

DEPARTMENT OF THE TREASURY
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU

Supporting Statement -- Information Collection Request

OMB Control Number 1513-NEW

**Certificates of Label Approval (COLAs) and Label and Advertising Claims
Substantiation Records**

A. Justification

- 1. What are the circumstances that make this collection of information necessary, and what legal or administrative requirements necessitate the collection? Also align the information collection to TTB's Line of Business/Sub-function and IT Investment, if one is used.*

The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the Federal Alcohol Administration Act (FAA Act, 27 U.S.C. chapter 8), pursuant to section 1111(d) of the Homeland Security Act of 2002, as codified at 6 U.S.C. 531(d). In addition, the Secretary of the Treasury (Secretary) has delegated certain FAA Act administrative and enforcement authorities to TTB through Treasury Order 120–01.

To provide consumers with adequate information as to the identity of alcohol beverage products, to prevent consumer deception, and to prohibit false or misleading statements on labels and in advertisements of such products, the Federal Alcohol Administration Act at 27 U.S.C. 205(e) requires that alcohol beverages sold or introduced into interstate or foreign commerce be labeled in conformity with regulations issued by the Secretary. Under this statutory authority, the TTB regulations require that the producer, bottler, or importer of an alcohol beverage receive approval of the product's label from TTB prior to the product's introduction into interstate or foreign commerce.

The TTB regulations implementing the labeling and advertising provisions of the FAA Act, including the requirements to apply for and receive certificates of label approval (COLAs) or certificates of exemption of label approval are found in 27 CFR parts 4 (wine), 5 (distilled spirits), and 7 (malt beverages).¹ When applicable, domestic bottlers and importers apply for COLAs or certificates of exemption using TTB F 5100.31, Application for and Certification/Exemption of Label/Bottle Approval, which is approved under OMB control number 1513–0020.

Currently, in Notice No. 176, Modernization of the Labeling and Advertising Regulations for Wine, Distilled Spirits, and Malt Beverages, TTB is proposing to comprehensively amend its regulations governing the labeling and advertising of alcohol beverages in order to improve understanding of the regulatory requirements and to make compliance easier and less burdensome for industry members. As proposed, 27 CFR parts 4, 5, and 7 continue to contain the labeling regulations for wine, distilled spirits, and malt beverages, respectively,

¹. Domestic bottlers and importers apply for COLAs or certificates of exemption using TTB F 5100.31, Application for and Certification/Exemption of Label/Bottle Approval, or its electronic equivalent, COLAs Online, which are approved under OMB control number 1513–0020.

while the current subparts of parts 4, 5, and 7 that relate to advertising are removed from those parts and consolidated into a new part 14. These revisions are intended to simplify and clarify TTB's alcohol beverage labeling and advertising regulatory standards, and incorporate statutory changes, international agreements, recent case law, and current TTB guidance documents and policy into the regulations.

In the proposed rule, TTB also is proposing new recordkeeping requirements, which are contained in proposed §§ 4.211, 4.212, 5.211, 5.212, 7.211, 7.212, and 14.4. The new recordkeeping requirements in proposed §§ 4.211, 5.211, and 7.211 provide that, upon request by the appropriate TTB officer, a bottler or importer must provide evidence that a label used on an alcohol beverage container is covered by a COLA or a certificate of exemption. This requirement may be satisfied by providing original certificates, photocopies or electronic copies of COLAs, or records showing the TTB Identification number assigned to the COLA. Where labels on containers reflect revisions to the approved label that have been made in compliance with allowable revisions authorized on the COLA form or otherwise authorized by TTB, the bottler or importer must be able to identify the COLA covering the product. Under these proposed regulations, bottlers and importers are required to keep records identifying each COLA for a period of five years from the date the products covered by the COLA were removed from the bottler's premises or from customs custody, as applicable.

