

agrees that the questions should be straightforward and specific and designed them with those objectives in the forefront. The terms “healthier” and “more desirable” are not included among the study questions. Use of a fat content disclosure statement in this study will be consistent with current regulations (21 CFR 101.13(h)(1)). The sugar disclosure used in this proposed study would accompany a “good source of carb” claim. In the study, the disclosure would appear on a product with “good source of carb” on the front panel and information in the Nutrition Facts box that indicates that most of the carbohydrate in the product is sugars. The goal of this test is to better understand how consumers react to a “good source of carb” claim on a product high in sugar and low in other carbohydrates. The agency disagrees with the comment’s suggestion to test a declaration of calories per serving or “see nutrition information for calorie content” in lieu of “not a low calorie food.” The agency considers the statement “not a low calorie food” to be an appropriate, explicit statement to make consumers more aware of calories. The disclosure “not a low calorie food” is currently seen by consumers in the marketplace when “sugar-free” claims

are made on products that are not low calorie. The experimental study looks at ranges of carbohydrate content levels for the products to explore differences in consumer reaction.

The sixth comment argues that the study methods are sound and suggests ways to enhance quality, utility, and clarity of the information to be collected. The comment suggests substituting the soda and frozen dinner stimuli with pasta, cereal, orange juice or any fruit. The comment does not offer a reason for these preferences. The comment also proposes testing white bread and whole grain bread as separate products.

The three products proposed for this study were selected to understand whether consumer perception of carbohydrate content claims varies when the claim is on a label for a traditionally high-carbohydrate staple (bread), a beverage (soda), and a complete meal (frozen dinner). The agency does not agree that any of the substitutions suggested in the comment would improve the study. The label for the bread does not indicate whether it is white, wheat, or another grain. Consumers will view a label claim on the front panel for bread labeled simply “home-style.” Some of the respondents

who view the Nutrition Facts Panel for the bread will see a higher-fiber, lower-fat bread, while others see a lower-fiber, higher-fat bread. The analysis will evaluate the differences in perception of the claims when the nutrient profile suggests a more healthful versus a less healthful product.

The seventh comment and eighth comments address the quality, utility, and clarity of the information to be collected. The comments request that this data collection test changes to the carbohydrate section of the Nutrition Facts Panel. One of these comments requests that fiber and sugar alcohols be listed separately from other carbohydrates. The other of the comments proposes moving carbohydrates with reduced caloric value from the carbohydrate listing on the Nutrition Facts Panel and adding a listing called “low calorie ingredients,” which would include the subheadings listings “fiber” and “other.”

Evaluating any proposed changes to the Nutrition Facts Panel is outside the scope of this data collection. This data collection is designed to evaluate consumer understanding of carbohydrate claims on the front panel.

FDA estimates the burden of the collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Cognitive Interviews	9	1	9	0.5	5
Pretest	150	1	150	0.17	26
Screener	150,000	1	150,000	0.01	1,500
Experiment	10,000	1	10,000	0.12	1,200
Total					2,731

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on FDA’s experience with previous consumer studies. The cognitive interviews are designed to ensure that the questions are worded as clearly as possible to consumers. The cognitive interviews would take each respondent 30 minutes to complete. The pretest of the final questionnaire is designed to minimize potential problems in the administration of the interviews. The pretest is predicted to take each respondent approximately 10 minutes to complete.

The screener would be sent via the Internet to the entire 600,000-household Internet panel, of which 25 percent (150,000 households) are predicted to respond. The brief screener is predicted

to take each respondent 36 seconds to complete.

The experiment would be conducted with 10,000 panel members. The experiment is predicted to take each respondent approximately 7 minutes to complete.

Dated: August 9, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket Nos. 2005C-0302, 2005C-0303, and 2005C-0304]

**CIBA Vision Corp.; Filing of Color Additive Petitions**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that CIBA Vision Corp. has filed three petitions proposing that the color additive regulations be amended to

provide for the safe use of Color Index (C.I.) Pigment Violet 19, C.I. Pigment Yellow 154, and C.I. Pigment Red 122 as color additives in contact lenses.

**FOR FURTHER INFORMATION CONTACT:**

*Regarding CAPs 5C0278 and 5C0280:*

Celeste Johnston, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1282.

*Regarding CAP 5C0279:* Harold Woodall, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1259.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 721(d)(1) (21 U.S.C. 379e(d)(1))), notice is given that three color additive petitions (CAP 5C0278, Docket No. 2005C-0302; CAP 5C0279, Docket No. 2005C-0303; CAP 5C0280, Docket No. 2005C-0304) have been filed by CIBA Vision Corp., 11460 Johns Creek Pkwy., Duluth, GA 30097-1556. The petitions propose to amend the color additive regulations in 21 CFR part 73 to provide for the safe use of C.I. Pigment Violet 19 (CAP 5C0278), C.I. Pigment Yellow 154 (CAP 5C0279), and C.I. Pigment Red 122 (CAP 5C0280), as color additives in contact lenses.

The agency has determined under 21 CFR 25.32(l) 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: July 22, 2005.

**Laura M. Tarantino,**

*Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.*  
[FR Doc. 05-16332 Filed 8-16-05; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Request for Nominations for Voting Consumer Representative Members on Public Advisory Committees

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting nominations for voting consumer representatives to serve on the National

Mammography Quality Assurance Advisory Committee (NMQAAC) in the Center for Devices and Radiological Health (CDRH). FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

**DATES:** Nominations will be accepted through January 31, 2006.

**ADDRESSES:** All nominations should be sent to the contact person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

**FOR FURTHER INFORMATION CONTACT:** Michael Ortwerth, Advisory Committee Oversight and Management Staff (HF-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, e-mail: *Michael.Ortwerth@fda.gov*.

**SUPPLEMENTARY INFORMATION:** FDA is requesting nominations for voting consumer representatives to serve on the NMQAAC.

#### I. Functions of NMQAAC

The functions of the committee are to advise FDA on the following topics: (1) Developing appropriate quality standards and regulations for mammography facilities; (2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program; (3) developing regulations with respect to sanctions; (4) developing procedures for monitoring compliance with standards; (5) establishing a mechanism to investigate consumer complaints; (6) reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities; (7) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (9) determining the costs and benefits of compliance with these requirements.

#### II. Criteria for Members

Persons nominated for membership on the committee as a consumer representative must meet the following criteria: (1) Must be from among national breast cancer or consumer health organization with expertise in mammography, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy

of products under review. The consumer representative must be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

#### III. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include use of organizations representing the public interest and consumer advocacy groups. The organizations have the responsibility of recommending candidates of the agency's selection.

#### IV. Nomination Procedures

All nominations must include a cover letter, a curriculum vita or resume (which should include nominee's office address, telephone number, and e-mail address), and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Any interested person or organization may nominate one or more qualified persons for membership on the NMQAAC to represent consumer interests. Self-nominations are also accepted. Nominations shall include complete curriculum vitae of each nominee, current business address and telephone number, and shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest. The term of office is up to 4 years, depending on the appointment date.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: August 10, 2005.

**Scott Gottlieb,**

*Deputy Commissioner for Policy.*

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