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Rockville, MD 20852

Comment on proposed rule to require labeling of cochineal extract and carmine  
Docket Number 1998P-0724  
RIN Number 0910-AF12

As the petitioner (in August 1998) in this matter, the Center for Science in the Public Interest<sup>1</sup> ("CSPI") supports the proposed rule to require the labeling of cochineal extract and carmine on foods and cosmetics to protect consumers who know they are allergic to these color additives.<sup>2</sup> However, we urge the Food and Drug Administration ("FDA"), for the reasons stated below, to reconsider its refusal to ban these two color additives as a way to protect those consumers who do *not* know they are allergic to them. We also urge that the final labeling rule – if a ban is rejected – should require disclosure that these color additives are derived from insects or animals. The effective date for the final rule should be the next uniform effective date, though the FDA should encourage companies to label their products as soon as possible.

**The FDA should ban the use of cochineal extract and carmine in food and cosmetics in order to protect people who do not know they are allergic to them.**

The FDA says it is aware of 14 cases in the United States over a ten-year period of hypersensitivity to carmine, carminic acid, or cochineal extract.<sup>3</sup> The FDA went on to say that "passive reporting systems generally capture only a small fraction of adverse events....Therefore, we assume that we are aware of only about 1 percent of the adverse events involving these

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<sup>1</sup> The Center for Science in the Public Interest, a nonprofit organization based in Washington, D.C., is supported by about 900,000 members in the United States and Canada who subscribe to its *Nutrition Action Healthletter*. CSPI has been working to improve the nation's health through better nutrition and safer food since 1971.

<sup>2</sup> 71 Fed. Reg. 4839-4851 (January 30, 2006).

<sup>3</sup> 71 Fed. Reg. at 4848.

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products....This corresponds to an annual rate of 31 adverse events.”<sup>4</sup>

There are three problems with the FDA’s estimate. It is not clear why the FDA chose a multiplier of 100 and not 10, or 1,000.<sup>5</sup> Second, the FDA’s arithmetic is wrong. Using its data and its assumption, there are 140 – not 31 – adverse events annually in the United States. Third, CSPI has received reports of allergic reactions, including severe reactions, from 32 individuals since we filed our petition in August 1998 (summary of reactions attached). Several people went multiple times – as many as six – to the emergency room. Thus, using the FDA’s assumption that only about 1 percent of adverse events are reported, one gets about 400 – not 31 – adverse events annually in the United States.

According to the FDA, about 43 percent of these adverse events are serious enough to warrant emergency room treatment or hospitalization.<sup>6</sup> The FDA estimates that the average total cost for a severe allergic reaction to carmine or cochineal extract is between \$33,000 and \$139,000.<sup>7</sup> Thus, the total annual cost of severe reactions to those two color additives is between about \$6 million<sup>8</sup> and \$24 million<sup>9</sup> (not the 0 to \$2 million estimated by the FDA).<sup>10</sup> The FDA estimates that labeling “would eliminate between 10 percent and 90 percent of these [adverse] events.”<sup>11</sup> If only half of the severe reactions were prevented, the annual medical costs would still be \$3 million to \$12 million. These costs clearly exceed the relabeling costs and might well exceed the reformulation costs.

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<sup>4</sup> 71 Fed. Reg. at 4848.

<sup>5</sup> For instance, the British maker of Quorn, an allergenic fungus-based food, claims, based on reports it received, that the incidence of adverse reactions is 1/143,000. CSPI’s telephone survey of British consumers of Quorn found that the true incidence is closer to 1/25.

<sup>6</sup> 71 Fed. Reg. at 4848. About 34 percent (11 out of 32) of the incidents reported to CSPI involved treatment in an emergency room.

<sup>7</sup> *Id.*

<sup>8</sup> 0.43 times 400 times \$33,000 equals \$5.7 million..

<sup>9</sup> 0.43 times 400 times \$139,000 equals \$23.9 million.

<sup>10</sup> The FDA estimates that the one-time reformulation costs resulting from a ban on cochineal extract and carmine are between \$3 million and \$1.390 billion and the one-time labeling costs resulting from the FDA’s proposal are between zero and \$3 million. 71 Fed. Reg. at 4849, 4848. Thus, considering the modest number of foods contain carmine/cochineal and that it appears that competing brands contain different coloring agents (or even real fruit or fruit juice!), we believe that the FDA grossly over-estimated the costs of reformulation.

<sup>11</sup> 71 Fed. Reg. at 4848.

