DEPARTMENT OF THE TREASURY

ALCOHOL AND TOBACCO TAX AND TRADE BUREAU

Supporting Statement - Information Collection Request

OMB Control Number 1513-0121

TTB Recordkeeping Requirement – 4.32, 5.32, 7.22, 4.32a, 5.32a, 7.22a, 4.32b, 5.32b, 7.22b
Labeling of Major Food Allergens

A. JUSTIFICATION

1. What are the circumstances that make this collection of information necessary and what legal or administrative requirements necessitate the collection?

This collection of information involves mandatory labeling of major food allergens used in the production of alcohol beverages and includes a petition procedure to permit less than full allergen labeling. The information collection corresponds to the recent amendments to the Federal Food, Drug and Cosmetic Act (FD&C Act), 21 U.S.C. 301, *et seq.*, contained in the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), Title II of Public Law 108–282, 118 Stat. 905.

The allergen labeling requirements in the FALCPA do not directly apply to alcohol beverages subject to the labeling requirements of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 201 *et seq.*, and TTB regulations. However, the House of Representatives Committee on Energy and Commerce called for TTB to work with FDA to promulgate appropriate allergen labeling regulations for these alcohol beverages pursuant to our MOU with FDA.

The Committee Report accompanying FALCPA stated:

> The Committee expects, consistent with the November 30, 1987 Memorandum of Understanding, that the Alcohol and Tobacco Tax and Trade Bureau (TTB) of the Department of Treasury will pursuant to the Federal Alcohol Administration Act determine how, as appropriate, to apply allergen labeling of beverage alcohol products and the labeling requirements for those products. The Committee expects that the TTB and the FDA will work together in promulgation of allergen regulations, with respect to those products. H.R. Rep. No. 608, 108th Cong., 2d Sess., at 3 (2004).

The implementing regulations setting forth the requirements for mandatory major food allergen declarations on product labels will be published as a proposed rule

adding the requirements to Title 27 of the CFR, Parts 4, 5, and 7, “Mandatory labeling information” at §§ 4.32, 5.32, and 7.22, “Major food allergens” at §§ 4.32a, 5.32a, and 7.22a, and “Petitions for exemption from major food allergen labeling” at §§ 4.32b, 5.32b, and 7.22b.

2. How, by whom, and for what purpose is this information used?

The information collection will require alcohol beverage producers to declare major food allergens on their product labels. This information will provide a health warning to allergic consumers. A producer must declare all allergens used in production except when a petition for exemption from labeling has been granted for a particular allergen.

This information collection also helps TTB enforce our primary statutory responsibility under the FAA Act of providing the consumer with adequate information concerning the identity and quality of alcohol beverage products.

3. To what extent does this collection of information involve the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology? What consideration is given to use information technology to reduce burden?

TTB will approve, on a case-by-case basis, the use of improved technology for the maintenance of this information.

4. What efforts are used to identify duplication? Why can the agency not use or modify for use any similar information already available for the purposes described in Item 2 above?

No similar information is available from other sources.

5. If this collection of information impacts small businesses or other small entities, what methods are used to minimize burden?

The collection of information does not have a significant impact on a substantial number of small businesses or other small entities.

6. What consequences to Federal program or policy activities and what, if any, technical or legal obstacles to reducing burden will occur if this collection is not conducted or is conducted less frequently?

This information collection requirement is mandatory and considered to be the minimum necessary to comply with the congressional intent as announced in the FALCPA. Less frequent collection of this information would be contrary to the Congressional intent announced in the FALCPA.

7. Are there any special circumstances associated with the information collection?

This information collection requirement is considered to be the minimum necessary to ensure that consumers are adequately warned that major food allergens may be present in alcohol beverages, and it complies with the congressional intent as announced in the FALCPA.

8. What effort was made to notify the general public about this collection of information?

A 60-day Federal Register notice was published for this information collection on Wednesday, July 26, 2006, 71 FR 42329. The notice solicits comments from the general public.

9. What decision was made to provide any payment or gift to respondents, other than reenumeration of contractors or grantees?

No payment or gift is associated with this collection.

10. What assurance of confidentiality was provided to respondents and what was the basis for the assurance in statute, regulations, or agency policy?

Records associated with this collection are maintained at the premises of the regulated individual. However, 18 U.S.C. 1905, and 5 U.S.C. 552 protect the confidentiality of proprietary or personal information obtained by the agency.

11. What justification is there for questions of a sensitive nature?

We ask no questions of a sensitive nature.

12. What is the estimated hour burden of this collection of information?

The estimated number of petition respondents, 20, and the estimated average number of records prepared annually by each such respondent, 1, are based on informal surveys of our industry. The estimated average number of hours per response, 20 hours, is based on information provided by our laboratory personnel.

The estimated number of respondents for allergen labeling, 5,000, and the estimated average number of records prepared annually by each respondent, 1, are based on industry data provided by TTB field personnel and our industry analysts. The estimated average number of hours per response, 0.66 hours, is based on information provided by our industry analysts.

The total burden for industry is approximately 3,700 hours.

13. What is the estimated total annual cost burden to respondents or recordkeepers resulting from this collection of information?

Total annual cost estimate associated with this paperwork requirement is allocated entirely to preparation and maintenance. Annual costs are allocated as follows:

Personnel time requirements:

Senior level preparation of 0.66 hours @ $75.00/hour per allergen labeling respondent	=	$ 49.50
Total industry cost burden for 5,000 labeling respondents	=	$247,500
Senior level preparation of 20 hours @ $100.00/hour per petition respondent	=	$ 2,000
Total industry cost burden for 20 petition respondents out of 5,000 labeling respondents	=	$ 40,000
Total estimated annual cost burden for all labeling and petition respondents	=	$287,500

14. What is the annualized cost to the Federal Government?

Records are prepared and maintained by the respondent; therefore there is no cost to the Government for preparation of these records.

15. What is the reason for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-I?

The previous collection of information for labeling of major food allergens was voluntary. We estimate approximately 500 businesses would voluntarily label major food allergens.

We are proposing to make major food allergen labeling mandatory. Accordingly more industry members will be required to comply with the information collection, our records indicate that approximately 5,000 businesses will be required to comply with the proposed regulations.

16. Outline plans for tabulation and publication for collections of information whose results will be published.

The results of this collection will not be published.

17. If seeking approval to not display the expiration date for OMB approval of this information collection, what are the reasons that the display would be inappropriate?

We do not intend to display the expiration date of OMB approval for this collection because there is no appropriate medium for displaying it.

18. What are the exceptions to the certification statement?

(c) See question 5 above.
(f) This is a labeling requirement therefore there is no record retention period.
(i) N/A

B. This collection does not employ statistical methods.