Temporary Marketing Permit Applications

0910-0133

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

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 "[w]henever * * * 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 (§ 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 request OMB approval for the following information collection requirements contained in §130.17:

21 CFR 130.17(c) Reporting

Provides format and information for a request for a temporary marketing permit.

21 CFR 130.17(i) Reporting

Provides format and information for a request for an extension of a temporary marketing permit.

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: The likely respondents include businesses manufacturing, packing, or distributing food sold in the United States. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

Industry is increasingly turning to the use of 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. Firms may submit temporary marketing permit applications by e-mail. The agency estimates that about twenty-five percent (25%) of the temporary marketing permit applications will be submitted electronically in the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only Federal agency with the authority to issue temporary marketing permits for market testing of experimental foods under FDA jurisdiction. No similar information collection requirement exists.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that ten percent (10 %) of respondents are small businesses. The reporting requirements of these regulations are mandated by the act and there is no statutory exception for small businesses. FDA aids 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. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. There are no consequences to Federal program or policy activities if the information is not collected or is collected less frequently. 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 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), FDA published a 60 day notice for public comment in the Federal Register of June 10, 2011 (76 FR 34080). No comments were received. FDA communicates regularly with firms that have submitted recent requests for temporary marketing permits. None of these firms had comments concerning the provisions of § 130.17.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

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).

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection of information as follows:

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

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
130.17(c)	13	2	26	25	650
130.17(i)	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 for the past 3 years, and information from firms that have submitted recent requests for temporary marketing permits. Based on this information, we estimate that there will be, on average, approximately 13 firms submitting requests for two temporary marketing permits per year over the next 3 years.

Thus, FDA estimates that 13 respondents will submit 2 requests for temporary marketing permits annually under § 130.17(c). The estimated number of respondents for § 130.17(i) is minimal because this section is seldom used by the respondents; therefore, the Agency estimates that there will be one or fewer respondents annually with two or fewer requests for extension of the marketing permit under § 130.17(i). The estimated number of hours per response is an average based on the Agency's experience and information from firms that have submitted recent requests for temporary marketing permits. We estimate that 13 respondents each will submit 2 requests for temporary marketing permits under § 130.17(c) and that it will take a respondent 25 hours per request to comply with the requirements of that section, for a total of 650 hours. We estimate that one respondent will submit two requests for extension of its temporary marketing permits under § 130.17(i) and that it will take a respondent 2 hours per request to comply with the requirements of that section, for a total of 4 hours.

12 b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is approximately $ 55,799.28 per year. FDA estimates that the average hourly wage for the employee preparing and submitting the temporary marketing permit application would be equivalent to a GS-13/Step-1 level in the locality pay area of Washington-Baltimore in 2011, approximately $42.66/hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $85.32/hour. Thus, the overall estimated cost incurred by the respondents is $55,799.28 (654 burden hours x $85.32/hr = $55,799.28.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

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

14. Annualized Cost to Federal Government

FDA estimates that approximately 0.4 of a professional person per year is used annually to process applications for temporary marketing permits. The salaries of the professionals involved are estimated to average approximately $84,855 per year. Therefore, about $33,942 per year (0.4 X $84,855) is spent on professional salaries alone. This estimate also presumes that overhead will be equal to salary for a total cost to the Federal Government to process applications for temporary marketing permits of approximately $67,884 per year.

15. Explanation for Program Changes or Adjustments

There was no change in the 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

Approval to not display the expiration date for OMB approval of the information collection is not being sought.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.