DEPARTMENT OF THE TREASURY

ALCOHOL AND TOBACCO TAX AND TRADE BUREAU

Supporting Statement – Information Collection Requirement

OMB Control Number – 1513-0084

Labeling of Sulfites in Alcoholic Beverages

A. JUSTIFICATION

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

The Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e)(2), vests broad authority in the Secretary of the Treasury to prescribe regulations which will provide "adequate information" regarding the identity and quality of alcohol beverages. Under this authority, labeling requirements are prescribed in Title 27 CFR Parts 4, 5, and 7, for wines, distilled spirits, and malt beverages, respectively.

In the July 9, 1986 issue of the Federal Register (51 FR 25012), the Department of Health and Human Services and the O.S. Food and Drug Administration published in a final rule establishing 10 parts per million (ppm) as the threshold for declaration of sulfites in the labeling of foods, nonalcoholic beverages, and wine products containing less than seven percent of alcohol by volume. In the preamble of the proposed rule published in the Federal Register on April 3, 1985, it was stated that, "sulfiting agents have been shown to produce allergic-type responses in humans, and the presence of these ingredients in food may have serious health implications for those persons who are intolerant of sulfites." FDA stated further that "a label declaration of sulfites in food will enable persons intolerant to sulfites to minimize their exposure to these ingredients."

Consistent with the FAA Act and the determinations made by FDA and HHS, regulations were adopted in 27 CFR Parts 4, 5, and 7 of TTB regulations (27 CFR 4.32, 5.32 and 7.22) that require a declaration of sulfites on alcoholic beverages labels when sulfites are present at levels of 10 or more parts per million (ppm).

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

In accordance with our consumer protection responsibilities pursuant to the FAA Act, we require label disclosure statements on all alcoholic beverage products released from U.S. bottling premises or customs custody that contain 10 parts per million (ppm) or more of sulfites because sulfiting agents at and above that level have been shown to produce

allergic-type responses in humans, particularly asthmatics. The presence of these ingredients in alcohol beverages may have serious health implications for those who are intolerant of sulfites, and disclosure of the existence of these levels of sulfites on the labels of alcohol beverages will allow consumers to minimize their exposure to these ingredients.

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 believes that improved information technology would not prove cost effective as a means for reducing burden, since the collection information requirement must appear on an actual label, as it would appear on the finished product.

4. What efforts are used to identify duplication? Why can't any similar information already available be used or modified for use for the purposes described in Item 2 above?

Efforts to identify duplication are not applicable to the collection of information for the purpose of disclosure to the general public through labeling or advertising.

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

The collection of information requirement contained in this information collection is considered to be the minimum necessary to insure compliance. The information collection burden cannot be reduced on the basis of the size of the respondent entity.

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?

Respondents complete this information only as necessary to comply with TTB regulations, specifically, as it relates to the requirement for a Certificate of Label Approval (TTB F 5100.31). No similar information is available from any other source.

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

There are no special circumstances associated with this information collection.

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 Thursday, June 8, 2006, 71 FR 33335. The notice solicited comments from the general public. TTB received no comments.

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?

Assurance of confidentiality is not applicable for this third party disclosure.

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 burden of the collection of information requirement contained in this information collection is estimated to be -

| | |
|---|---|
| Total number in universe - | 6,060 |
| No. of respondents affected by collection of information requirement | 4,787 |

(TTB has determined the affected respondents represent 5% of brewers, 100% of winemakers, 80% of importers, and 1% of DSP plants.)

This requirement will have the following results -

| | |
|---|---|
| No. of respondents - | 4,787 |
| Frequency of response - | 1 |
| Hours per response - (Based on calculations derived through consultation with TTB Laboratory personnel) | .66 |
| Annual burden hours | 3,159 |

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

No new cost is associated with this collection.

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

There is no cost to the Federal government.

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

There are no program changes or adjustments associated with this collection.

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?

It would be inappropriate to display the expiration date for OMB approval because this request is a labeling requirement. Therefore, unlike the form, there is no medium to display the expiration date.

18. What are the exceptions to the certification statement?

There are no exceptions to the certification statement.

## B. Collection of Information Employing Statistical Methods

This collection does not employ statistical methods.