Section 721(b)(8)(C) of the Federal Food, Drug, and Cosmetic Act (“FFDCA”) directs the FDA to “take into account” – when determining whether a particular color additive can be safely used – “the availability, if any, of other color additives suitable and safe for one or more of the uses proposed.” In our 1998 petition we said that FD&C Red No. 40 (possibly mixed with FD&C Yellow No. 6), anthocyanins, and betanin are possible alternatives to cochineal extract and carmine. In some foods, actual real food might be a suitable alternative.

Ignoring the availability of these alternatives and making no inquiry as to their costs, the FDA said it is not proposing a ban on cochineal extract and carmine because “there is no evidence of a significant hazard to the general population when [these] color additives are used as specified by the color additive regulations...”<sup>12</sup>

Congress has, however, made it clear that in the case of allergens the impact on “the general population” is not the correct test. Congress passed the Food Allergen Labeling and Consumer Protection Act of 2003 (“FALCPA”) even though only 2 percent of adults and 5 percent of infants and young children suffer from food allergies.<sup>13</sup> Moreover, the FDA’s own color additive regulations say that “[s]afe means that there is convincing evidence that establishes with reasonable certainty that *no* harm will result from the intended use of the color additive.”(emphasis added)<sup>14</sup>

There is no reason to expose consumers to the unnecessary risk posed by these colorings. The FDA should, therefore, adhere to its own regulations and ban cochineal extract and carmine in food and cosmetics.<sup>15</sup>

**If it refuses to ban cochineal extract and carmine, the FDA should require that the ingredient label reveal that those color additives come from animals (or insects).**

In our 1998 petition we noted that the FDA requires that the wax coating used for fresh fruits and vegetables indicate whether it is derived from vegetables, petroleum, beeswax, or

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<sup>12</sup> 71 Fed. Reg. at 4844.

<sup>13</sup> P.L. 108-282, section 202(1)(A)

<sup>14</sup> 21 C.F.R. 70.3(i).

<sup>15</sup> In our 1998 petition we asked that the FDA either require labeling of cochineal extract and carmine or ban their use. At that time we were aware of only three cases in the United States of a severe anaphylactic reaction. The magnitude of the number of cases identified by the FDA and by CSPI now warrants a complete ban.

shellac.<sup>16</sup> Similar origin information for cochineal extract and carmine is important to vegetarians, Jews who eat only kosher food, and others.

Ignoring its own precedent of wax coating, the FDA simply said it was not proposing to require label to indicate the origin of cochineal extract and carmine because “this information is provided in standard dictionaries under the definitions for the words ‘cochineal’ and ‘carmine.’” This explanation is unpersuasive. It is unrealistic to expect consumers to resort to their dictionaries to learn what this ingredient really is. Just as the FALCPA requires “plain English” declarations for the eight most common allergens, the spirit of that law – as well as the misbranding section of the FFDCFA, which calls for the disclosure of relevant information – indicates the need to provide consumers with a clearer explanation of the ingredients. As *The Chicago Tribune*, a newspaper not normally supportive of government regulation, editorialized on February 2, 2006:

Industry lobbyists fought the "insect" part of the label, arguing that when lard is listed as an ingredient, they aren't required to say "from pigs."

That's a pretty lame argument--we all know lard comes from pigs, but who knew about the bugs? Apparently, though, it carried the day. The FDA's compromise proposal would require labels to say "carmine" or "cochineal extract," period.

It takes a pretty savvy consumer to figure out that's code for bug juice. The groups that stand to gain the most from the new labels tend to be more vigilant than the average shopper, sniffing out the hidden allergens and stealth animal products. For everybody else, carmine sounds like just another Crayola shade of red, and cochineal sounds like, oh, we don't know, but it sure doesn't scream, "You're eating crushed female cactus beetles."

**The FDA should set as the effective date for its final rule the next uniform effective date.**

The FDA is proposing to make the effective date for any final rule two years after it is announced and asks for comments on what the effective date should be.

In its final trans fat labeling rule the FDA set as the effective date “the next uniform effective date following publication of this rule.”<sup>17</sup> The FDA rejected proposals that the effective date “be extended several years (e.g., 4 to 7 years) for small businesses.”<sup>18</sup> The FDA should adopt that approach on its final cochineal extract and carmine rule. The FDA also should

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<sup>16</sup> 21 C.F.R. 101.4(b)(22).

<sup>17</sup> 68 Fed. Reg. 41434 (July 11, 2003) at 41466.

<sup>18</sup> *Id.*

immediately (and also in its final rule) encourage companies to declare the presence of carmine/cochineal (and its insect/animal source) as soon as possible, even before the rule is issued or it goes into effect.

Respectfully submitted,



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attachment: Allergic Reactions to Carmine

## Allergic Reactions to Carmine

9/11/98 – A girl had severe asthma-like symptoms, swelling, and hives after eating ice cream or Ocean Spray ruby red grapefruit juice containing carmine.

