Format and Content Requirements for
Over-the-Counter Drug Product Labeling

OMB Control No. 0910-0340

SUPPORTING STATEMENT

Terms of Clearance: None.

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 have been required to comply with the labeling requirements set forth in 21 CFR 201.66 since December 2012, when the specific exemption of OTC sunscreen drug products for complying with Drug Facts labeling requirements was effectively lifted.

2. Purpose and Use of the Information Collection

   The labeling information required under 21 CFR 201.66 is 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]

   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

[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.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the Federal Register of April 1, 2016 (81 FR 18861); no comments were received.

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.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Table 1.—Estimated Annual Third-Party Disclosure Burden

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Response	Total Hours
201.66(c) and (d) for new OTC drug products	300	3	900	12	10,800
201.66(c) and (d) for new OTC sunscreen products	20	3	60	12	720
201.66(e)	1	0.125	.125	24	3
Total					11,523

12b. Annualized Cost Burden Estimate

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 estimated for 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 NDA 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.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

    There are no capital or start-up costs associated with the information collection. We estimate any previous capital costs resulting from relabeling is now realized under the regulations.

14. Annualized Cost to the Federal Government

    Review of information submitted to the agency under the collection will be covered by existing resource allocations.

15. Explanation for Program Changes or Adjustments

    The burden remains unchanged.

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.