The new recordkeeping requirements in proposed §§ 4.212, 5.212, 7.212, and 14.4 set forth specific substantiation requirements that apply to any claim made on any label or container subject to the requirements of part 4, 5, or 7, or any claim made in an advertisement subject to part 14. These substantiation requirements are new to the regulations, but they reflect TTB's current expectations as to the level of evidence that industry members should have to support labeling claims. Proposed §§ 4.212, 5.212, and 7.212 provide that the appropriate TTB officer may request that bottlers and importers provide evidence that labeling claims are adequately substantiated, and that such requests may be made at any time within five years from the time the alcohol beverage was removed from the bottling premises or from customs custody, as applicable. Proposed § 14.4(c) provides that the appropriate TTB officer may request that the responsible advertiser provide evidence that advertising claims are adequately substantiated at any time within a period of five years from the time the advertisement was last disseminated or published.

TTB believes that these COLA approval and label and advertising claim substantiation records are necessary to ensure that:

- Labels applied to alcohol beverage containers are covered by a COLA or label approval exemption; and
- Claims made on the labels of alcohol beverage containers and claims made in advertisements for alcohol beverages are truthful, accurate, and not misleading and do not contain any prohibited practices.

TTB believes that alcohol beverage industry members currently keep usual and customary records during the normal course of business that substantiate label approvals and exemptions and label and advertising claims, regardless of any regulatory requirement to do so. Such records may include copies of COLAs and certificates of exemption, product evaluation and testing records, consumer preference studies, and invoices regarding the purchase and source of raw materials. As such, TTB believes that while this new

recordkeeping requirement will assist TTB in meeting its statutory obligation to protect the public, the requirement will impose no additional burden on alcohol beverage industry members.

This information collection is aligned with —

- Line of Business/Sub-function: Law Enforcement/Substance Control.
- IT Investment: None.

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

The records mandated in this proposed new information collection will be kept and maintained by the regulated alcohol industry members at their business premises. These records will be subject to inspection by TTB personnel during field product integrity examinations, which TTB conducts to ensure that alcohol beverage products are labeled and advertised in a truthful and non-misleading manner as required by the FAA Act and the TTB regulations. During these examinations, TTB personnel would verify that:

- Labels applied to alcohol beverage containers are covered by a COLA or label approval exemption; and
- Claims made on the labels of alcohol beverage containers and claims made in advertisements for alcohol beverages are truthful, accurate, and not misleading and do not contain any prohibited practices.

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?

The records mandated in the proposed new information collection requirement will be kept and maintained by the regulated alcohol industry members at their business premises. Industry members may use information technology to keep and maintain these records, provided that TTB personnel have ready access to the records during field inspections.

4. What efforts are used to identify duplication? Can similar information already available be used or modified for use for the purposes described in Item 2 above?

The records required under this information collection contain information pertinent to each respondent and that are applicable to the specific issue of substantiation of the information provide on labels and in advertisements of alcohol beverage products. As far as TTB is able to determine, similar information is not available to it elsewhere.

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

All entities, regardless of size, are required by the TTB regulations to keep and maintain the records required under this information collection approval. While TTB has not previously specifically required the keeping of these records, TTB believes that industry members keep

such records during the usual and customary course of business. As such, this information collection will place no additional burden on small businesses.

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?

TTB believes that this information collection requirement is the minimum necessary to protect the public by ensuring compliance with FAA Act and TTB alcohol beverage labeling and advertising regulations. Alcohol products with unverifiable labels could jeopardize the public by allowing untruthful or misleadingly-labeled products to enter interstate commerce.

7. Are there any special circumstances associated with this information collection that would require it to be conducted in a manner inconsistent with OMB guidelines?

Under the OMB regulations at 5 CFR 1320.5(d)(2)(iv), a requirement to retain records for more than three years is a special circumstance. Under the proposed TTB regulations, alcohol beverage bottlers and importers will be required to keep records identifying each COLA for a period of five years from the date the products covered by the COLA were removed from the bottler's premises or from customs custody, as applicable. In addition, bottlers and importers will be required to keep records substantiating label and advertising claims for five years from the time an alcohol beverage was removed from the bottling premises or from customs custody, or from the time an advertisement was last disseminated or published, as applicable. TTB believes that this five-year retention period for the usual and customary business records substantiating label approvals and exemptions, and substantiating label and advertising claims, is necessary to adequately protect the public.

