

Issued in Renton, Washington, on October 19, 1999.

D.L. Riggins,

*Acting Manager, Transport Airplane
Directorate, Aircraft Certification Service.*

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DEPARTMENT OF THE TREASURY

27 CFR Parts 4, 5, and 7

Bureau of Alcohol, Tobacco and Firearms

[Notice No. 884]

RIN 1512-AB97

Health Claims and Other Health- Related Statements in the Labeling and Advertising of Alcohol Beverages (99R-199P)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: ATF is proposing to amend the regulations to prohibit the appearance on labels or in advertisements of any statement that makes a substantive claim regarding health benefits associated with the consumption of alcohol beverages unless such claim is properly qualified, balanced, sufficiently detailed and specific, and outlines the categories of individuals for whom any positive health effects would be outweighed by numerous negative health effects. ATF is also proposing to prohibit any advertisements that attribute health benefits to the consumption of alcohol beverages unless such statement is appropriately qualified in a manner that is not likely to result in any consumer confusion or deception. This notice seeks comments on whether the negative consequences of alcohol consumption or abuse disqualify, as misleading, these products entirely from entitlement to any health-related statements. This notice also seeks comments on whether health-related statements on alcohol beverage labels and advertising directing consumers to sources, such as the U.S. Government Dietary Guidelines, of information are misleading and whether ATF should continue to approve such statements.

The proposed regulations are intended to ensure that labels and advertisements do not contain statements or claims that would tend to mislead the consumer about the significant health consequences of alcohol consumption.

DATES: Comments must be received on or before February 22, 2000.

ADDRESSES: Send written comments to: Chief, Regulations Division; Bureau of Alcohol, Tobacco and Firearms; P.O. Box 50221; Washington, DC 20091-0221; *ATTN: Notice No. 884*. Submit e-mail comments to:

nprm.notice.884@atfhq.atf.treas.gov. E-mail comments must contain your name, mailing address, and e-mail address. They must also reference this notice number and be legible when printed on not more than three pages 8½" × 11" in size. We will treat e-mail as originals and we will not acknowledge receipt of e-mail.

FOR FURTHER INFORMATION CONTACT:

James P. Ficaretta, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226 (202-927-8230).

SUPPLEMENTARY INFORMATION:

I. Background

Under the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e) and (f), we are authorized to issue regulations on the packaging, labeling, and advertising of alcohol beverages in order to prohibit deception of the consumer and, without regard to their truth or falsity, statements relating to analyses, guarantees, and scientific or irrelevant matters that are likely to mislead the consumer.

Regulations that implement the provisions of section 205(e) and (f), as they relate to the labeling and advertising of wine, distilled spirits, and malt beverages, are set forth in Title 27, Code of Federal Regulations (CFR), parts 4, 5, and 7, respectively. Under these regulations, labels and advertisements are prohibited from containing any statement, design, representation, pictorial representation, or device representing that the use of wine, distilled spirits, or malt beverages has curative or therapeutic effects if such representation is untrue in any particular or tends to create a misleading impression. This prohibition originated more than 60 years ago with the initial labeling and advertising regulations issued under the FAA Act.

ATF and our predecessor agencies have historically taken a very strict view of the regulatory prohibition on curative or therapeutic claims about alcohol beverages. This strict interpretation is based on the view that "distilled spirits, wines and malt beverages are, in reality, alcoholic beverages and not medicines of any sort, * * *" (FA-129, dated January 5, 1938).

In view of the undisputed health risks associated with alcohol consumption, it has always been our position that statements attributing positive health effects to the consumption of alcohol beverages are misleading unless such statements are appropriately qualified and properly balanced.

II. Our Existing Policy Regarding Health Claims and Other Health-Related Statements—Summary

The following is a summary of our existing policy with respect to health claims and other health-related statements in the labeling and advertising of alcohol beverages.

