



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2012-C-0224]

E. & J. Gallo Winery; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is announcing that E. & J. Gallo Winery has filed a petition proposing that the color additive regulations be amended to provide for the expanded safe use of mica-based pearlescent pigments as color additives in certain distilled spirits.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that a color additive petition (CAP 2C0294) has been filed by E. & J. Gallo Winery, c/o Keller and Heckman LLP, One Embarcadero Center, Suite 2110, San Francisco, CA 94111. The petition proposes to amend the

color additive regulations in 21 CFR 73.350 to provide for the safe use of mica-based pearlescent pigments prepared from titanium dioxide and mica as color additives in distilled spirits containing not less than 18% and not more than 23% alcohol by volume but not including distilled spirits mixtures containing more than 5% wine on a proof gallon basis.

The Agency has determined under 21 CFR 25.32(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: March 13, 2012.

Francis Lin,
Acting Director,
Office of Food Additive Safety,
Center for Food Safety and Applied Nutrition.

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