U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

Petition to Require Front of Package)		
Disclosure of Food Color Additives)	Docket No.	

Submitted by the

Center for Science in the Public Interest

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Division of Dockets Management Food and Drug Administration Department of Health and Human Services 5630 Fishers Lane, Room 1061 (HFA-305) Rockville, MD 20852

CITIZEN PETITION

The Center for Science in the Public Interest (CSPI) submits this petition under sections 403, 201(n), and 701(a) of the Federal Food, Drug, and Cosmetic Act (FDCA).¹ CSPI requests that the Food and Drug Administration (FDA) issue regulations requiring food and beverage manufacturers to disclose, on the Principal Display Panel (PDP) of a food product, that the product contains any synthetic (21 C.F.R. Part 74) or natural (21 C.F.R. Part 73) color additive.²

I. Preliminary Statement

Color additives permeate the American food supply. Products as disparate as sausage, bread, gelatin desserts, soft drinks, breakfast cereals, candy, snack foods, baked goods, frozen desserts, and even pickles are colored with added natural or synthetic colorings to enhance their visual attractiveness and imply greater quality. Fruit-flavored drinks contain color additives that mimic the presence of real fruit juice.³ Caramel color and molasses are added to some breads made mostly from white flour and

¹ CSPI gratefully acknowledges the assistance of Professor Marsha Cohen of the University of California Hastings College of the Law and her students in the preparation of this Petition.

² This petition will refer to color additives listed in Part 74 as "synthetic" or "dyes." *See* 75 Fed. Reg. 74,735, 74,736 (Dec. 1, 2010). This petition will refer to color additives listed in Part 73 as "natural" because the majority of such color additives are not "made by a process of synthesis or similar artifice" as described in the definition of "color additive." Such color additives are derived from fruits, vegetables, animals, or minerals. *See* 21 C.F.R. § 70.3(f).

³ *See, e.g.,* Tropicana.com, Cherry Berry Blast, www.tropicana.com/#/trop_products/productsLanding.swf?Twister/111 (last visited Nov. 23, 2011).

some rye flour to simulate the presence of more whole grains. Farm-raised salmon may be fed color additives to mimic the deep red flesh of wild salmon.⁴

Despite the ubiquity of food colorings, consumers still may be unaware of their presence in the foods they buy. That creates three factually supported harms.

First, consumers who wish to eat healthfully may purchase food that appears to contain wholesome ingredients, but instead contains different, less-nutritious ingredients masked by a color additive.

Second, color additives have the tendency and capacity to mislead consumers into believing that a product contains healthful ingredients that it does not contain, thus making the product appear to be of higher quality or nutritional value than it actually is.

Third, colorings may pose health risks. In March 2011, the FDA Food Advisory Committee reviewed the relationship between synthetic food dyes and child behavior. ⁵ Although the Advisory Committee ultimately accepted FDA's prior conclusion that no causal relationship had been established between color additives and hyperactivity in the general population of children, the committee voted strongly in favor of continued research, and was closely divided on the issue of warning labels. Also, the FDA has acknowledged a suggested link between dyes and hyperactive behavior in some children. ⁶ In addition, some dyes and natural colorings cause allergic reactions, and several

⁴ See In re Farm Raised Salmon Cases, 175 P.3d 1170 (Cal. 2008).

⁵ See infra III.A.3.

⁶ See CFSAN, Background Document for the Food Advisory Committee: Certified Color Additives in Food and Possible Association with Attention Deficit Hyperactivity Disorder in Children (Mar. 30–31, 2011), available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeeting Materials/FoodAdvisoryCommittee/UCM248549.pdf (last visited Nov. 23, 2011).

dyes are either carcinogenic or contain significant amounts of cancer-causing contaminants.⁷

Given those concerns, CSPI now petitions for the presence of natural and synthetic color additives to be prominently disclosed on PDPs of food packaging, just as the use of characterizing flavorings must already be disclosed if the label, labeling, or advertising of the product makes any reference to them.⁸

A nationally representative public opinion survey of 1,000 adults commissioned by CSPI and conducted by Opinion Research Corporation in January 2010 asked participants if foods that are artificially colored should be required to disclose that fact on the fronts of packages. The results show that 74% of consumers favor that addition to PDPs. Furthermore, in an open letter to food manufacturers in March 2010, Dr. Margaret A. Hamburg described "improving the scientific accuracy and usefulness of food labeling" as "one of [her] priorities as Commissioner of Food and Drugs." Therefore, requiring disclosure of color additives is in line with both public sentiment and with the stated priorities of FDA.