We view statements that make substantive claims regarding health benefits associated with alcohol beverage consumption as making therapeutic or curative claims. Claims which set forth only a partial picture or representation might be as likely to mislead the consumer as those that are actually false. A claim which is supported by scientific evidence may still mislead the consumer without appropriate qualification and detail. Any such claim is considered misleading unless it is properly qualified, balanced, sufficiently detailed and specific, and outlines the categories of individuals for whom any positive health effects would be outweighed by numerous negative health effects.

III. Negative Consequences of Alcohol Consumption

The risks associated with alcohol consumption are well-documented.

In an article entitled "Alcohol and Risk of Coronary Events,"¹ Charles H. Hennekens, M.D. outlines these risks as follows:

The hazards of heavy alcohol consumption are clear and substantial and have far-reaching health and social consequences. Alcohol is the second leading cause of preventable deaths in the United States as well as most industrialized countries, second only to cigarette smoking. Drinking increases the risk of cancer of the liver, mouth, tongue, and esophagus and has been implicated as a cause of 3 to 5 percent of all cancer deaths. Heavy alcohol consumption is also associated with increased risks of hemorrhagic stroke and cardiomyopathy, and it predisposes to hepatic cirrhosis, the ninth most common cause of death in the United States. In pregnant women, heavy alcohol consumption is associated with fetal alcohol syndrome. Alcohol drinking is also implicated in over 40 percent of all fatal traffic crashes, which are a chief cause of premature deaths in younger people, and it is associated with suicides, industrial accidents, sex crimes, robberies, and murders. It is estimated that 14 million U.S.

¹ Endnotes to preamble appear at end of article.

residents suffer from alcohol abuse and dependence, and 76 million are affected by its presence in a family member.

It is true that many of these health risks are caused by heavy levels of alcohol consumption. It is also true that there are millions of Americans with alcohol dependency problems who find themselves unable or unwilling to control their consumption of alcohol. Given the serious health risks associated with higher levels of alcohol consumption, and given the fact that most medical studies agree that the effects of moderate consumption differ from individual to individual, any claim associating health benefits with moderate alcohol consumption must be carefully evaluated to ensure that it does not mislead the consumer about the various health consequences related to the consumption of alcohol beverages.

We recognize that there are several scientific studies suggesting a link between moderate alcohol consumption and a lower risk of coronary artery disease ("CAD").² However, at this time, we do not believe there is significant scientific evidence to support an unqualified conclusion that moderate wine (alcohol) consumption has health benefits for all or even most individual consumers. Some studies have suggested that only older drinkers will accrue any health benefits from moderate alcohol consumption.³ This is because younger individuals have such a low risk for coronary artery disease and are much more likely to be at risk from alcohol consumption even at lower levels. This difference in risk factors has been explained as follows:⁴

The net contents of all-cause mortality associated with a certain alcohol consumption level therefore also depends on the drinker's absolute risk of dying from these various causes. Accordingly, older people—who are at high absolute risk of coronary heart disease and ischemic stroke and at low risk for injury, cirrhosis, and other alcohol-related diseases—are most likely to benefit from low levels of alcohol consumption. In contrast, for men and women under age 40, who have relatively low absolute risk of dying from strokes, heart disease, and alcohol-related diseases but a high absolute risk of dying from injury, all-cause mortality will increase even at relatively low alcohol-consumption rates * * *. Finally, the absolute risk of death from injury or coronary heart disease is lower in young women than in young men, leading to an increase in all-cause mortality even in young women who are light drinkers (less than two drinks every 3 days) compared with abstainers.

Overall, the available scientific literature suggests that there may be serious health risks associated with heavy as well as moderate alcohol

consumption, depending on the individual.⁵ In light of the negative health consequences of alcohol consumption or abuse, it is possible that these products may not be entitled to any health-related statement. As noted below in section VII, the Federal Trade Commission has adopted a policy that unqualified health claims on products that pose increased health risks are deceptive. Accordingly, we are soliciting comments on whether alcohol beverages should not be entitled to health-related statements.