8. What effort was made to notify the general public about this collection of information? Summarize the public comments that were received and describe the action taken by the agency in response to those comments.

To solicit comments from the general public regarding the proposed recordkeeping requirements, TTB published a proposed rule, Notice No. 176, Modernization of the Labeling and Advertising Regulations for Wine, Distilled Spirits, and Malt Beverages, in the Federal Register on November 26, 2018, at 83 FR 60562–60693, which will be open for public comment for 120 days, until March 26, 2019.

9. Was any payment or gift given to respondents, other than remuneration of contractors or grantees? If so, why?

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?

No specific assurance of confidentiality is provided for this information collection, which consists of usual and customary records maintained by regulated industry members at their

business premises. While most of the records kept under this information collection requirement are related to alcohol beverage labels, which are publically disclosed, Federal law at 5 U.S.C. 552 protects the confidentiality of any proprietary information obtained by the Government from regulated businesses and individuals.

11. What is the justification for questions of a sensitive nature? If personally identifiable information (PII) is being collected in an electronic system, identify the Privacy Impact Assessment (PIA) that has been conducted for the information collected under this request and/or the Privacy Act System of Records notice (SORN) issued for the electronic system in which the PII is being stored.

This information collection contains no questions of a sensitive nature. In addition, this information collection does not collect personally identifiable information (PII) in an electronic system. Therefore, no Privacy Impact Assessment (PIA) or System of Records Notice (SORN) is required for this collection.

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

This information collection requires the keeping of usual and customary business records that would be kept by regulated industry members at their premises during the normal course of business, even without the TTB regulatory requirements to keep such records. Therefore, in accordance with 5 CFR 1320.3(b)(2), there is not annual burden for the estimated 10,982 current alcohol beverage industry members required to keep these usual and customary business records.

The retention requirement for the records kept and maintained under this information collection is five years. Specifically, records identifying each COLA is five years after the COLA is last used on a product removed from the bottler's premises or from customs custody, as applicable. The retention requirement for records substantiating claims made on labels and in advertisements is five years from the time the label or advertisement was last disseminated or published.

13. What is the estimated annual cost burden to respondents or record keepers resulting from this information collection request (excluding the value of the hour burden in Question 12 above)?

This information collection consists of usual and customary business records that respondents keep at their premises during the normal course of business. Therefore, there is no cost to respondents associated with this collection.

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

There is no cost to the Federal Government for the maintenance of usual and customary business records by proprietors at their business premises.

15. What is the reason for any program changes or adjustments reported?

Program changes: This is a new information collection associated with a proposed rule, Notice No. 176, Modernization of the Labeling and Advertising Regulations for Wine, Distilled Spirits, and Malt Beverages, published by TTB in the Federal Register on November 26, 2018 (83 FR 60562), as part of its regulations modernization program. The proposed rule contains several new recordkeeping requirements related to alcohol beverage labels and advertising, to be approved under this single information collection request, and which are contained in proposed §§ 4.211, 4.212, 5.211, 5.212, 7.211, 7.212, and 14.4. Details of the recordkeeping and record retention requirements related to substantiation of alcohol beverage label approvals or exemptions and label and advertising claims are discussed in detail above in the response to Question 1.

While TTB has not previously specifically required the maintenance of such records, TTB believes that the required records are usual and customary records kept by industry members during the course of business. TTB now believes that the keeping of such records should be mandatory in order to allow the bureau to ensure and verify that:

- Labels applied to alcohol beverage containers are covered by a COLA or label approval exemption; and
- Claims made on the labels of alcohol beverage containers and claims made in advertisements for alcohol beverages, including claims of origin for wine or of age or origin for distilled spirits, are truthful, accurate, and not misleading to the consumer.

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

TTB will not publish the results of this collection.

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?

This information collection consists of usual and customary business records that respondents keep at their premises during the normal course of business. Therefore, there is no prescribed TTB form for this collection, and, as such, there is no medium for TTB to display the OMB approval expiration date.

18. What are the exceptions to the certification statement?

- (c) See item 5 above.
- (i) No statistics are involved.
- (j) See item 3 above.

B. Collections of Information Employing Statistical Methods.

This collection does not employ statistical methods.