II. Action Requested

CSPI requests that FDA require manufacturers of foods that contain color additives to disclose that fact prominently on PDPs of packaged foods.

⁷ See CSPI, FOOD DYES: A RAINBOW OF RISKS (2010), available at http://cspinet.org/new/pdf/food-dyes-rainbow-of-risks.pdf (last visited Nov. 23, 2011) (appendix compiles genotoxicity studies); CSPI, Food Additives, Chemical Cuisine, http://www.cspinet.org/reports/chemcuisine.htm (last visited Nov. 23, 2011) (listing allergenic potential of many food additives).

⁸ 21 C.F.R. § 101.22(i).

⁹ See Attachment 1, an excerpt of CSPI's survey, Question B12. We attach only the sections of the survey to which we refer in this letter.

¹⁰ Open Letter to Industry from Dr. Margaret A. Hamburg, Comm'r of Food and Drugs (Mar. 3, 2010), *available at* www.fda.gov/Food/LabelingNutrition/ucm202733.htm (last visited Nov. 23, 2011).

Current FDA regulations require that synthetic color additives, carmine, and cochineal extract be listed by name in ingredient lists. 11 Other colorings may be listed as "Artificial Colors," "Added Colors," or similar terms. 12 However, ingredient lists are often difficult for consumers to read because of their location, design, and typography. Because consumers express a preference for clear communication of color additives, and because color additives may pose risks to health or may be used to deceive consumers, the presence of color additives should be disclosed more prominently on PDPs than current regulations require.

CSPI requests that FDA initiate a rulemaking to amend the labeling requirements set forth at 21 C.F.R. § 101.22. CSPI suggests amending subsection § 101.22(k), as follows:

(k) The label of a food to which any coloring has been added shall declare state "Artificially Colored" on the product display package next to the product name in bold letters not less than half the height and weight of the name of the food. The coloring shall also be declared in the statement of ingredients in the manner specified in paragraphs (k)(1) and (k)(2) of this section, except that colorings added to butter, cheese, and ice cream, if declared, may be declared in the manner specified in paragraph (k)(3) of this section, and colorings. Colorings added to foods subject to §§ 105.62 and 105.65 of this chapter shall be declared in accordance with the requirements of those sections.¹³

Paragraph 21 C.F.R. § 101.22(k)(3) should be deleted, along with all references to labeling exceptions for butter, cheese, and ice cream.¹⁴

¹¹ 21 C.F.R. § 101.22(k)(1). Carmine and cochineal extract, as allergens, specifically must be listed by name according to 21 C.F.R. § 73.1100(a).

¹² 21 C.F.R. § 101.22(k)(2). Certain natural colorings specifically must be listed by name according to 21 C.F.R. § 73. For example, carmine and cochineal extract, as allergens, must be listed according to 21 C.F.R. § 73.100. *See supra* note 11.

¹³ Added language is underlined; deleted is stricken.

¹⁴ That subsection provides: "When a coloring has been added to butter, cheese, or ice cream, it need not be declared in the ingredient list unless such declaration is required by a regulation in part 73 or part 74 of this chapter to ensure safe conditions of use for

III. Statement of Grounds

A. Factual Grounds

1. Declaring on PDPs the usage of added colorings would promote public health.

The use of any color additive, whether synthetic or natural, may mask the absence of a fruit, vegetable, or other valuable ingredient and thus make a food product appear to have greater nutritional value than it actually does.