IV. Industry Circular 93-8

On August 2, 1993, we published Industry Circular 93-8. The circular generally restated our existing position regarding misleading curative and therapeutic claims, i.e., we view statements that make substantive claims regarding health benefits associated with alcohol beverage consumption as making therapeutic or curative claims. Any claim that sets forth only a partial picture or representation might be as likely to mislead the consumer as those that are actually false. Thus, a statement which attributes health benefits to the moderate consumption of alcohol beverages, even if supported by medical evidence, might have an overall misleading effect if such statement is not properly qualified, does not give all sides of the issue, and does not outline the categories of individuals for whom any such positive effect would be outweighed by numerous negative health effects.

We also explained that our existing policy regarding health claims on labels had been reinforced by the 1988 enactment of the Alcoholic Beverage Labeling Act (ABLA), 27 U.S.C. 213 *et seq.* The ABLA contains a declaration of policy and purpose that states that the Congress finds that "the American public should be informed about the health hazards that may result from the consumption or abuse of alcoholic beverages, and has determined that it would be beneficial to provide a clear, nonconfusing reminder of such hazards, and that there is a need for national uniformity in such reminders in order to avoid the promulgation of incorrect or misleading information and to minimize burdens on interstate commerce." 27 U.S.C. 213. As a result of this concern, the ABLA requires that any alcohol beverage container held for sale or distribution in the United States must bear the following statement on the label:

GOVERNMENT WARNING: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2)

Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.

It is clear that one of the purposes of the ABLA was to avoid confusing the American public about the health hazards associated with the consumption of alcohol beverages. In order to accomplish this goal, Congress prescribed specific language that must appear on the labels of alcohol beverage products. It is our position that to the extent that the overall message of any health claim is inconsistent with the message of the health warning statement, it may result in label information that is misleading and confusing to the consumer and would be prohibited under the FAA Act.

In Industry Circular 93-8, we further noted that other Federal agencies, such as the Food and Drug Administration and the Federal Trade Commission, may have jurisdiction over certain aspects of labeling and advertising issues involving health claims. We will address this issue further in section VII (*Role of Other Federal Agencies With Respect to Health Claims and Other Health-Related Statements*).

We also stated that the distribution of advertising materials which included the full text of the April 1992 edition of "Alcohol Alert," published by the National Institute on Alcohol Abuse and Alcoholism (NIAAA), would not be in violation of current regulations. This NIAAA publication provides a comprehensive discussion of the health consequences of moderate alcohol consumption. If such advertising materials also contain editorializing, advertising slogans, or exhortations to consume the product, we would evaluate such additional text to determine whether or not the advertisement presents a balanced picture of the risks associated with alcohol consumption. In addition, we stated that the use of buttons, shelf talkers, table tents, and similar items that excerpt any portion of the NIAAA publication, that contain health slogans or other inferential statements drawn from this publication, or that are based upon any other publication or article citing the health benefits of alcohol consumption, will be closely scrutinized to determine if they present a balanced picture of the risks associated with alcohol consumption.

In addition, we reminded industry members in Industry Circular 93-8 that substantive health claims on labels are considered to be misleading unless they are properly qualified, present all sides of the issue, and outline the categories of individuals for whom any positive effects would be outweighed by

numerous negative health effects. We concluded that it would be extremely unlikely that any such balanced claim would fit on a normal alcohol beverage label. Our policy with respect to substantive health claims has not changed since the issuance of the industry circular. Finally, we stated that it was our intent to initiate rulemaking on this issue; however, pending rulemaking, we would continue to evaluate claims in labeling and advertising on a case-by-case basis.

