UNITED STATES FOOD & DRUG ADMINISTRATION

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

OMB Control No. 0910-0340

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency, us or we) regulations. 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 Cosmetic Act (the FD&C Act). Our regulations at § 201.66 (21 CFR 201.66) establish standardized content and format requirements for the labeling of all marketed OTC drug products. The regulations set forth specific content and format requirements for the Drug Facts portion of labels on OTC drug products. The regulations require OTC drug product labeling to include uniform headings and subheadings, and be presented in a standardized order, with minimum standards for font size and other graphical features. Currently marketed OTC drug products are required to comply with these labeling requirements.

We consider labeling modifications requiring conformance with the Drug Facts format to be "*usual and customary*" as part of routine redesign practice, such that any attendant information collection activities do not create additional burden under the PRA. Therefore, this information collection request supports burden necessary to comply with the labeling requirements in § 201.66 applicable to new OTC drug products and OTC sunscreen drug products introduced to the marketplace under NDAs, ANDAs, or OTC drug monographs. New OTC drug products must comply with the labeling requirements in § 201.66 as they are introduced to the marketplace.

We therefore request extension of OMB approval for the information collection provisions found in 21 CFR 201.66 and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The labeling information required under § 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. Manufacturers may seek exemption or deferral from the requirements under § 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 several years.

3. Use of Improved Information Technology and Burden Reduction

Currently, all listing information must be submitted electronically. Because labeling, including Drug Facts, is included in drug listing, we expect that all respondents will use electronic means to fulfill the requirements of § 201.66. We believe 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. We are unaware of duplicative information collection associated with the requirements in 21 CFR § 201.66.

5. Impact on Small Businesses or Other Small Entities

We do not believe the information collection imposes undue burden on small entities. Under the regulations (§ 201.66(e)), respondents may request an exemption and/or deferral on the basis that the requirement is inapplicable, impracticable, or contrary to public health or safety. We assist small businesses in complying with our regulations through small business compliance resources available from our website at www.fda.gov and through assistance from program staff within the agency.

6. Consequences of Collecting the Information Less Frequently

We believe information collection under § 201.66 is 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, and presents the minimal burden necessary for ensuring the safety of these products.

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

There are no special circumstances relating to this information collection.

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

In accordance with 5 CFR 1320.8(d), we published a 60-day notice inviting public comment in the Federal Register of June 19, 2019 (84 FR 28555). We received one comment that encouraged the use of "*provider-neutral language*" in the Medication Guide regulations. Because the comment did not pertain to the immediate information collection, or the associated burden estimates provided in the 60-day notice, we have not addressed them here.

9. Explanation of Any Payment or Gift to Respondents

No remuneration is provided to respondent to the information collection.

10. Assurance of Respondent Privacy and Confidentiality

No personally identifiable information (PII) or other data of a personal nature is being collected. The information collected is from sunscreen manufacturers and manufacturers of new over-the-counter (OTC) drug products introduced to the marketplace under new drug applications (NDAs), abbreviated new drug applications (ANDAs), or OTC drug monographs regarding standardized content and format requirements for the labeling of all marketed OTC drug products. In preparing this supporting statement, we consulted with our Privacy Office to ensure appropriate handling of information collected and have determined that PII is not collected and the Privacy Act of 1974 does not apply. Further, 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

There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Based on our electronic drug registration and listing database, we estimate that approximately 7,858 new OTC drug product stock keeping units (SKUs) are introduced to the marketplace each year, including sunscreen products. We estimate that these SKUs are marketed by 855 manufacturers. We estimate that the preparation of labeling for new OTC drug products requires 12 hours to prepare, complete, and review prior to submitting the new labeling to us. Based on this estimate, the annual reporting burden for this type of labeling is 94,296 hours. All currently marketed sunscreen products are also required to comply with the Drug Facts labeling requirements in § 201.66, so they will incur no further burden under the information collection provisions in the regulation. When determining the burden for § 201.66, it is also important to consider exemptions or deferrals of the regulation allowed products under § 201.66(e). We receive very few requests for exemption or deferral. We also estimate that a request for deferral or exemption requires approximately 24 hours to complete.

Our estimate of the burden of this collection of information is as follows:

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

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
§ 201.66(c) and (d) for new OTC drug products (including OTC sunscreen products)	855	9.19	7,858	12	94,296
§ 201.66(e)	1	1	1	24	24
Total					94,320

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

12b. Annualized Cost Burden Estimate

We estimate one-time capital costs for manufacturers of products marketed under new NDAs or ANDAs will be approximately $1.8 to $2.1 million for NDA and ANDA labels, and therefore use an average of $1.95 million. We rely on previous figures for this estimate and divide the total cost by the number of annual disclosures. Using this formula the cost per disclosure is calculated to be $248.00 per disclosure.

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 FDA under the collection is covered through existing resource allocations.

15. Explanation for Program Changes or Adjustments

The information collection reflects adjustments. We have adjusted our estimate to reflect an increase of 82,797 hours and a corresponding increase of 6,898 disclosures. The increase corresponds with agency data on the number of labeling reviews associated with new OTC drug product submissions. We have also included currently and past reported cost information so that it will be reflected at www.reginfo.gov, and have combined two IC elements in our burden table. We believe these changes will assist readers in understanding burden associated with the information collection. Finally, although we include and discuss our burden figures in both the supporting statement as well as our Federal Register notices, after publication we noted an inadvertent error in the figures that were discussed in the narrative of the 30-day notice. We have verified the figures reflected currently in our burden table and presented here in this supporting statement, but regret this error.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no publications or other schedules.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.