The undisclosed use of color additives is particularly detrimental to consumers who are actively attempting to follow U.S. Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA) guidelines by eating healthful foods. When food manufacturers add color to their products, the added color may misrepresent or exaggerate the presence of ingredients that are perceived as healthful or economically valuable, such as whole grains, fruits, vegetables, and eggs. Consumers who desire to eat healthfully must scrutinize often-lengthy and hard-to-read ingredient labels to determine whether, for example, blueberries featured on the PDP of a package of food are actually present in the product, or if the product is simply dyed to mimic the presence of fruit. FDA could aid consumers who seek to purchase wholesome, healthy

the color additive. Voluntary declaration of all colorings added to butter, cheese, and ice cream, however, is recommended." For consistency, CSPI recommends mandatory declaration in these instances as well.

¹⁵ U.S. DEPT. OF AGRICULTURE & U.S. DEPT. OF HEALTH & HUMAN SERVICES, DIETARY GUIDELINES FOR AMERICANS 37 (2010. 7th ed. 2010), available at www.cnpp.usda. gov/Publications/DietaryGuidelines/2010/PolicyDoc/PolicyDoc.pdf (last visited Nov. 23, 2011).

¹⁶ See, e.g., Aunt Jemima to Correct Labels for 'Blueberry' Waffles, CSPINET.ORG (Aug. 11, 2005), www.cspinet.org/new/200508111.html (last visited Nov. 23, 2011) ("the 'blueberries' in Aunt Jemima Blueberry Waffles are fake, despite the bounty of plump berries bursting forth on the product labels").

food by requiring PDP disclosure on products that use color additives to imply quality or healthfulness.

2. Declaring all color additives on PDPs would help prevent consumer deception.

By requiring prominent disclosure of color additives, FDA may also prevent consumer deception and unfair marketing of low-quality products to consumers who believe they are purchasing higher-quality ingredients.

For example, marketing of purported "whole grain" foods is particularly rife with consumer deception related to color additives. USDA recommends that individuals "consume at least half of all grains as whole grains," and many consumers seek out and are willing to pay a premium for products that they believe are 100% whole grain. However, many products on the market contain artificial colorings that create the impression that the product has more whole grain than is actually the case, making it difficult for all but the most diligent and informed consumers to purchase genuinely healthful products.

Coloring food to mask its true ingredients or to mislead consumers into believing that certain ingredients are present when they are not is deception of the consumer that FDA is obligated to prevent. FDA could fulfill this obligation by requiring that the presence of color additives be prominently displayed on product PDPs. That would protect consumers, counteract the unfair and deceptive practices of companies that exaggerate the value and wholesomeness of their food through the use of color additives, and create a level playing field for all companies.

 $^{^{17}}$ Dietary Guidelines for Americans, supra note 14, at xi.

¹⁸ E.g., Nabisco Wheatsworth Stone Ground Wheat Crackers (caramel color), General Mills Whole Grain & Calcium Guaranteed Cinnamon Toast Crunch ("color added"), Keebler Wheatables Made with Stone Ground Wheat (caramel color), and Dare Vinta Baked with 8 grains & seeds crackers (turmeric).

3. The potential behavioral and other health risks associated with consumption of synthetic color additives warrant disclosure on the PDP when a product contains those additives.

FDA recognizes certain natural color additives, such as cochineal extract and carmine, as food allergens and requires the specific declaration of these additives by name on the ingredient label of a product.¹⁹ However, allergic reactions are not the only harms that may result from color additives.

In June 2008, CSPI submitted a petition to FDA regarding the risks of color additives. ²⁰ In our petition, we recounted convincing evidence from studies of food dyes and hyperactivity over the previous 30 years, as well as a 2004 meta-analysis of 23 non-duplicative studies that concluded that a statistically significant link between dyes and behavior exists. CSPI's petition also referenced two large studies funded by the British Food Standards Agency (FSA) that led to the recommendation in the United Kingdom that "these colours . . . be taken out of . . . all foods." ²¹

In March 2011, the FDA's Food Advisory Committee (FAC) met to discuss the data on food dyes and behavior. The FAC heard from health professionals, consumers, scientists, trade representatives, and other interested parties. Because of the copious evidence of risk, but remaining open questions, a significant majority of the Committee voted in favor of conducting additional studies to assess what conditions are safe for

¹⁹ Cochineal Extract and Carmine Declaration, 74 Fed. Reg. 207 (Jan. 5, 2009) (codified at 21 C.F.R. § 73.100).

