

UNITED STATES FOOD & DRUG ADMINISTRATION

Food Labeling Regulations

OMB Control No. 0910-0381

RIN 0910-AI13

SUPPORTING STATEMENT--Revision

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA or we) rulemaking that revises 21 CFR 101.65 so manufacturers who use the term “*healthy*” in the labeling of their products must create and maintain written records to verify that the products comply with the applicable requirement. In addition, and consistent with current provisions, manufacturers must provide these records upon request from FDA during an inspection for official review and photocopying or other means of reproduction. The final rule also requires that some manufacturers relabel products to comply with the new requirement and allows manufacturers to relabel products using the term “healthy” if it now meets the new definition. Products that do not comply with the requirement are subject to regulatory enforcement under provisions of the Federal Food, Drug, and Cosmetic Act.

We therefore request OMB approval of the information collection provisions applicable to 21 CFR 101.65, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The purpose of our food labeling requirements allows consumers to be knowledgeable about the foods they purchase. The primary user of the information to be disclosed on the label or labeling of food products is the consumer that purchases the food product. Consumers use the information to assist them in making choices concerning their purchase of a food product. This information also enables the consumer to determine the role of the food product in a healthful diet. Nutrition labeling provides information for use by consumers in selecting a nutritious diet. Other information enables a consumer to comparison shop.

Additionally, we use the information to determine whether a manufacturer or other supplier of food products is meeting its statutory and regulatory obligations. Recordkeeping requirements enable us to monitor the basis upon which certain label statements are made for food products and whether those statements are in compliance with the requirements of the FD&C Act or the Fair Packaging and Labeling Act. Failure of a manufacturer or other supplier of food products to label its products in compliance with section 403 of the FD&C Act and parts 101, 102, 104, and 105 of FDA’s food labeling regulations may result in a product being misbranded under the FD&C Act and the manufacturer and the product subject to regulatory action.

Description of Respondents: The respondents to this information collection are manufacturers of food products using the “*healthy*” implied nutrient content claim marketed in the United States.

3. Use of Improved Information Technology and Burden Reduction

Revised § 101.65 does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by manufacturers. Manufacturers are free to use whatever forms of information technology may best assist them in retaining the appropriate records and making them available upon request from FDA during an inspection for official review and photocopying or other means of reproduction. Manufacturers are also free to use whatever forms of information technology may best assist them in meeting labeling requirements for food.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We estimate that approximately ten percent (10%) of the respondents are small businesses. The requirements are the minimum requirements for complying with the provisions of the FD&C Act. In most cases, the information that is required for recordkeeping is information that is available to a manufacturer, including a small business, as a normal course of its doing business. We aid small businesses in dealing with the requirements of the FD&C Act through the agency’s Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We also provide assistance via FDA’s Small Business Assistance webpage on the agency’s website at <https://www.fda.gov/industry/small-business-assistance>.

6. Consequences of Collecting the Information Less Frequently

The information collection is consistent with statutory and regulatory requirements.

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

There are no special circumstances associated with 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 1320.11 we published a proposed rule in the *Federal Register* of September 29, 2022 (87 FR 59168), including a request for comments on the proposed information collection. Our responses to the comments are found in Section V of the final rule to be published in the *Federal Register* of December 27, 2024 (Docket No. FDA-2016-D-2335).

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR does not collect personally identifiable information (PII) or information of a personal nature. This information collection supports the Labeling of Certain Foods Subject to the Labeling Jurisdiction of the Food and Drug Administration Guidance for Industry and will be merged with an existing collection of information that includes PII but is not subject to the requirements of the Privacy Act of 1974 (*see* OMB control no. 0910-0381). All records included in this collection are maintained at the manufacturing facility. Because neither FDA nor any party acting on behalf of the agency collects PII, the ICR is not subject to the Privacy Act of 1974 and the requirements of the Privacy Act such as displaying a Privacy Act Statement on a collection form do not apply.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. *Annualized Hour Burden Estimate*

Table 1.--Estimated Annual Recordkeeping Burden¹

21 CFR Section/Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
101.65; recordkeeping to verify “ <i>healthy</i> ” nutrient content claim	1,900	1	1,900	0.5 (30 minutes)	950

