in the Federal Register. The need for a maximum SPF value in sunscreen labeling has been the subject of much public discussion during the rulemaking process, and the current proposal represents FDA's response to public comment on this issue.

9. Explanation of Any Payment or Gift to Respondents

This section is not applicable.

10. Assurance of Confidentiality Provided to Respondents

Any labeling developed under an OTC monograph is not considered confidential.

11. Justification for Sensitive Questions

Questions of a sensitive nature are not applicable to this information collection.

12. Estimates of Annualized Burden Hours and Costs

12a. Estimated Annual Third Party Disclosure Burden

FDA estimates that approximately 60 new products will be introduced each year, and based on currently marketed products, that 2 percent of these will have SPF values greater than 50, for a total of 1 such product per year.

This labeling is estimated to require no more than the 0.5 hours estimated for creating labeling bearing a specific SPF value, which is already included in the estimate for the 2011 final rule.

Table 1. -- Estimated Annual Third-Party Disclosure Burden

Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Responses	Average Burden per Disclosure	Total Hours
Labeling new sunscreen products with SPF values greater than 50 with “Broad Spectrum SPF 50 plus” or “SPF 50 plus” in lieu of specific SPF values	1	1	1	0.5	0.5
Reexamining/ relabeling of effectiveness statement on existing sunscreen PDPs to replace specific SPF values above 50 with the phrase “50+” or “50 plus” in accordance with revisions to 201.327(a)(1)[1]	17	1.4	24	0.5	12
TOTAL					12.5

[1] Actual first year burden hours have been divided by 3 to avoid double counting in the ROCIS system.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General	12.5	46.33	579.12

FDA estimates that a respondent's employees responsible for implementing the relabeling required would make an average wage equivalent to that of a Federal government employee at the GS-14/step 1 general rate schedule, which makes the annual wage cost for the burden hours approximately $579.12.

13.Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital costs or operating, and maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

FDA does not anticipate that costs associated with the labeling requirements will be borne by the federal government.

15. Explanation for Program Changes or Adjustments

This is a new data collection, however, the burden for the broad spectrum average burden per disclosure is .5 in the supporting statement but will round to 1 in the ICRAS/ROCIS system.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not seeking approval to exempt display of the expiration date of the OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.