²⁰ Petition to Ban the Use of Yellow 5 and Other Food Dyes, in the Interim to Require a Warning on Foods Containing these Dyes, to Correct the Information FDA Gives to Consumers on the Impact of these Dyes on the Behavior of Some Children, and to Require Neurotoxicity Testing of New Food Additives and Food Colors (Jun. 2008), *available at* www.cspinet.org/new/pdf/petition-food-dyes.pdf (last visited Nov. 23, 2011).

²¹ *Id.* at 13. We recognize that those studies are not dispositive because the test materials included sodium benzoate and several dyes not used in the United States.

the continued use of color additives.²² However, when asked, "[if] additional information [should] be disclosed on the product label of food containing certified color additives," the FAC narrowly voted against a warning label.²³

On another health matter, the FDA and Health Canada discovered the presence of cancer-causing carcinogens (benzidine, 4-amino-biphenyl) in Yellow 5 and Yellow 6 dyes. (Those carcinogens are not found in routine FDA certification tests of dyes, because the carcinogens are bound to the dye itself.) Judging from FDA's calculations, the amounts of the contaminants occur at levels that pose a risk of cancer greater than one in one million people over their lifetimes.²⁴ In addition, CSPI has reminded the FDA that the agency has considered Red 3 dye to be a carcinogen and in the 1980s wanted to ban it, but pressure from food processors forced it to stop.²⁵ CSPI's report "Food Dyes: A Rainbow of Risks" highlights weaknesses (such as lack of *in utero* exposure, brevity of tests) in long-term feeding studies, which are designed to detect carcinogenesis and other harms, of several other dyes.²⁶

In summary, numerous considerations —public health concerns, consumer deception, allergic reactions in some consumers, small cancer risk, behavioral reactions in some children—underscore the need for disclosure on PDPs of the presence of added colorings.

²² *Id*.

²³ *Quick Minutes: Food Advisory Committee Meeting March 30–31, 2011, FDA.GOV (June 16, 2011), www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/ucm250901.htm (last visited Nov. 23, 2011).*

²⁴ See CSPI, FOOD DYES: A RAINBOW OF RISKS (2010), available at http://cspinet.org/new/pdf/food-dyes-rainbow-of-risks.pdf (last visited Nov. 23, 2011)

²⁵ *Id*.

²⁶ *Id*.

B. Legal Grounds

1. FDA has statutory authority under the misbranding provisions of the FDCA to require labeling for the presence of color additives.

Under the FDCA's misbranding provisions, a food is "misbranded" if its label is "false or misleading in any particular."²⁷ To determine whether a product is misbranded, FDA must evaluate whether, *inter alia*, the label "fails to reveal facts material in the light of . . . representations [made] or material with respect to consequences which may result from the use of the article[]."²⁸ Under its general authority, FDA can "promulgate regulations for the efficient enforcement of this Act."²⁹ Furthermore, under 403(i) of the FDCA, the Secretary has specific authority to promulgate exemptions to labeling laws relating to color additives "[t]o the extent that compliance with [these laws] . . . results in deception or unfair competition."³⁰

Thus, FDA has the authority to require that manufacturers provide key additional information—beyond information already on product labels—to prevent consumers from being misled.³¹ Failing to prominently disclose the presence of color additives misbrands a product and results in deception—lack of prominent disclosure conceals material facts about the product and has the tendency and capacity to mislead reasonable consumers about the presence of color additives, including synthetic ingredients that could cause behavioral effects³², cancer, or allergic reactions. Other color additives

²⁷ FDCA § 403(a) (codified at 21 U.S.C. § 343(a)).

²⁸ FDCA § 201(n) (codified at 21 U.S.C. § 321(n)).

²⁹ FDCA § 701(a) (codified at 21 U.S.C. § 371(a)).

³⁰ FDCA § 403(i) (codified at 21 U.S.C. § 343(i)).

³¹ See supra A.2. See also Frederick H. Degnan, The Food Label and the Right-to-Know, 52 Food, Drug L.J. 49, 51 (1977).