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

The final rule requires that each manufacturer of a food that bears the implied nutrient content claim “*healthy*” must create and maintain written records to verify that the food meets the food group equivalent requirements when it is not apparent from the label of the food. Examples of records include analyses of databases, recipes, formulations, information from recipes or formulations, or batch records. However, the product label (including the Nutrition Facts Label (NFL), the ingredient list, the statement of identity, and any other information) may be used to verify compliance with the food group requirements for certain foods. For example, it would be apparent from the ingredient list of an oil product whether the product contains 100 percent oil. Similarly, it would likely be ascertainable from the ingredient list of a frozen spinach product that contains only spinach and salt whether the product contains enough spinach (vegetables) to bear the “*healthy*” claim. Thus, this recordkeeping estimate does not include food groups where the equivalent requirements are apparent from the label of the food. These estimates are based on the analysis in Table 12 of the Final Regulatory Impact Analysis (FRIA) (Docket No. FDA-2016-D-2335). Table 12 of the FRIA estimates that 5,702 products will need recordkeeping,

which equals about 1,900 products annually over a 3-year period (5,702 ÷ 3). We estimate that each year 1,900 manufacturers will each create and maintain 1 written record for a total of 1,900 records. We estimate that each record will require 15 to 30 minutes of recordkeeping for an annual recordkeeping burden of 950 hours (1,900 records × 0.5 hour).

Table 2.--Estimated One-Time Relabeling Burden¹

21 CFR Section/ Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours	Total Capital Costs ²
101; Relabel for “healthy” claim	7,109	1	7,109	1	7,109	\$19,750,964

¹ One-time labeling burden.

² There are no operating and maintenance costs associated with this collection of information.

We assume there are two categories of UPCs that could require re-labeling. First, if a UPC currently labeled “healthy” does not meet the required criteria, the manufacturer could choose to remove the “healthy” claim or reformulate. In either case, the label would need to be changed, either to remove the “healthy” claim or to change the NFL after reformulation. Given the current UPCs labeled “healthy” that do not meet the required criteria, we estimate the number of UPCs that would remove the “healthy” claim or reformulate. Second, if a UPC not labeled “healthy” now meets the required criteria, the manufacturer could choose to add the “healthy” claim. Table 8 of the FRIA estimates the need for 21,328 total label changes, which would be about 7,109 label changes annually over a 3-year period. Because this claim is voluntary, we do not know how many establishments will make labeling changes. For the purpose of this analysis, we assume that the number of respondents is the same as the number of disclosures. Each disclosure will take an estimated 1 hour to complete for an annual third-party disclosure burden of 7,109 hours. (For the purpose of ROCIS entry, we have entered one-third of the respondents, one-third of the total annualized burden hours and one-third of the total capital costs for the one-time relabeling.)

12b. Annualized Cost Burden Estimate

We estimate that the total annualized cost burden to respondents associated with the requirements of the new § 101.65 to be approximately \$910,989.36. We estimate a respondent’s average wage to be commensurate to that of a federal government employee at the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2024, \$56.52 per hour. To account for overhead, this cost is increased by 100 percent, making the estimated cost burden to the respondent \$113.04 per hour. Using these figures, we estimate the cost burden for recordkeeping to be \$107,388.00 (950 hours × \$113.04 per hour) and the cost burden for relabeling to be \$803,601.36 (7,109 hours × \$113.04 per hour), for a total annualized burden hour cost of \$910,989.36.

Table 3.--Estimated Annual Cost Burden

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Recordkeeping	950	\$113.04	\$107,388.00
Relabeling	7,109	\$113.04	\$803,601.36
Total			\$910,989.36

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

Table 8 of the FRIA estimates capital costs of \$59,252,892 for labeling, which equals \$19,750,964 annually over a 3-year period. Thus, we estimate capital costs of \$19,750,964 attributable to one-time costs for relabeling products and for revising new labels into the manufacturing process.

14. Annualized Cost to the Federal Government

Currently, FDA estimates \$6,542,114 for costs of administering food labeling requirements, including this rulemaking.

15. Explanation for Program Changes or Adjustments

The information collection includes a one-time burden of 7,109 responses and 7,109 hours to reflect relabeling activities. The information collection will also result in an additional 1,900 records and 950 hours annually, which we attribute to new recordkeeping requirements.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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

Display of OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.