12/30/98 – A woman broke out in hives after eating Good & Plenty candy colored with carmine.

3/15/99 – A woman suffered numerous, increasingly severe reactions to foods (such as Skittles candy, Trader Joe's sundried tomato pasta, or Ben & Jerry's Cherry Garcia ice cream) containing carmine. Symptoms include swollen eyes, throat, and lips; hives, nausea, and difficulty breathing. She sought treatment at the emergency room a half dozen times and now carries an EpiPen.

3/17/99 – A doctor treated a patient for an itchy throat and swollen eyes. The symptoms began forty minutes after the woman ate strawberry-flavored Yoplait yogurt.

7/6/99 – After eating foods containing carmine, a girl suffered from stomach pains and a severe rash.

8/10/99 – A woman drank pink lemonade, then suffered dizziness, nausea, and a racing pulse.

9/24/99 – A woman suffered a reaction immediately after eating pasta colored with carmine. Her tongue swelled and she broke out in hives before seeking medical attention. She was treated with steroids and must now carry an EpiPen.

6/15/00 – A woman went into anaphylactic shock after eating a vitamin supplement colored with carmine.

8/15/00 – A woman suffered reactions to several foods (Ocean Spray ruby red grapefruit juice, imitation crab, and tomato sauce) containing carmine.

8/22/00 – After consuming several different products (including frozen lasagna, Dannon cherry yogurt, and Ocean Spray grapefruit juice) containing carmine on different occasions, a woman went into anaphylactic shock, suffering from swelling, hives, and difficulty breathing. She now carries an EpiPen at all times.

8/24/00 – After eating Dannon yogurt and Vons frozen fruit bars, a woman came down with symptoms including swollen eyes and nasal congestion.

11/9/00 – A man sought treatment on two occasions for a racing, irregular heartbeat after eating candy or drinking Fruitopia juice colored with carmine.

12/11/00 – A nurse suffered a reaction after eating Dannon strawberry yogurt, with symptoms

including severe itching, swollen eyes and throat, and stomach pains. She treated herself with Benadryl and later saw an allergist.

1/25/01 – A nurse reported a patient who suffered from hives (treated at the emergency room) after eating a variety of foods containing carmine.

2/5/01 – A woman broke out in hives and had difficulty breathing after eating Dannon strawberry yogurt. She went to the emergency room, where she was put on steroids to reduce facial swelling.

2/28/01 – A woman broke out in a rash after drinking Ocean Spray red grapefruit juice.

3/1/01 – A woman was hospitalized for five days after eating red “gummy” candies. She suffered from severe itching, swelling, hives, rash, and difficulty breathing.

3/15/01 – A girl developed itchy eyes, swelling, and hives after eating yogurt containing carmine.

5/9/01 – A woman had anaphylactic reactions on four occasions after eating strawberry-flavored yogurt. She sought treatment from a doctor and was given Benadryl.

5/11/01 – A woman visited the emergency room after eating a product containing carmine, suffering from hives. Also, her tongue and eyes were swollen.

5/29/01 – A boy developed a rash after drinking strawberry-flavored soy milk.

8/22/01 – In seven years, a woman made four visits to the emergency room after ingesting products containing carmine. Her symptoms included vomiting, diarrhea, swollen eyes, and difficulty breathing.

8/27/01 – After eating Yoplait yogurt containing carmine, a registered nurse suffered from swollen eyes, an itchy throat, and difficulty breathing.

8/30/01 – A young boy suffered from swelling, headaches, and vomiting after eating candy containing carmine.

10/31/01 – After eating Good & Plenty candy or drinking small amounts of Ocean Spray juice, a woman developed a severe rash and swelling, along with vomiting and diarrhea.

11/12/01 – A woman went to the emergency room with hives after consuming Good & Plenty candy containing carmine. She had suffered a similar reaction two years previously after eating a Yoplait yogurt pop.

2/12/02 – Immediately after consuming half a container of Dannon yogurt containing carmine, a

woman broke out in a rash and her tongue swelled. She was treated at the emergency room.

2/28/02 – A woman had a severe allergic reaction after consuming Dannon yogurt containing carmine.

3/7/02 – A woman developed hives and her eyes were swollen shut after eating Yoplait yogurt containing carmine.

1/18/05 – A woman visited the emergency room after suffering increasingly severe anaphylactic reactions after eating foods containing carmine.

4/23/05 – On two occasions, after eating Yoplait strawberry yogurt and drinking Tropicana fruit punch, a woman had difficulty breathing, a swollen tongue and mouth, and hives.

5/26/05 – A girl broke out in hives after eating a red popsicle. Her parents suspect that carmine was the cause.