UNITED STATES FOOD AND DRUG ADMINISTRATION

Recordkeeping Requirements for Gluten-Free Labeling
of Fermented or Hydrolyzed Foods

OMB Control No. 0910-0817
RIN 0910-AH00

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) rulemaking to establish requirements for "*gluten-free*" labeling for foods that are fermented or hydrolyzed or that contain fermented or hydrolyzed ingredients. These requirements are intended to help ensure that individuals with celiac disease receive truthful and accurate information with respect to fermented or hydrolyzed foods labeled as "*gluten-free*." Celiac disease, a hereditary, chronic inflammatory disorder of the small intestine, has no cure, but individuals who have this disease are advised to avoid all sources of gluten in their diet to protect against adverse health effects associated with the disease. Section 21 CFR 101.91 defines the term "*gluten-free*" and establishes requirements for the voluntary use of that term in food labeling. Section 101.91 is intended to ensure that individuals with celiac disease are not misled and are provided with truthful and accurate information with foods so labeled. The regulation provides that "*[w]hen compliance with [the regulation] is based on an analysis of the food, FDA will use a scientifically valid method that can reliably detect the presence of 20 parts per million (ppm) gluten in a variety of food matrices, including both raw and cooked or baked products.*" See § 101.91(c). We established this 20-ppm limit for intact gluten considering multiple factors, including currently available analytical methods and the needs of individuals with celiac disease, as well as factors such as ease of compliance and enforcement, stakeholder concerns, economics, trade issues, and legal authorities. Although test methods for the detection of gluten fragments in fermented and hydrolyzed foods have advanced, there is still uncertainty in interpreting the results of these test methods on a quantitative basis that equates the test results to an equivalent amount of intact gluten. Thus, alternative means are necessary to verify compliance with the provisions of the regulation for fermented and hydrolyzed foods, such as cheese, yogurt, vinegar, sauerkraut, pickles, green olives, beers, and wine, or hydrolyzed plant proteins used to improve flavor or texture in processed foods such as soups, sauces, and seasonings.

Consistent with section 206 of the Food Allergen Labeling and Consumer Protection Act (FALCPA) and sections 403(a)(1), 201(n), and 701(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(a)(1), 321(n), and 371(a)), we are implementing requirements to permit the voluntary use of the term *gluten free* in the labeling of foods that are fermented, hydrolyzed, or distilled, or that contain fermented, hydrolyzed, or distilled ingredients. While the regulations at 21 CFR 101.91 define the term "*gluten-free*" and set forth requirements for the voluntary use of the term in food labeling, they do not require

manufacturers who label their foods as *gluten free* to test those foods for its presence. The rulemaking would amend our regulations to provide alternative means for us to verify compliance based on records that are maintained by the manufacturer of the food bearing the *gluten free* claim and made available to us for inspection and copying.

We therefore request OMB approval of recordkeeping associated with requirements in 21 CFR 101.91 regarding the *gluten free* labeling of food, and as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The rulemaking amends § 101.91 to require that manufacturers of fermented or hydrolyzed foods bearing the "*gluten-free*" claim create and maintain records regarding the food demonstrating adequate assurances that the food is "*gluten- free*" before fermentation or hydrolysis and that gluten has not been introduced during the manufacturing process. Likewise, for foods containing one or more fermented or hydrolyzed ingredient and bearing the "*gluten-free*" claim, manufacturers would be required to create and maintain records demonstrating adequate assurance that the fermented or hydrolyzed ingredients are "*gluten-free*" under the regulations. Such adequate assurance can include test results, certificates of analysis (CoAs), or other appropriate verification documentation for each of the ingredients used in the food. Alternatively, adequate assurance can include test results of the food before fermentation or hydrolysis of the food. Finally, the rulemaking would require manufacturers to document that any potential for gluten cross-contact has been adequately assessed, and where such a potential has been identified, that measures have been implemented to prevent the introduction of gluten into the food during the manufacturing process.

We believe these information collection requirements will help ensure that the subject foods are adequately labeled and that consumers may rely on the product labeling.

Description of Respondents: Respondents are manufacturers of foods that are fermented, hydrolyzed, or contain fermented or hydrolyzed ingredients and bear the claim "*gluten-free*," "*no gluten*," "*free of gluten*," or "*without gluten*." Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

While the rulemaking does not require the use of specific information technology, we believe that respondents will utilize electronic means to create and maintain the proposed recordkeeping. The records required would need to be reasonably accessible by FDA during an inspection at each manufacturing facility to determine whether the food has been manufactured and labeled in compliance with the regulations. Records that can be immediately retrieved from another location by electronic means are considered reasonably accessible.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Upon implementation of the regulation we will review our food labeling regulations, currently approved under OMB control no. 0910-0381, to determine whether consolidating burden attendant to activities related to this request is appropriate.

