UNITED STATES FOOD AND DRUG ADMINISTRATION

Temporary Marketing Permit Applications

OMB Control No. 0910-0133

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection request supports Food and Drug Administration (FDA or we) regulations. Specifically, section 401 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 341), directs FDA to issue regulations establishing definitions and standards of identity for food "*whenever … such action will promote honesty and fair dealing in the interest of consumers* …." Under section 403(g) of the FD&C Act (21 U.S.C. 343(g)), a food that is subject to a definition and standard of identity prescribed by regulation is misbranded if it does not conform to such definition and standard of identity. Section 130.17 (21 CFR 130.17) provides for the issuance by FDA of temporary marketing permits that enable the food industry to test consumer acceptance and measure the technological and commercial feasibility in interstate commerce of experimental packs of food that deviate from applicable definitions and standards of identity. Section 130.17(c) enables the agency to monitor the manufacture, labeling, and distribution of experimental packs of food that deviate from applicable definitions and standards of identity. The information so obtained can be used in support of a petition to establish or amend the applicable definition or standard of identity to provide for the variations. Section 130.17(i) specifies the information that a firm must submit to FDA to obtain an extension of a temporary marketing permit.

We therefore request OMB extension of approval of the information collection provisions under 21 CFR § 130.17 as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Any interested person (institutional customer, industrial customer, or food industry member, i.e., manufacturer, packer, or distributor) desiring to apply for a temporary marketing permit must file a written application, at any time, responding to § 130.17. After the information in the application is received by FDA, it is reviewed to assure that it is sufficient. When information is lacking, the applicant is promptly contacted and told of the deficiencies. When the information received warrants the issuance of a permit, a letter granting the permit is issued to the applicant and a notice of issuance of the permit is published in the *Federal Register*.

The industry is aware that the issuance of a temporary marketing permit is contingent upon the submission of finished labels. Thus, the industry's labeling of an experimental food not only alerts consumers that the food may vary from their expectations of the standardized food, but also protects consumers against false and misleading labeling.

The penalties for shipping foods that deviate from their applicable standards without an approved temporary marketing permit are seizure and injunction, as well as criminal actions such as fines and imprisonment.

Description of Respondents: Respondents to this collection of information include private sector businesses including institutional and/or industrial customers and food industry members such as manufacturers, packers, or distributors desiring to apply for a temporary marketing permit or permit extension.

3. Use of Improved Information Technology and Burden Reduction

Industry is increasingly using automatic production facilities. The use of automated printouts is acceptable for purposes of evaluating new food products prior to submitting a petition to amend a standard. Any use of improved technology appropriate to satisfy FDA regulation is acceptable. We estimate that 90% of respondents will use electronic means to satisfy the information collection provisions found in the regulations.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. FDA is specifically charged with issuing temporary marketing permits for market testing of experimental foods under its jurisdiction.

5. Impact on Small Businesses or Other Small Entities

While the regulations provide for no exemptions and some respondents may be small businesses, 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 have provided a Small Business Guide on the agency's website at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

There are no legal obstacles to reduce the burden for this collection of information. However, information generated under temporary marketing permits on the acceptability of the variation in the standardized food is an important factor in the agency's decision on whether to propose to amend the applicable standard of identity to provide for the variation.

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

There are no special circumstances associated for 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 for public comment in the *Federal Register* of April 16, 2020 (85 FR 21247). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement we consulted with our Privacy Office to ensure appropriate handling of the information collected. The existence of the application for a temporary marketing permit is regarded as confidential commercial information because it would disclose the intent of the company to pursue the marketing of a new product. Once a notice is published announcing the issuance of the permit, the application is no longer regarded as confidential. Confidential commercial information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20).

Privacy Act

This ICR does not collect personally identifiable information (PII) or information of a personal nature. The information collected is for business contact purposes only and includes business name, business address, business telephone numbers. The business contact information is maintained and stored at the vendor facility. We further determined that the business information is collected and stored at the vendor facility, the collection is not subject to the Privacy Act of 1974, and the particular notice and other requirements of the Act do not apply. Specifically, we (including vendors or service providers acting on behalf of FDA) do not use name or any other personal identifier to retrieve records from the information collected.

11. Justification for Sensitive Questions

This information collection does not involve any questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
130.17(c); permit request	13	2	26	25	650
130.17(i); extension request	1	2	2	2	4
Total					654

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

The estimated number of temporary marketing permit applications and hours per response is an average based on the agency's experience with applications received and information from firms that have submitted recent requests for temporary marketing permits. Based upon this prior history, we estimate that, on an annual basis, we will receive approximately 26 temporary marketing permits from 13 applicants and 2 requests for extensions from 1 applicant. The total reporting burden for these applications is 654 hours.

12b. Annualized Cost Burden Estimate

We estimate the annualized burden hour cost to respondents to be approximately $64,340.52. We estimate that this collection of information will involve an employee making an average wage similar that of a Federal government employee at the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2020, which is $49.19 per hour. To account for overhead, this cost is increased by 100 percent, which is $98.38 per hour. Thus, the annual wage cost imposed by this collection of information is approximately $64,340.52 (654 hours x $98.38 per hour).

Table 2.--Estimated Annual Cost Burden

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Applying for permit	650	$98.38	$63,947.00
Applying for extension	4	$98.38	$393.52
Total			$64,340.52

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

There are no capital, start-up, operating or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

Assuming approximately 0.4 (four-tenths) FTE is allocated annually to process applications for temporary marketing permits; using a salary rate of $92,091 per year (equivalent to a GS-12/Step-3 rate for the Washington-Baltimore locality pay area for the year 2020) and doubling it to account for overhead; we estimate an annual cost to the Federal government of $73,672.80 ($36,836.40 x 2).

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

The agency has no plans for publication of information from this information collection. However, the issuance of a temporary marketing permit is announced in the *Federal Register*.

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

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.