[INSERT DATE AND OTHER HEADER INFORMATION]

Subject: FDA Responses to Submission from the Personal Care Products Council dated September 13, 2010

The Personal Care Products Council (PCPC) submitted comments to the docket in response to the August 13, 2010, 30-day notice (75 FR 49495) on our proposed collection of information for the Drug Facts regulation (21 CFR 201.66) for all over-the-counter (OTC) drug products. As explained below, in response to these comments, we are revising the estimated number of hours per submission to prepare Drug Facts labeling in compliance with § 201.66 but are not otherwise revising the proposed information collection. Also, based on our discussions with OMB, we are limiting our estimates to new drug products other than sunscreens. We are removing our estimated burden for sunscreens because they are not subject to § 201.66 at this time.

By way of background, it is important to remember what the specific information collection provisions in § 201.66 cover. This information collection standardizes the format and general section content & headings (e.g., "Active ingredients", "Uses," "Directions") for the Drug Facts panel on all OTC drug products. This regulation does not address other aspects of OTC labeling, such as the Principal Display Panel (PDP) or other areas of labeling outside of the "Drug Facts" panel. It does not address the specific content of the above mentioned sections of Drug Facts labeling, which differs among products. The specific content of Drug Facts for each drug category is addressed by other regulations. It is also important to note that, 2004, we delayed implementation of § 201.66 for sunscreens indefinitely (69 FR 53801); all other OTC drugs must comply with § 201.66 at this time.

PCPC's comments concentrated on sunscreens, rather than all OTC products subject to § 201.66. For example, while purporting to frame its comments as a response to our estimated capital costs of $22-25 million for all OTC drugs to comply with the information collection provisions of § 201.66, PCPC proceeded to discuss primarily "[t]he cost to relabel products as a result of the Proposed Rule" (i.e., the full economic burden of the 2007 sunscreen proposed rule (72 FR 49070)). Rather than addressing the particular burden associated with the information collection provisions of § 201.66 itself, PCPC's comments address in large part the costs of complying with all of the proposed specific requirements for sunscreen labeling, including areas of labeling outside of the Drug Facts panel. We address those economic comments in the analysis of impacts for the sunscreen final rule (establishing § 201.327), currently under review by OMB. In addition, we are preparing a separate PRA notice to seek OMB approval of the information collection provisions included in § 201.327, and PCPC's comments have informed our burden estimates there.

In the remainder of this memo, we focus on the PCPC comments that address our estimated burden for the collection of information for the Drug Facts regulation (§ 201.66). The PCPC comments are repeated below with our responses (in italics) following each comment.

1. "FDA must include the cost of testing when calculating the economic impact of 21 CFR 201.66."

None of the provisions of the Drug Facts regulation (§ 201.66) requires testing to determine labeling. Sunscreens require efficacy testing to determine the SPF value used in labeling, but the SPF value is not included in Drug Facts part of labeling. The SPF value is included on the principal display panel (PDP). The burden of SPF testing is included in the PRA burden estimates being prepared for the sunscreen final rule (§ 201.327) currently being reviewed by OMB and for the accompanying draft guidance on enforcement policy currently being reviewed by OMB. The costs of testing are also included in the analysis of economic impacts included in the sunscreen final rule, which is mandated by authorities other than the PRA.

2. “”FDA’s estimate of two hours per submission is grossly under the actual 24 to 48 hours of time required per submission.”

In light of PCPC’s comment, we are revising our burden estimate for compliance with § 201.66. We agree that our estimate of two hours is too low but find PCPC’s estimate of 24-48 hours is too high an estimate of the burden associated with § 201.66 alone. As we stated in the Drug Facts labeling final rule, PCPC (then NMDA) included in its estimate the entire burden of re-labeling (i.e., PDP, Drug Facts, and other parts of container labeling) (64 FR 13254 at 13279). The collection of information approval that we are seeking here only concerns Drug Facts labeling. We estimate the burden of re-labeling the Drug Facts part of the label to be no more than half the total burden of revising all aspects of the sunscreen labeling (which includes the PDP and other parts of the label outside of the Drug Facts panel). We, therefore, estimate that no more than 12 hours, or half of the 24 hours in PCPC’s example (page 4 of the PCPC submission), will be necessary to create, review, and design the Drug Facts part of the labeling. We estimate this same burden not only for labeling OTC sunscreen drug products, but also for other new OTC drug products (regardless of pharmacological category) being introduced into the market.

Based on the submission from PCPC and our discussions with OMB, we suggest revising the table showing the Annual Reporting Burden for Respondents complying with the Drugs Facts regulation. Suggested revisions are highlighted in yellow. In addition, we have deleted the burden for sunscreens in the table. Along with this memo, we are also including a revised Supporting Statement that reflects these revisions to the estimated annual burden.

TABLE 1.—Estimated Annual Third-Party Disclosure Burden[1]

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

[1]We estimate that capital costs of 1.8 to 2.1 million dollars will result from preparing labeling content and format in accordance with § 201.66. There are no operating or maintenance costs associated with this collection of information.