V. Competitive Enterprise Institute Petition

On May 9, 1995, the Competitive Enterprise Institute (CEI) submitted a petition asking us to issue a rule allowing alcohol beverage labels and advertisements to carry statements regarding the purported benefits of moderate alcohol consumption of alcohol beverages. More specifically, CEI proposed that the following language be permitted on labels and in advertisements: "There is significant evidence that moderate consumption of alcoholic beverages may reduce the risk of heart disease." We would consider this statement to be an example of a substantive health claim. By letter dated January 13, 1997, we denied this rulemaking petition stating that the specific health claim proposed by CEI was not appropriately qualified, was not balanced regarding the health consequences of alcohol consumption and, as such, its use on labels could mislead consumers.

VI. Dietary Guidelines

The Fourth Edition (1995) of the "Dietary Guidelines for Americans" was published by the U.S. Department of Agriculture and the U.S. Department of Health and Human Services in 1996. The Guidelines contain a detailed discussion concerning the consequences and effects of alcohol beverage consumption. There have been suggestions that the Federal government itself, in its issuance of the Dietary Guidelines, has officially recognized the health benefits of moderate alcohol consumption. It is true that the Guidelines acknowledge that "[c]urrent evidence suggests that moderate drinking is associated with a lower risk for coronary heart disease in some individuals." However, this is not a statement of a health benefit; it is merely a conclusion that in some individuals, moderate drinking may be associated with a lower risk of coronary heart disease. The Dietary Guidelines then go on to discuss the "serious health problems" caused by alcohol consumption as follows:

However, higher levels of alcohol intake raise the risk for high blood pressure, stroke, heart disease, certain cancers, accidents, violence, suicides, birth defects, and overall mortality (deaths). Too much alcohol may cause cirrhosis of the liver, inflammation of the pancreas, and damage to the brain and heart. Heavy drinkers also are at risk of malnutrition because alcohol contains calories that may substitute for those in more nutritious foods.

The Dietary Guidelines recommend that if adults choose to drink alcohol beverages, they should consume them only in moderation. The term "moderation" is defined as no more than one drink per day for women and no more than two drinks per day for men. However, the Dietary Guidelines also conclude that for some people, even moderate drinking is not recommended. Thus, many people should not drink alcohol beverages at all, including children and adolescents, women who are trying to conceive or who are pregnant, individuals who plan to drive or take part in activities that require attention or skill, and individuals using prescription and over-the-counter medications. Finally, the Dietary Guidelines also suggest that individuals of any age who cannot restrict their drinking to moderate levels should not drink at all. This last category is obviously hard to define, and may include many individuals who do not even realize that they fall within this category.

It is clear that the Dietary Guidelines explicitly recognize that moderate alcohol consumption is not an activity that has only beneficial effects to the health of the consumer. Millions of adult consumers fall within the categories of people who should not drink alcohol beverages at all. The Dietary Guidelines do not represent an unqualified endorsement of the health benefits of moderate alcohol consumption. Thus, without appropriate qualifications and explanations, any such statement to that effect would tend to mislead consumers. However, we have no objections to the dissemination of the entire Dietary Guidelines as advertising materials by industry members or to the dissemination of the two pages from the Guidelines dealing with alcohol beverages (pages 40 and 41).

VII. Role of Other Federal Agencies With Respect to Health Claims and Other Health-Related Statements

While ATF has primary jurisdiction over the labeling and advertising of alcohol beverages, under certain circumstances the labeling and advertising of alcohol beverages may

also be subject to the jurisdiction of the Food and Drug Administration (FDA) or the Federal Trade Commission (FTC). For example, since certain wine products containing less than 7 percent alcohol by volume are not wines subject to the FAA Act, the labeling of such products falls within FDA's jurisdiction. We have always utilized the scientific and public health expertise of FDA in approving ingredients in alcohol beverages, requiring label disclosure of certain substances, and identifying adulterated alcohol beverages that are deemed mislabeled.

