FOOD & DRUG ADMINISTRATION:
Food Labeling Regulations

OMB Control No. 0910-0381

Non-Substantive Change Request:

After reviewing the active information collection requests identified below, FDA believes that the burden reflected is currently accounted for in the instant collection 0910-0381 – *Food Labeling Regulations*. Additionally, we believe that the guidance documents supported by these independent collections may be appropriately included here to reflect agency efforts at reducing burden on respondents. We discuss our reasoning below:

1. OMB Control No. 0910-0374: *Guidance for Industry: Notification of a Health Claim Based on an Authoritative Statement of a Scientific Body.* As explained in the agency's supporting statement for the collection and discussed more fully in the guidance itself, this document communicates to respondents our recommendations regarding food labeling claims associated with regulations found in 21 CFR Parts 101.13, 101.14, 101.54, 101.69, and 101.70. Specifically, and also as explained, the guidance was developed to assist respondents in satisfying criteria found or discussed in these regulations. The guidance was issued consistent with our Good Guidance Practices regulations found at 21 CFR Part 10.115 and the agency invites and receives comment on agency guidance at any time. While the guidance recommends that notifications for certain health claims submitted to us include specific information and identifies specific information we will evaluate in determining compliance with statutory requirements (for example – supporting literature; discussion of the analytical methodology or methodologies used in support of a particular claim), we believe the recommendations impose no additional burden beyond that we already attribute to activities associated with the regulations themselves. Nor do we believe that recommendations found in the guidance introduce new collection. Rather, the guidance was developed to help respondents to whom food labeling regulations apply better understand FDA's current thinking on those requirements in an effort to reduce time spent on their associated regulatory activities. The currently approved burden for the information collection is 4 annual responses and 702 hours. Given our experience with the collection and our recent evaluation and extension of OMB Control No. 0910-0381, we believe we have accounted for any burden that may be attributable to the guidance document within the latter collection. We have enumerated burden associated with the various regulations found in 21 CFR Part 101 in our supporting statement for OMB Control No. 0910-0381 at Question 12. At the same time, FDA will reference this guidance specifically in future extension requests under Question 3 as a means by which we hope to reduce respondent burden.

2. OMB Control No. 0910-0626: *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act.* Similarly, as explained in both the agency's supporting statement and the guidance for which this collection was established, the document communicates our recommendations and thinking on the implementation of specific statutory requirements codified in agency

regulations. We believe any burden attributable to information collection activities discussed in the guidance is already accounted for under OMB Control No. 0910-0381. To be clear, our estimate of the time necessary to satisfy the information collection provisions found in the regulations includes time we believe is associated with specific elements of those activities discussed in the relevant guidance. Accordingly, we will reference this guidance specifically in future extension requests for 0910-0381 under Question 3 to demonstrate our efforts at reducing burden for respondents. The guidance was issued consistent with our Good Guidance Practices regulations at 21 CFR 10.115 and we invite and accept public comment on agency guidance at any time. The currently approved burden for this information collection is 667 responses and approximately 189,500 hours attributable to recordkeeping. In reviewing OMB Control No. 0910-0381, where we have enumerated our estimates for recordkeeping associated with 21 CFR Part 101 at Question 12, we include those activities covered in the related guidance. In fact, FDA issues guidance to help respondents meet the regulatory requirements found in the Federal Food, Drug, and Cosmetic Act, particularly as new statutory requirements are introduced or existing statutes are modified.

3. OMB Control No. 0910-0642: *Guidance for Industry: Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act*. Finally, like the others above, this information collection was established to support the referenced agency guidance. The guidance was issued consistent with our Good Guidance Practices regulations at 21 CFR 10.115 and we invite and accept public comment on agency guidance at any time. The currently approved burden for this information collection is 11,120 responses and approximately 2,224 burden hours attributable to third-party disclosure recommendations "*for complying with the labeling requirements prescribed for dietary supplement manufacturers, packers, and distributors by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109-462, 120 Stat. 3469)*." The referenced labeling requirements are codified under 21 CFR Part 101. In reviewing OMB Control No. 0910-0381, where we have enumerated our burden estimates associated with third-party disclosure activities, we include those activities covered in the related guidance. In future extension requests for 0910-0381, we will specifically reference the guidance under Question 3 to represent efforts at reducing burden on respondents to the information collection.

Because the guidance documents identified above serve to clarify FDA's thinking on respective labeling topics that may arise upon implementation of the various food labeling regulations covered by applicable statutes, we believe they serve to minimize rather that create additional burden on respondents. As the guidance documents elaborate more fully on activities we believe are necessarily associated with the labeling requirements covered in the regulations, we have already accounted for the corresponding time in the estimate we provide to OMB supporting our food labeling regulations. Accordingly, we seek to consolidate the above information collection requests (0910-0374, 0910-0626, and 0910-0642) into OMB Control No. 0910-0381.

Submitted: November 2017.