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]''.

[FR Doc. C1–2011–16089 Filed 8–10–11; 8:45 am]

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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

claim. The Agency notes that a final rule may vary from the proposal. To the extent that manufacturers have labeled their products consistent with the proposed requirements, and the final requirements differ from what the Agency proposed, manufacturers will be required to change their labels to conform to the final rule.

III. How To Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–20406 Filed 8–10–11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2011–0470, FRL–9450–8]

Approval and Promulgation of Implementation Plans; Iowa: Prevention of Significant Deterioration; Greenhouse Gas Permitting Authority and Tailoring Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a revision to the Iowa State Implementation Plan (SIP) relating to regulation of Greenhouse Gases (GHGs) under Iowa's Prevention of Significant Deterioration (PSD) program. This revision was submitted by the Iowa Department of Natural Resources (IDNR) to EPA on December 22, 2010. It is intended to align Iowa's regulations with the ''PSD and Title V Greenhouse Gas Tailoring Final Rule.'' EPA is proposing to approve the revision because the Agency has made the preliminary determination that the SIP revision, already adopted by Iowa as a final effective rule, is in accordance with the Clean Air Act (CAA or Act) and EPA regulations regarding PSD permitting for GHGs.

DATES: Comments must be received on or before September 12, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2011–0470, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *E-mail: gonzalez.larry@epa.gov.*
3. *Fax:* (913) 551–7844.
4. *Mail:* Air Planning and Development Branch, Air and Waste Management Division, U.S. Environmental Protection Agency, Region 7, 901 North 5th Street, Kansas City, Kansas 66101.
5. *Hand Delivery or Courier:* Mr. Larry Gonzalez, Air Planning and Development Branch, Air and Waste Management Division, U.S. Environmental Protection Agency, Region 7, 901 North 5th Street, Kansas City, Kansas 66101. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R07–OAR–2011–0470. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through *http://www.regulations.gov* or e-mail, information that you consider to be CBI or otherwise protected. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air Planning and Development Branch, Air and Waste Management Division, U.S. Environmental Protection Agency, Region 7, 901 North 5th Street, Kansas City, Kansas 66101. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: For information regarding the Iowa SIP, contact Mr. Larry Gonzalez, Air Planning and Development Branch, Air and Waste Management Division, U.S. Environmental Protection Agency, Region 7, 901 North 5th Street, Kansas City, Kansas 66101. Mr. Gonzalez's telephone number is (913) 551–7047; *e-mail address: gonzalez.larry@epa.gov.*

SUPPLEMENTARY INFORMATION:

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I. What action is EPA proposing in today's notice?

On December 22, 2010, IDNR submitted a request to EPA to approve revisions to the State's SIP and Title V program to incorporate recent rule amendments adopted by the Iowa Environmental Protection Commission. These adopted rules became effective in the Iowa Administrative Code on that date. These amendments establish thresholds for GHG emissions in Iowa's PSD and Title V regulations at the same emissions thresholds and in the same