FDA has advised us that certain curative, therapeutic, or disease-prevention claims for an alcohol beverage might place the product in the category of a drug under the Federal Food, Drug, and Cosmetic Act (FFD&C Act), 21 U.S.C. 321(g)(1)(B). FDA evaluates health claims on food labels pursuant to its authority under the FFD&C Act, as amended by the Nutrition Labeling and Education Act (NLEA), Public Law 101-535 (1990). The law provides that a food product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with certain procedures mandated by the FDA. See 21 U.S.C. 343(r)(1)(B). FDA's regulations provide that FDA will only approve a health claim when it determines, "based on the totality of publicly available scientific evidence" that there is "significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence." 21 CFR 101.14(c). ATF would continue to review health-related statements to ensure consistency with FDA's statutory and regulatory authorities.

The FTC's general jurisdiction over advertising extends to alcohol beverages. A problem that is of particular relevance to the area of alcohol beverage advertising is that of the "qualified" health claim. In their policy statement, published in the **Federal Register** on June 1, 1994 (59 FR 28394), the FTC stated that it is necessary to examine "whether qualified claims are presented in a manner that ensures that consumers understand both the extent of the support for the claim and the existence of any significant contrary view within the scientific community." We would also note that the FTC policy statement stated that an unqualified health claim in the advertising of a food was likely to be deceptive if the food also contained a nutrient that increased the

risk for another disease or health-related condition, and the risk-increasing nutrient was closely related to the subject health claim.

VIII. Notice of Proposed Rulemaking

We are proposing to revise the regulations to reflect our current policy and to provide that labels or advertisements may not contain any statement, design, representation, pictorial representation, or device, whether explicit or implicit, representing that consumption of alcohol beverages has curative or therapeutic effects if such statement is untrue in any particular or tends to create a misleading impression. A substantive claim regarding health benefits associated with the use of an alcohol beverage is misleading unless such claim is properly qualified, balanced, sufficiently detailed and specific, and outlines the categories of individuals for whom any positive health effects would be outweighed by numerous negative health effects.

While industry members are not required to submit advertising materials to us for pre-approval, we encourage the use of our voluntary pre-clearance process for any advertisements that refer to the health effects of alcohol consumption.

We believe that the proposed regulations will ensure that labels and advertisements do not contain statements or claims that would tend to mislead the consumer about the significant health consequences of alcohol consumption.

IX. First Amendment Issues

Various members of the alcohol beverage industry have suggested that under the First Amendment to the United States Constitution, ATF is precluded from preventing the dissemination of truthful information about health benefits from alcohol beverage labels and advertisements. We are prohibiting the use of misleading statements regarding health claims that are by definition not protected by the First Amendment. Commercial speech is protected by the First Amendment only if it is truthful and not misleading. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York*, 447 U.S. 557, 566 (1980). This longstanding position has been upheld by the Supreme Court in its most recent commercial speech decision. See *44 Liquor Mart, Inc. v. Rhode Island*, 1996 U.S. LEXIS 3020 (1996).

X. Footnotes Appearing in Text of Supplementary Information

1. Hennekens, C.H., "Alcohol and Risk of Coronary Events," Research Monograph No. 31, "Alcohol and the Cardiovascular System" at 15 (National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, Bethesda, MD, 1996).

2. See, e.g., Boffetta, P. & Garfinkel, L., "Alcohol drinking and mortality among men enrolled in an American Cancer Society prospective study," *Epidemiology* 1(5):343-348, 1990; Stampfer, M.J.; Colditz, G.A.; Willett, W.C.; Speizer, F.E. & Hennekens, C.H., "A prospective study of moderate alcohol consumption and the risk of coronary disease and stroke in women," *New England Journal of Medicine*, 319(5):267-273, 1988; Klatsky, A.L.; Armstrong, M.A.; and Friedman, G.D., "Alcohol and Mortality," *Annals of Internal Medicine*, 117:646-654, 1992. See generally National Institute on Alcohol Abuse and Alcoholism, "Moderate Drinking," "Alcohol Alert," No. 16, April 1992, at 2, and studies cited therein.

3. See, e.g., Criqui, M.H., "Moderate Drinking: Benefits and Risks," "Alcohol and the Cardiovascular System," at 117-118 ("Clearly, younger persons cannot possibly benefit much from alcohol consumption, at least in the short term, because their risk of ischemic CVD events is so low.").

