

§ 5.45

substance found within the distilled spirits, and a disease or health-related condition.

(C) *Health-related directional statement* is a type of health-related statement that directs or refers consumers to a third party or other source for information regarding the effects on health of distilled spirits or alcohol consumption.

(ii) *Rules for labeling*—(A) *Health-related statements*. In general, labels may not contain any health-related statement that is untrue in any particular or tends to create a misleading impression as to the effects on health of alcohol consumption. TTB will evaluate such statements on a case-by-case basis and may require as part of the health-related statement a disclaimer or some other qualifying statement to dispel any misleading impression conveyed by the health-related statement.

(B) *Specific health claims*. (1) TTB will consult with the Food and Drug Administration (FDA), as needed, on the use of a specific health claim on a distilled spirits label. If FDA determines that the use of such a labeling claim is a drug claim that is not in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act, TTB will not approve the use of that specific health claim on a distilled spirits label.

(2) TTB will approve the use of a specific health claim on a distilled spirits label only if the claim is truthful and adequately substantiated by scientific or medical evidence; sufficiently detailed and qualified with respect to the categories of individuals to whom the claim applies; adequately discloses the health risks associated with both moderate and heavier levels of alcohol consumption; and outlines the categories of individuals for whom any levels of alcohol consumption may cause health risks. This information must appear as part of the specific health claim.

(C) *Health-related directional statements*. A statement that directs consumers to a third party or other source for information regarding the effects on health of distilled spirits or alcohol consumption is presumed misleading unless it—

(1) Directs consumers in a neutral or other non-misleading manner to a third party or other source for bal-

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anced information regarding the effects on health of distilled spirits or alcohol consumption; and

(2)(i) Includes as part of the health-related directional statement the following disclaimer: “This statement should not encourage you to drink or to increase your alcohol consumption for health reasons;” or

(ii) Includes as part of the health-related directional statement some other qualifying statement that the appropriate TTB officer finds is sufficient to dispel any misleading impression conveyed by the health-related directional statement.

(26 U.S.C. 7805 (68A Stat. 917, as amended); 27 U.S.C. 205 (49 Stat. 981, as amended))

[T.D. 7020, 34 FR 20637, Dec. 30, 1969, as amended by T.D. ATF-62, 44 FR 71621, Dec. 11, 1979; T.D. ATF-180, 49 FR 31673, Aug. 8, 1984; 49 FR 35768, Sept. 12, 1984; T.D. ATF-198, 50 FR 8464, Mar. 1, 1985; 50 FR 23410, June 4, 1985; TTB T.D.-1, 68 FR 10104, Mar. 3, 2003]

Subpart E—Standards of Fill for Bottled Distilled Spirits

§ 5.45 Application.

No person engaged in business as a distiller, rectifier, importer, wholesaler, or warehouseman and bottler, directly or indirectly, or through an affiliate, shall sell or ship or deliver for sale or shipment, or otherwise introduce in interstate or foreign commerce, or receive therein or remove from customs custody any distilled spirits in bottles unless such distilled spirits are bottled and packed in conformity with §§ 5.46 through 5.47a.

(Sec. 5, 49 Stat. 981, as amended (27 U.S.C. 205); 26 U.S.C. 5301)

[T.D. ATF-25, 41 FR 10221, Mar. 10, 1976; T.D. ATF-146, 48 FR 43321, Sept. 23, 1983]

§ 5.46 Standard liquor bottles.

(a) *General*. A standard liquor bottle shall be one so made and formed, and so filled, as not to mislead the purchaser. An individual carton or other container of a bottle shall not be so designed as to mislead purchasers as to the size of the bottles.

(b) *Headspace*. A liquor bottle of a capacity of 200 milliliters or more shall be held to be so filled as to mislead the