**TEMPORARY MARKETING PERMIT APPLICATIONS**

**OMB No. 0910-0133**

**SUPPORTING STATEMENT**

## A. Justification

### 1. Circumstances Making the Collection of Information Necessary

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 "[w]henever * * * such action will promote honesty and fair dealing in the interest of consumers * * *." 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. 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 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.

**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.

**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**

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. The agency, however, does have an office of Small Manufacturers Assistance which may be contacted if help is needed.

**6. Consequences of Collecting the Information 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 Relating to the Guidelines of 5 CFR 1320.5**

There are no special circumstances associated with 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), FDA published a 60 day notice for public comment in the Federal Register of April 2, 2008 (73 FR 17986). 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**

This information collection does not provide for 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 of a sensitive nature.

**12. Estimates of Annualized Burden Hours and Costs**

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

| Total Estimated Annual Reporting Burden[1] | | | | | |
|---|---|---|---|---|---|
| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours 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 October 1, 2004, through September 30, 2007, and information from firms that have submitted recent requests for temporary marketing permits. Based upon this prior history, FDA estimates that, on an annual basis, it will receive approximately 2 temporary marketing permits from 13 applicants and 2 requests for extensions from 1 applicant. The burden for these applications is approximately 654 hours.

Estimated Annualized Cost for the Burden Hours

FDA estimates the annualized cost to respondents for the hour burden associated with the requirements of this regulation to be approximately $49,926.36. This estimate presumes that the hourly cost to affected firms will not exceed the base hourly rate of a GS-13 salary ($38.17) plus overhead expenses estimated as being equal to salary, or $76.34. Thus, 654 hours x $76.34 per hour equals $49,926.36

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

There are no capital costs or operating and 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 $79,397 per year. Therefore, about $31,759 per year (0.4 X $79,397) 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 $63,518 per year.

## 15. Explanation for Program Changes or Adjustments

The increase in the estimated reporting burden is due primarily to an increase in the estimated number of applications for temporary marketing permits.

## 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

No exceptions are requested.