4. DuFour, M.C., "Risks and Benefits of Alcohol Use Over the Life Span," "Alcohol Health & Research World," Vol. 20, No. 3:145-150 at 147, 1996.

5. See, e.g., Hennekens, C.H., "Alcohol and risk of coronary events," Research Monograph No. 31, "Alcohol and the Cardiovascular System" at 20 (National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, Bethesda, MD 1996) ("while the health risks of excessive drinking are clear, there may also be hazards associated with moderate intake that must be weighed, on an individual basis, against the apparent protection against CHD.").

How This Document Complies With the Federal Administrative Requirements for Rulemaking

A. Executive Order 12866

We have determined that this proposed rule is not a significant regulatory action as defined in E.O. 12866. Therefore, a Regulatory Assessment is not required.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. We have determined that this proposed rule

will not have a significant economic impact on a substantial number of small entities. The proposed regulations merely clarify ATF's existing policy concerning the use of health claims in the labeling and advertising of alcohol beverages and impose no burdens on the industry. Accordingly, a regulatory flexibility analysis is not required.

C. Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Public Law 104-13, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this notice of proposed rulemaking because no requirement to collect information is imposed.

Public Participation

We are requesting comments on the proposed regulations from all interested persons. In particular, we are asking for public comment on our existing policy relating to health claims and other health-related statements on alcohol beverage labels and in advertisements (see section II). We also ask whether health-related statements on alcohol beverage labels and advertising directing consumers to balanced sources of information are misleading and whether ATF should continue to approve such statements. We are also asking whether the negative health consequences of alcohol consumption or abuse disqualify, as misleading, these products entirely from entitlement to any health-related statements (see section III). In addition, we are specifically requesting comments on the clarity of this proposed rule and how it may be made easier to understand.

Comments received on or before the closing date will be carefully considered. Comments received after that date will be given the same consideration if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before the closing date.

ATF will not recognize any material in comments as confidential. Comments may be disclosed to the public. Any material that the commenter considers to be confidential or inappropriate for disclosure to the public should not be included in the comment. The name of the person submitting a comment is not exempt from disclosure.

Any interested person who desires an opportunity to comment orally at a public hearing should submit his or her request, in writing, to the Director within the 120-day comment period. The Director, however, reserves the right to determine, in light of all

circumstances, whether a public hearing is necessary.

Disclosure

Copies of this notice and the comments received will be available for public inspection during normal business hours at: ATF Public Reading Room, Room 6480, 650 Massachusetts Avenue, NW, Washington, DC.

Drafting Information

The author of this document is James P. Ficaretta, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects

27 CFR Part 4

Advertising, Consumer protection, Customs duties and inspection, Imports, Labeling, Packaging and containers, and Wine.

27 CFR Part 5

Advertising, Consumer protection, Customs duties and inspection, Imports, Labeling, Liquors, and Packaging and containers.

27 CFR Part 7

Advertising, Consumer protection, Customs duties and inspection, Imports, and Labeling.

Authority and Issuance

For the reasons discussed in the preamble, ATF amends 27 CFR parts 4, 5, and 7 as follows:

PART 4—LABELING AND ADVERTISING OF WINE

Paragraph 1. The authority citation for 27 CFR part 4 continues to read as follows:

Authority: 27 U.S.C. 205.

Par. 2. Section 4.39(h) is revised to read as follows:

§ 4.39 Prohibited practices.

* * * * *

(h) *Curative and therapeutic claims.* Labels may not contain any statement, design, representation, pictorial representation, or device, whether explicit or implicit, that represents that the use of wine has curative or therapeutic effects if such statement is untrue in any particular or tends to create a misleading impression. A substantive claim regarding health benefits associated with the use of wine is misleading unless such claim is properly qualified, balanced, sufficiently detailed and specific, and outlines the categories of individuals for whom any positive health effects would

be outweighed by numerous negative health effects.