³² See supra III. A.3.

that mimic the presence of desired and more healthful ingredients can also cause allergic reactions.³³

The United States Court of Appeals for the Ninth Circuit recently spoke to the issue of consumer deception and the purpose of FDA-mandated ingredient listing, and pointed out that PDP representations should not undercut the disclosure function of ingredient lists:

Reasonable consumers should [not] be expected to look beyond misleading representations on the front of the box to discover the truth from the ingredient list in small print on the side of the box. . . . We do not think that the FDA requires an ingredient list so that manufacturers can mislead consumers and then rely on the ingredient list to correct those misinterpretations Instead, reasonable consumers expect that the ingredient list contains more detailed information about the product that confirms other representations on the packaging.³⁴

If "reasonable consumers" are misled then a product is misbranded, and FDA has the authority to promulgate regulations that limit such misleading practices under the FDCA.

2. FDA has a preexisting regulatory framework for disclosure of artificial flavors on PDPs, and disclosure of artificial colors should be treated the same.

FDA recognizes that prominent display of information regarding flavorings in food is necessary to inform consumers and prevent deception. Current regulations state that when a product contains natural or artificial flavors that simulate or reinforce its characterizing flavor, 35 disclosure of that specific flavoring is required on the PDP. 36 The

³³ *Id*.

³⁴ Williams v. Gerber, 552 F.3d 934, 939–40 (9th Cir. 2008).

^{35 &}quot;Characterizing flavors" are established when "the label, labeling or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor(s), by word, vignette, e.g., depiction of a fruit, or other means, or if for any other reason the manufacturer or distributor wishes to designate the type of flavor in the food other than through the statement of ingredients." 21 C.F.R. § 101.22(i).

statement must appear in letters at least half the size of the letters used in the name of the characterizing flavor.³⁷

The same requirement should apply equally to added colorings. Despite the fact that the use of color additives is important to consumers, product labels are not currently required to indicate prominently the presence of color additives, natural or artificial, on the PDP. There is no justification for that difference. Since the use of added flavorings is already declared on PDPs, declaring added colorings on the PDP as well would pose a minimal burden on producers in return for significant benefit to consumers.

Also, PDP disclosure of color additives should not be dependent upon whether the color is a characterizing color. The presence of any color additive, whether a characterizing color or not, should be enough to trigger consumer health concerns. Therefore, the presence of a color additive should be disclosed on the PDP regardless of whether the added coloring is a characterizing color.

C. Policy Considerations: Amending FDA policy would promote consistency with USDA requirements for food coloring.

FDA's failure to adopt consistent labeling policies for flavors and for color additives differs from the policy followed by the U.S. Department of Agriculture (USDA) for certain foods. USDA's regulations provide that when an artificial coloring is added to an edible fat or sausage casing, its use should be noted "in a prominent manner and contiguous to the name of the product by the words 'Artificially Colored' or 'Artificial

³⁶ 21 C.F.R. § 101.22(i)(1)–(3).

³⁷ *Id.* Because the font is not specified, companies sometimes use light, condensed letters to fulfill the requirement, but such lettering is difficult to read. That is why we urge FDA to be specific if and when it requires added coloring to be disclosed on PDPs.

³⁸ Under 21 C.F.R. § 101.22(a)(4), "artificial color" is defined as "any color additive as defined in § 70.3(f)." *See supra* note 2.

Coloring Added' or 'With Added Artificial Coloring.'"³⁹ Natural colorings such as annatto are included within this regulation, and labeling for meats that contain annatto must prominently state, for example, "Colored with annatto."⁴⁰

This requirement differs completely from FDA's labeling regime for coloring in foods, and results in consumer confusion and marketplace inconsistency. Although FDA and USDA may operate according to different policy considerations, the average consumer is unlikely to be unaware of the complicated interaction between these agencies' regulatory regimes.