5. Impact on Small Businesses or Other Small Entities

The labeling applies to all products labeled *gluten free* and we do not believe this poses undue burden on small entities. We estimate that ten percent (10%) of respondents are small businesses. We aid small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We also provide assistance via our 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 schedule 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 1320.8(d), we published a 60-day notice requesting public comment in the *Federal Register* of November 18, 2015 (80 FR 71990). Because of an inadvertent error that resulted in conflicting dates by which comments would be received, we extended the comment period to April 25, 2016 (see 81 FR 8869). Comments received in response to the proposed rule are discussed in our final rule published on August 12, 2020 (85 FR 49240).

We received over 500 comments on the proposed rule from consumers; consumer groups; trade organizations; industry; public health organizations; public advocacy groups; and other organizations. In our final rule, we numbered each comment to help distinguish among different topics. We grouped similar comments together under the same number, and, in some cases, we separated different issues discussed in the same comment letter and designated them as distinct comments for purposes of our responses. The number assigned to each comment topic is for organizational purposes only and does not signify the comment's value, importance, or the order in which it was received. At comment 13, we address potential concerns pertaining to electronic records. At the same time, none of the comments suggested a revision or alternative to burden estimates proffered in our proposed rule.

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

Records that may be reviewed during FDA inspections are subject to FDA regulations in 21 CFR part 20. Confidential commercial information is protected from disclosure under the Freedom of Information Act in accordance with section 552(a) and (b) (5 U.S.C. 552(a) and (b)) and by part 20. To the extent that § 20.64 applies, we will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

Privacy Act

This ICR does not request any personally identifiable information and does not include a form that requires a Privacy Act Statement.

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 One-Time Recordkeeping Burden

Activity under 21 CFR 101.91	No. of Respondents	Records per Respondent	Total Annual Records	Burden per Recordkeeping	Total Hours
Developing SOP for gluten control and associated documentation	5000	17.75	88,750	.51	45,203

Table 2.--Estimated Annual Recordkeeping Burden

21 CFR 101.91	No. of Respondents	Records per Respondent	Annual Records	Burden per Recordkeeping	Total Hours
Documentation necessary to verify compliance with gluten free labeling	5000	56.25	281,250	.43	120,458

In our Regulatory Impact Analysis (RIA), available under docket no. FDA-2014-N-1021, for the final rule, we provide a breakdown of specific calculations regarding potential burden we expect manufacturers of affected products will incur along with the associated recordkeeping activities and contributing considerations. These figures are based on an upper-bound estimated 5,000 product manufacturers. Here we provide a cumulative estimate of the average recordkeeping burden we believe attributable to the information collection tasks, acknowledging a one time assimilation period to establish procedures necessary to comply with the *gluten free* labeling requirement, including the establishment of standard operating procedures, sample testing, and documentation and retention of results.

12b. Annualized Cost Burden Estimate

We assume records will be retained by an employee whose position is commensurate to a production manager in the food manufacturing industry. The mean wage for Standard Occupations Classification (SOC) 11-9013 Farmers, Ranchers, and Other Agricultural Managers in the North American Industry Classification System (NAICS) code 311000 Food Manufacturing in 2018 was $38.43. (Bureau of Labor Statistics, Occupational Employment Statistics, May 2018, National Industry-Specific Occupational Employment and Wage Estimates for NAICS 31100 - Food Manufacturing, (first,

https://www.bls.gov/oes/current/oes_nat.htm, then choose 11-0000, Management Occupations at https://www.bls.gov/oes/current/oes_nat.htm#11-0000.)) We increased this wage by 50 percent to $57.65 to account for overhead. The overall estimated cost incurred by the respondents is $3,279,939.10 (56,894 burden hours x $57.65/hour), which we have rounded to $3,279,939.

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Recordkeeping	56,894	$57.65	$3,279,939

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

We estimate no other cost burden to respondents.

14. Annualized Cost to the Federal Government

Assuming we allocate 14 full-time employees (FTEs) per year to inspect firms and review records to determine compliance with 21 CFR 101.91, and a salary rate equal to an inspector at the GS-13, step 5 level in the locality pay area of Washington-Baltimore ($116,353/year) in 2020, double it to account for overhead; we calculate a cost of $232,706 per FTE. Using this figure, we estimate a cost to the Federal government of approximately $3,257,884 per year for inspecting and reviewing records for compliance with § 101.91 ($232,706/FTE x 14 FTEs).

15. Explanation for Program Changes or Adjustments

This is a new information collection. We have not adjusted estimates from our proposed rule.

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

The information collection establishes recordkeeping requirements; display of the OMB control number is not applicable.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.