* * * * *

Par. 3. Section 4.64(i) is revised to read as follows:

§ 4.64 Prohibited practices.

* * * * *

(i) *Curative and therapeutic claims.* Advertisements may not contain any statement, design, representation, pictorial representation, or device, whether explicit or implicit, that represents that the use of wine has curative or therapeutic effects if such statement is untrue in any particular or tends to create a misleading impression. A substantive claim regarding health benefits associated with the use of wine is misleading unless such claim is properly qualified, balanced, sufficiently detailed and specific, and outlines the categories of individuals for whom any positive health effects would be outweighed by numerous negative health effects.

* * * * *

PART 5—LABELING AND ADVERTISING OF DISTILLED SPIRITS

Par. 4. The authority citation for 27 CFR part 5 continues to read as follows:

Authority: 26 U.S.C. 5301, 7805; 27 U.S.C. 205.

Par. 5. Section 5.42(b)(8) is revised to read as follows:

§ 5.42 Prohibited practices.

* * * * *

(b) * * *
(8) *Curative and therapeutic claims.* Labels may not contain any statement, design, representation, pictorial representation, or device, whether explicit or implicit, that represents that the use of distilled spirits has curative or therapeutic effects if such statement is untrue in any particular or tends to create a misleading impression. A substantive claim regarding health benefits associated with the use of distilled spirits is misleading unless such claim is properly qualified, balanced, sufficiently detailed and specific, and outlines the categories of individuals for whom any positive health effects would be outweighed by numerous negative health effects.

Par. 6. Section 5.65(d) is revised to read as follows:

§ 5.65 Prohibited practices.

* * * * *

(d) *Curative and therapeutic claims.* Advertisements may not contain any statement, design, representation, pictorial representation, or device,

whether explicit or implicit, that represents that the use of distilled spirits has curative or therapeutic effects if such statement is untrue in any particular, or tends to create a misleading impression. A substantive claim regarding health benefits associated with the use of distilled spirits is misleading unless such claim is properly qualified, balanced, sufficiently detailed and specific, and outlines the categories of individuals for whom any positive health effects would be outweighed by numerous negative health effects.

* * * * *

PART 7—LABELING AND ADVERTISING OF MALT BEVERAGES

Par. 7. The authority citation for 27 CFR part 7 continues to read as follows:

Authority: 27 U.S.C. 205.

Par. 8. Section 7.29(e) is revised to read as follows:

§ 7.29 Prohibited practices.

* * * * *

(e) *Curative and therapeutic claims.* Labels may not contain any statement, design, representation, pictorial representation, or device, whether explicit or implicit, that represents that the use of malt beverages has curative or therapeutic effects if such statement is untrue in any particular or tends to create a misleading impression. A substantive claim regarding the health benefits associated with the use of malt beverages is misleading unless such claim is properly qualified, balanced, sufficiently detailed and specific, and outlines the categories of individuals for whom any positive health effects would be outweighed by numerous negative health effects.

* * * * *

Par. 9. Section 7.54(e) is revised to read as follows:

§ 7.54 Prohibited practices.

* * * * *

(e) *Curative and therapeutic claims.* Advertisements may not contain any statement, design, representation, pictorial representation, or device, whether explicit or implicit, that represents that the use of malt beverages has curative or therapeutic effects if such statement is untrue in any particular or tends to create a misleading impression. A substantive claim regarding health benefits associated with the use of malt beverages is misleading unless such claim is properly qualified, balanced, sufficiently detailed and specific, and outlines the categories of individuals for whom any positive health effects would

be outweighed by numerous negative health effects.

* * * * *

Signed: October 19, 1999.

John W. Magaw,
Director.

Approved: October 20, 1999.

