

SUPPORTING STATEMENT
Applications for Temporary Marketing Permits
(21 CFR 130.17(c) and (I))
OMB No. 0910-0133

A. JUSTIFICATION

1. Necessity for the Information Collection

Section 401 of the Federal Food, Drug, and Cosmetic Act (the 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." These actions, intended to resolve economic problems, may result from petitions from consumer groups, the food industry, or interested persons, or from the agency's own initiative. Under section 403(g) of the 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 (Attachment A).

To enable the food industry to obtain data in support of petitions to amend food standards, FDA issues temporary marketing permits for interstate shipment of experimental packs of food varying from requirements of standards of identity, in accordance with the regulation in §130.17 (21 CFR 130.17) (Attachment B). This regulation allows a manufacturer, packer, or distributor, etc., to conduct investigations of a potential advance in food technology to determine the advantages to, and acceptance by, consumers of a variation in a food from an applicable standard of identity.

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. How, by Whom, and for What Purpose Information is Used

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.

3. Use of Improved Information Technology

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.

4. Identification of Duplication and Similar Information Already Available

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. Small Business

The same information is requested from large and small firms and is the minimal amount needed. There is no special burden placed on small businesses by this regulation. To exempt a small business would only hurt that business since it could not market test an experimental food. Of the approximately 6 companies per year that request temporary marketing permits, only 1 or 2 could be considered to be small companies. The agency, however, does have an office of Small Manufacturers Assistance which may be contacted if help is needed.

6. **Consequences if Data Were Collected Less Frequently**

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**

There are no special circumstances associated with this information collection.

8. **Outside Consultation**

FDA contacted a sampling of firms that have submitted recent requests for temporary marketing permits. None of these firms had comments concerning the provisions of § 130.17.

In accordance with 5 CFR 1320.8(d), on Tuesday, June 8, 1999, (64 FR 30524), a 60-day notice for public comment (Attachment C) was published in the Federal Register. No comments were received from the public.

9. **Gifts**

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

10. **Confidentiality**

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.

11. **Sensitive Questions**

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

12. **Respondent Hour Burden and Annualized Burden Hour Costs Estimates**

Burden Hours.

The annual burden hour for this information collection is 91 hours, as follows:

Estimated Annual Reporting Burden					
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
103.17(c)	3	1	3	25	75
103.17(I)	4	2	8	2	16
Total					91

Estimated Annualized Cost for the Burden Hours.

The estimated number of temporary marketing permit applications and hours per response is an average based on the agency's experience with applications received from October 1, 1995, through September 30, 1998 and information from firms that have submitted recent requests for temporary marketing permits. During that period FDA received a total of 10 requests for temporary marketing permits under 103.17(c) from a total of 10 applicants. During that same period, FDA received a total of 23 requests for temporary marketing permit extensions under 103.17(I) from a total of 17 applicants. Based upon this prior history, FDA estimates that it will receive approximately 3 temporary marketing permit and 8 requests for extensions annually from 3 and 4 applicants respectively. The burden for these applications is approximately 91 hours. FDA estimates the annualized cost to respondents for the hour burden associated with the requirements of this regulation to be approximately \$4,700. This estimate presumes that the hourly cost to affected firms will not

exceed the base hourly rate of a GS-13 salary (\$26) plus overhead expenses estimated as being equal to salary, or \$52.

13. **Annual Cost Burden to Respondent**

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

14. **Annualized Cost to the 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 \$58,000 per year. Therefore, about \$23,200 per year (0.4 X \$58,000) 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 \$46,400 per year.

15. **Changes or Adjustments in Burden**

The decrease in the total burden reflected in this statement (-139 hours) reflects a decrease in the number of applications (a decrease in the number of applicants and responses) and, therefore, a decrease in burden (negative adjustment).

16. **Statistical Analysis, Publication Plans, and Schedule**

Not applicable.

17. **Approval Not to Display Expiration Date**

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

18. **Exception to the Certification Statement Identified in Item 19**

No exceptions to the certification statement identified in item 19 of the instructions for completing OMB form 83-1 have been identified.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

There are no plans to publish the information collected under the provisions of this regulation for statistical use. The collection of information required under the provisions of this regulation does not employ statistical methods.

