DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket Nos. FDA–2011–C–0344 and FDA–2011–C–0463]

CooperVision, Inc.; Filing of Color Additive Petitions

Correction

In proposed rule document 2011–16089 appearing on page 37690 in the issue of Tuesday, June 28, 2011, make the following correction:

On page 37690, in the first column, in the twelfth line from the bottom of the page,

''methacryloxyethyl)phenstyamino]'' should read ''methacryloxyethyl)phenlyamino]''.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. FDA–2000–P–0102, FDA–2000–P–0133, and FDA–2006–P–0033]

Food Labeling; Health Claim; Phytosterols and Risk of Coronary Heart Disease; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the proposed rule published in the **Federal Register** of December 8, 2010, proposing to amend regulations on plant sterol/stanol esters and risk of coronary heart disease (CHD). FDA is reopening the comment period because the Agency received a request for additional time to comment on the proposed rule.

DATES: The comment period for the proposed rule published December 8, 2010 (75 FR 76526), is reopened. Submit either electronic or written comments by October 25, 2011.

ADDRESSES: Submit electronic comments *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Blakeley Fitzpatrick, Center for Food Safety and Applied Nutrition (HFS–830), 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2176.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 8, 2010 (75 FR 76526), FDA proposed to amend its regulations in § 101.83 (21 CFR 101.83) on plant sterol/stanol esters and risk of CHD (the phytosterols proposed rule). Among other revisions, the Agency proposed to: (1) Adopt the term ''phytosterols'' as inclusive of both plant sterols and stanols; (2) permit claims on products with phytosterols, derived from either vegetable oils or tall oils, containing at least 80 percent of beta-sitosterol, campesterol, stigmasterol, sitostanol, and/or campestanol (combined weight); (3) replace the analytical methods FDA uses to determine the amount and nature of the substance with the Sorenson and Sullivan method for evaluation of campesterol, stigmasterol, and beta-sitosterol in those foods for which the method has been validated; (4) revise the daily dietary intake of phytosterols necessary to justify the CHD risk reduction claim (2 grams (g) per day) and the minimum amount of phytosterols (non-esterified weight) required to be in a serving of the food (0.5 g per reference amount customarily consumed (RACC)); (5) for conventional food, limit the use of the claim to the food uses of phytosterols that have been submitted to FDA in a generally recognized as safe notification to which the Agency had no further questions and where the conditions of use are consistent with the eligibility requirements for the health claim; (6) remove the requirement that the health claim include a recommendation that phytosterols be consumed in two servings eaten at different times of the day, but require that the substance be taken with meals or snacks; (7) eliminate the enumeration of specific conventional foods eligible to bear the claim; (8) allow for the use of the health claim on phytosterol ester-containing dietary supplements (esterified with food-grade fatty acids) but not on nonesterified phytosterol-containing dietary supplements; (9) clarify that the limited exemption from the total fat disqualifying level of more than 13 g total fat per 50 g of food when the RACC is 30 g or less or 2 tablespoons or less applies to vegetable oil spreads resembling margarine; (10) permit liquid vegetable oils to be exempt from the total fat disqualifying level on a per RACC, per labeled serving size, and per 50 g basis; and (11) permit liquid vegetable oils to be exempt from the minimum nutrient requirement and vegetable oil spreads resembling margarine to meet the 10 percent minimum nutrient requirement by the addition of Vitamin A consistent with FDA's fortification policy.

Interested persons were originally given until February 22, 2011, to comment on the proposed rule.

II. Request for Comments

After publication of the phytosterols proposed rule, the Agency received two petitions for an administrative stay of action and two letters requesting that FDA extend its enforcement discretion based on FDA's February 14, 2003, letter of enforcement discretion to Cargill Health and Food Technologies. Based on concerns that 75 days was not enough time for industry to come into compliance with § 101.83 or to make the claim consistent with the proposed requirements in the phytosterols proposed rule, the Agency issued, in the **Federal Register** of February 18, 2011, an extension of its enforcement discretion based on the February 14, 2003, letter (76 FR 9525).

On February 10, 2011, the Agency received a comment on the phytosterols proposed rule by Venable LLP requesting an extension of the comment period until April 23, 2011, because the period of time allowed for comment did not provide enough time for them to collect, assess, and comment on the relevant data regarding the cholesterol-lowering efficacy of nonesterified phytosterols in dietary supplements. FDA did not respond to Venable LLP's request within the comment period and cannot extend a closed comment period. However, the Agency is reopening the comment period for this rule in response to Venable LLP's request. The Agency recognizes that additional time to review and comment on the data related to the relationship between nonesterified phytosterols and reduced risk of CHD would be helpful and consistent with sound public policy, therefore FDA is reopening the comment period for all interested persons on the phytosterols proposed rule to allow for comments to be submitted to the docket.

Following receipt of comments on this document, FDA intends to publish a final rule, which will amend § 101.83. The reopening of the comment period may result in the submission of additional information that may cause the Agency to reconsider its proposed amendments to the phytosterols and risk of coronary heart disease health