John P. Simpson,
Deputy Assistant Secretary (Regulatory, Tariff
and Trade Enforcement).
[FR Doc. 99-27774 Filed 10-20-99; 3:28 pm]
BILLING CODE 4810-31-P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01-99-179]

RIN 2115-AA97

Safety Zone: Christmas Party Fireworks, Hudson River, Manhattan, New York

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone on the Hudson River for the Christmas Party Fireworks display. This action is necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic on a portion of the Hudson River. **DATES:** Comments must reach the Coast Guard on or before November 24, 1999. **ADDRESSES:** Comments may be mailed to the Waterways Oversight Branch (CGD01-99-179), Coast Guard Activities New York, 212 Coast Guard Drive, Staten Island, New York 10305, or deliver them to room 205 at the same address between 8 a.m. and 3 p.m., Monday through Friday, except federal holidays.

The Waterways Oversight Branch of Coast Guard Activities New York maintains the public docket for this rulemaking. Comments, and documents as indicated in this preamble, will become part of this docket and will be available for inspection or copying at room 205, Coast Guard Activities New York, between 8 a.m. and 3 p.m., Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT:
Lieutenant J. Lopez, Waterways
Oversight Branch, Coast Guard
Activities New York (718) 354-4193.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to participate in this

rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their names and addresses, identify this rulemaking (CGD01-99-179) and the specific section of this document to which each comment applies, and give the reason for each comment. Please submit two copies of all comments and attachments in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. Persons wanting acknowledgment of receipt of comments should enclose stamped, self-addressed postcards or envelopes.

The Coast Guard will consider all comments received during the comment period. It may change this proposed rule in view of the comments.

The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the Waterways Oversight Branch at the address under **ADDRESSES**. The request should include the reasons why a hearing would be beneficial. If it determines that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

Fireworks by Grucci has submitted an Application for Approval of a Marine Event for a fireworks display on the Hudson River. This proposed regulation establishes a temporary safety zone in all waters of the Hudson River within a 360-yard radius of the fireworks barge in approximate position 40°44'49"N 074°01'02"W (NAD 1983), about 500 yards west of Pier 60, Manhattan, New York. The proposed safety zone would be effective from 8:30 p.m. until 10 p.m. on December 14, 1999. If the event is cancelled due to inclement weather, then this event will be held from 8:30 p.m. until 10 p.m. on December 15, 1999. The proposed safety zone prevents vessels from transiting a portion of the Hudson River and is needed to protect boaters from the hazards associated with fireworks launched from a barge in the area. Marine traffic will still be able to transit through the eastern 150 yards of the 850-yard wide Hudson River during the event. The Captain of the Port does not anticipate any negative impact on vessel traffic due to this event. Public notifications will be made prior to the event via local notice to mariners, and marine information broadcasts. The Coast Guard is limiting the comment period for this NPRM to 30 days because the proposed safety zone is only for a one and a half hour long local event and it should have negligible impact on

vessel transits. The Coast Guard expects to receive no comments on this NPRM due to the limited duration of the event and the fact that it should not interfere with vessel transits.

Discussion of Proposed Rule

The proposed safety zone is for a Christmas Party Fireworks display held on the Hudson River at Pier 60, Chelsea Piers, Manhattan, New York. This event will be held on Tuesday, December 14, 1999. If the event is canceled due to inclement weather, then the event will be held on Wednesday, December 15, 1999. This rule is being proposed to provide for the safety of life on navigable waters during the event and to give the marine community the opportunity to comment on this event.

Regulatory Evaluation

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. It has not been reviewed by the Office of Management and Budget under that Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. Although this regulation prevents traffic from transiting a portion of the Lower Hudson River during the event, the effect of this regulation will not be significant for several reasons: the minimal time that vessels will be restricted from the area, that vessels are not precluded from getting underway, or mooring at, Piers 59-62 and the Piers at Castle Point, New Jersey, that vessels may safely transit to the east of the zone, and advance notifications which will be made to the local maritime community by the Local Notice to Mariners, and marine information broadcasts.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this proposed rule, if adopted, will have a significant economic impact on a substantial number of small entities. "Small entities" include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.