IV. Conclusion

For the reasons discussed above, FDA should require manufacturers of artificially colored foods or beverages, whether colored by synthetic or natural sources, to disclose that fact prominently on the PDP of packaged foods. PDP labels disclosing the presence of color additives would enable consumers to better protect themselves and their children from the health risks posed by exposure to color additives, and they will allow consumers to more accurately assess the presence or absence of nutrient-rich ingredients such as fruits, vegetables, whole grains, and eggs in packaged food products.

V. Environmental Impact

The action requested is subject to a categorical exclusion under 21 C.F.R. §§ 25.30 and 25.32 and, therefore, does not require the preparation of an environmental assessment.

VI. Economic Impact

The Commissioner has not requested a statement of the economic impact of the requested action and, therefore, such a statement is not presented.⁴¹

³⁹ 9 C.F.R. § 317.2(j)(5).

⁴⁰ *Id*.

VII. Certification

The undersigned certify that, to their best knowledge and belief, this petition includes all information and views on which the petition relies, and it includes representative data and information known to the petitioner that are unfavorable to the petition.

Respectfully submitted,

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By

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⁴¹ 21 C.F.R. § 10.30(b).

Attachment 1

Excerpt from CSPI Survey

ORC STUDY #805031 ONLINE CARAVAN JANUARY 18-19, 2010 FOOD LABEL STUDY

Question B12

Foods that are artificially FLAVORED are usually required to list that fact on the fronts of packages. Should foods that are artificially COLORED have to disclose that fact on the fronts of packages, too?

														Race					
		Sex		Age							Region		White Black Only Only		His- panic				
	Total		Fe- male (C)	18- 24 (D)	25- 34 (E)	35- 44 (F)	45- 54 (G)	55- 64 (H)	N 65+ - (I)	orth east (J)	Mid- west &	South (L)	West	-	(Non-	(Any Race)			
Unweighted Total	1045	502	543		197	231	190	126	166	208	252	322	263	857	72	60			
Weighted Total	1000	484	516	126	179	188	195	148	164	186	221	367	226	690	114*	135*			
Yes	739 7 4 %	338 70%	402 78%B	65 51%	129 72%D	140 75%D	147 75%D	120 81%D	138 84%I FG	142 DE 76%K	147 66%	282 77%	169 K 75%	522 76%	75 66%	92 68%			
No	261 26%	147 30%C	114 22%	61 49%EF	50 28%I	47 25%I	48 25%I	28 19%	26 16%	44 24%	74 34%J	86 L 23%	57 25%	168 249	39 34%	43 32%			

Proportions/Means: Columns Tested (5% risk level) - B/C - D/E/F/G/H/I - J/K/L/M - N/O/P Overlap formulae used. * small base

ORC STUDY #805031 FOOD LABEL STUDY

Question B12

Foods that are artificially FLAVORED are usually required to list that fact on the fronts of packages. Should foods that are artificially COLORED have to disclose that fact on the fronts of packages, too?

			House	hold In	come										Education				
			\$25K- \$40K		\$50K-	\$75K	H.H. Size			Children In H.H			i. 	HS	Coll				
	Total	LT \$25K	LT \$40K	LT \$50K	LT \$75K	Or More	1	2	3 Or More	None '	Total	Under 13	13- 17		HS Grad	Incom- plete	Coll Grad		
	(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)	(I)	(J)	(K)	(L)	(M)	(N)	(0)	(P)	(Q)		
Unweighted Total	1045	248	208	120	216	253	194	379	472	701	344	267	159	32	200	436	377		
Weighted Total	1000	240	203	106	208	242	191	355	454	680	320	242	152	35**	189	425	351		
Yes	739 74%	175 73%	145 71%	78 73%	164 79%	178 73%	141 74%	27 4 77%	32 4 71%	507 75%	232 73%	176 73%	113 74%	27 77%	132 709	311 5 73%	270 77%		
No	261 26%	65 27%	59 29%	28 27%	44 21%	65 27%	50 26%	81 23%	129 29%	173 25%	88 27%	66 27%	39 26%	8 23%	57 309	114 5 27%	81 23%		

Proportions/Means: Columns Tested (5% risk level) - B/C/D/E/F - G/H/I - J/K - N/O/P/Q Overlap formulae used. ** very small base (under 30) ineligible for sig testing

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