

[Labeling Requirements – OTC Drugs]

0910-AA79

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

FDA's 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).

Regulations established in March 1999 (21 CFR 201.66) define format and content requirements for the labeling of OTC drug products. All OTC drug products except sunscreens have been required to comply with the labeling requirements set forth in 21 CFR 201.66 since June 2005. Sunscreen drug products are not required to comply with the labeling requirement until a final monograph is published for sunscreen drug products.

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

2. Purpose and Use of the Information Collection

The labeling information required under 21 CFR 201.66 is also a one-time burden for manufacturers of new OTC drug products introduced to the marketplace under new drug applications (NDAs), abbreviated new drug applications (ANDAs), or OTC drug monographs, except for products in "convenience size" packages.¹

¹ In a final rule published April 5, 2002, the agency delayed the compliance dates for the 1999 labeling final rule for all OTC drug products that: (1) Contain no more than two doses of an OTC drug; and (2) because of their limited available labeling space, would require more than 60 percent of the total surface area available to bear labeling to meet the requirements set forth in § 201.66(d)(1) and (d)(9) and, therefore, qualify for the labeling modifications currently set forth in § 201.66(d)(10) (67 FR 163004 at 16306). The agency issued this delay in order to develop additional rulemaking for these "convenience size" products (71 FR 74474). These products are not currently subject to the requirements of § 201.66. PRA approval for any requirements to which they may be subject in the future will be handled in a separate rulemaking.

Manufacturers may seek exemption or deferral from these requirement under 21 CFR 201.66(e). However, we believe the number seeking exemption or deferral will be extremely small, because we have received only one such request in the last eight years.

3. Use of Improved Information Technology and Burden Reduction

As of June 1, 2009, all drug registration and listing information must be submitted electronically (74 FR 26248). Because labeling, including Drug Facts, is included in drug listing, FDA expects that all respondents will use electronic means to fulfill the requirements of 21 CFR 201.66. The use of electronic means substantially reduces the burden associated with developing new labels. Currently available software and hardware greatly simplify the process of creating, manipulating, and printing new labels.

4. Efforts to Identify Duplication and Use of Similar Information

The information included in the Drug Facts portion of labeling is unique for each drug product. Similar drug products (i.e., in the same pharmacological category with the same dosage strengths) will have very similar (but not necessarily identical) Drug Facts content and format. The requirements in 21 CFR 201.66 are not duplicated by any other regulations.

5. Impact on Small Businesses or Other Small Entities

There are no exceptions for small businesses/marketing enterprises.

6. Consequences of Collecting the Information Less Frequently

We believe the response to 21 CFR 201.66 will be a one-time burden for sunscreen manufacturers and manufacturers of new OTC drug products introduced to the marketplace under NDAs, ANDAs, or OTC drug monographs (except those packaged in “convenience size” packages).

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

Regulations regarding the format and content of Drug Facts labeling were finalized in 1999 (64 FR 13254). As noted in the final rule, FDA met with representatives of industry on “numerous occasions” between 1995 and 1999 to discuss the utility of various label formats (64 FR 13254 at 13275). FDA addressed “numerous comments received concerning information collection” in the 1999 final rule (64 FR 13254 at 13275). OMB reviewed the requirements for information collection and approved it under OMB Control Number 0910-0340.

9. Explanation of Any Payment or Gift to Respondents

This section is not applicable.

10. Assurance of Confidentiality Provided to Respondents

Drug Facts labeling developed under an OTC monograph is not considered confidential. Industry interactions with FDA in the development of labeling for new NDAs or ANDAs is classified as confidential under 21 U.S.C. 360j(c).

11. Justification for Sensitive Questions

This section is not applicable. FDA does not ask questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

a. Annualized Hour Burden Estimate

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
201.66(c) and (d)	300	3	900	12	10,800
201.66(e)	1	0.125	0.125	24	3
Total					10,803

b. Annualized Cost Burden Estimate

See section A.13.

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

We estimate one-time capital costs for manufacturers of products marketed under new NDAs or ANDAs will be approximately 18.9 percent of the cost of relabeling sunscreen drug products. This estimate is based on the total number of annual disclosures. We expect approximately 900 disclosures of new NDA and ANDA labeling each year vs. approximately 4,750 disclosures of re-labeled sunscreen products. The number of NDA and ANDA labels is approximately 18.9 percent of the number of labels expected to be included on sunscreen drug products.

We estimate one-time capital costs for manufacturers of sunscreen drug products as \$9.4 to 11 million. This figure is derived from a recently calculated cost to re-label sunscreen drug products (unpublished sunscreen labeling and testing final rule). Total re-labeling costs for sunscreen drug products for which labeling changes are implemented outside normally scheduled relabeling has been estimated as \$18.8 to \$22.0 million. We estimate that 50 percent of these costs are applicable to re-labeling the Drug Facts part of the sunscreen label and that 50 percent will be applied to relabeling the principal display panel and other labeling outside the Drug Facts box. Fifty percent of \$18.8 to \$22 million is \$9.4 to \$11 million dollars. Multiplying these capital costs by 18.9 percent gives annualized capital costs of \$1.8 to \$2.1 million for NDA and ANDA labels.

14. Annualized Cost to the Federal Government

We do not anticipate that any costs associated with the labeling requirements will be borne by the federal government.

15. Explanation for Program Changes or Adjustments

This is a request for reinstatement without change in current or expected burden.

16. Plans for Tabulation and Publication and Project Time Schedule

This section is not applicable.

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

This section is not applicable.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

B. Statistical Methods (used for collection of information employing statistical methods)

This section is not applicable.