

FDC date	State	City	Airport	FDC No.	Subject
12/5/08	OR	Medford	Rogue Valley Intl/Medford	8/2640	Takeoff Minimums and (Obstacle) DP, Amdt 8.
12/5/08	TX	Dallas	Dallas Executive	8/2716	ILS OR LOC Rwy 31, Amdt 8.
12/9/08	IL	Belleville	Scott AFB/Midamerica	8/3076	ILS OR LOC Rwy 14R, Orig-B.
12/10/08	NC	Maxton	Laurinburg-Maxton	8/3203	RNAV (GPS) Rwy 5, Orig.
12/10/08	NC	Maxton	Laurinburg-Maxton	8/3204	ILS Rwy 5, Amdt 1.
12/10/08	NC	Mooreville	Lake Norman Airpark	8/3271	RNAV (GPS) Rwy 14, Orig.
12/11/08	DC	Washington	Washington Dulles Intl	8/3289	RNAV (GPS) Y Rwy 19C, Amdt 3.
12/10/08	FL	Tallahassee	Tallahassee Regional	8/3356	VOR Rwy 18, Amdt 11.
12/10/08	FL	Tallahassee	Tallahassee Regional	8/3357	NDB Rwy 36, Amdt 20.
12/10/08	PA	Pittsburgh	Pittsburgh Intl	8/3421	RNAV (RNP) Z Rwy 32, Orig.
12/10/08	PA	Pittsburgh	Pittsburgh Intl	8/3422	RNAV (GPS) Y Rwy 32, Amdt 4.
12/10/08	PA	Pittsburgh	Pittsburgh Intl	8/3423	ILS OR LOC Rwy 32, Amdt 12.
12/9/08	IL	Belleville	Scott AFB/Midamerica	8/8135	This NOTAM Published In TL 08-26 Is Hereby Rescinded In It's Entirety. ILS OR LOC Rwy 14R, Orig-B.
11/14/08	LA	Natchitoches	Natchitoches RGNL	8/9331	This NOTAM Published In TL 09-01 Is Hereby Rescinded In It's Entirety. LOC Rwy 35, Amdt 3D.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 73 and 101

[Docket No. FDA-1998-P-0032] (formerly Docket No. 1998P-0724)

RIN 0910-AF12

#### Listing of Color Additives Exempt From Certification; Food, Drug, and Cosmetic Labeling: Cochineal Extract and Carmine Declaration

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is revising its requirements for cochineal extract and carmine by requiring their declaration by name on the label of all food and cosmetic products that contain these color additives. This final rule responds to reports of severe allergic reactions, including anaphylaxis, to cochineal extract-containing food and carmine-containing food and cosmetics and will allow consumers who are allergic to

these color additives to identify and thus avoid products that contain these color additives. This action also responds to a citizen petition submitted by the Center for Science in the Public Interest (CSPI).

**DATES:** This regulation is effective January 5, 2011. All affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date shall fully comply, except as to any provisions that may be stayed by the filing of proper objections. Voluntary compliance with this final regulation, including making any required labeling changes, may begin immediately. Submit written or electronic objections and requests for hearing by February 4, 2009. See section IX of the **SUPPLEMENTARY INFORMATION** section of this document for information on filing of objections.

**ADDRESSES:** You may submit written or electronic objections and requests for a hearing on 21 CFR 73.100 and 73.2087, identified by Docket No. FDA-1998-P-0724 and RIN number 0910-AF12, by any of the following methods:  
**Electronic Submissions**

Submit electronic objections in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of objections, FDA is no longer accepting objections submitted to the agency by e-mail. FDA encourages you to continue to submit electronic objections by using the Federal eRulemaking Portal, as described in the **ADDRESSES** portion of this document under *Electronic Submissions*.

**Instructions:** All submissions received must include the agency name and docket number and Regulatory Information Number (RIN) for this rulemaking. All objections received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting objections, see the "Objections" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** For access to the docket to read background documents or objections received, go to <http://www.regulations.gov> and insert the

docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Mical Honigfort, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1278.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Cochineal extract is a color additive that is permitted for use in foods and drugs in the United States. The related color additive carmine is permitted for use in foods, drugs, and cosmetics. These certification-exempt color additives and conditions for their safe use are listed in §§ 73.100 (foods), 73.1100 (drugs), and 73.2087 (cosmetics) (21 CFR 73.100, 73.1100, and 73.2087, respectively). In the *Federal Register* of January 30, 2006 (71 FR 4839), FDA published a proposed rule to amend its requirements for cochineal extract and carmine by requiring their declaration on the label of all food and cosmetic products that contain these color additives. More specifically, for food products, FDA proposed to amend the color additive regulation (§ 73.100) that permits the use of cochineal extract or carmine in foods by adding new paragraph (d)(2) to require that all foods (including butter, cheese, and ice cream) that contain cochineal extract or carmine specifically declare the presence of the color additive by its respective common or usual name, "cochineal extract" or "carmine," in the ingredient statement of the food label. Because § 101.22(k) (21 CFR 101.22(k)) allows any certification-exempt color additive to be declared with a general phrase, such as "Artificial Color" or "Artificial Color Added," rather than by its specific common or usual name, FDA also proposed to amend § 101.22(k) to disallow generic declaration of color additives for which individual declaration is required by applicable regulations in part 73 (21 CFR part 73).

For cosmetic products, FDA proposed to amend the color additive regulation (§ 73.2087) permitting the use of carmine in cosmetics by adding new paragraph (d)(2) to require that cosmetics containing carmine that are not subject to the requirements of § 701.3 (21 CFR 701.3) specifically declare the presence of carmine prominently and conspicuously at least once in the labeling. This amendment

will cover all cosmetic products, including those cosmetics that are manufactured and sold for use only by professionals (e.g., makeup used in photography studios and by makeup artists for television, movie, and theater actors/actresses, products intended for use only by professionals in beauty salons, and camouflage makeup dispensed by physicians and aestheticians to clients with skin conditions such as scarring) and those cosmetics that are gifts or free samples. FDA also proposed to include in § 73.2087, as an example, the following statement: "Contains carmine as a color additive."

As the agency indicated in the proposed rule, it plans to initiate a separate rulemaking to implement section 412 of the Food and Drug Administration Modernization Act (FDAMA), which amended the misbranding provisions of the Federal Food, Drug, and Cosmetic Act (the act) to require declaration of inactive ingredients for drugs. The FDAMA provisions have already been implemented for over-the-counter (OTC) drugs.<sup>1</sup>

FDA issued the proposed rule in response to reports of severe allergic reactions, including anaphylaxis, to cochineal extract and carmine-containing food and cosmetics. The proposed rule also was in response, in part, to a 1998 citizen petition from CSPI, which asked FDA to take action to protect consumers who are allergic to cochineal extract and carmine. FDA did not propose to adopt CSPI requests that the agency do the following things: (1) Require labeling of animal (insect) origin of cochineal extract and carmine, (2) undertake or require scientific reviews or studies, or (3) prohibit, if necessary, the use of cochineal extract and carmine entirely (71 FR 4839 at 4845). Interested persons were given until May 1, 2006, to comment on the proposed rule.

**II. Summary of Comments and the Agency's Responses**

FDA received a total of 159 responses (including 83 form letters), each containing one or more comments, to the proposed rule. Responses were received from industry, trade associations, consumer advocacy

<sup>1</sup> The provisions of FDAMA have already been implemented for OTC drugs. See 64 FR 13254 at 13263 (March 17, 1999). Note also that current 21 CFR 201.100(b)(5) requires the label of a prescription drug that is not for oral use (such as a topical or injectable drug) to bear the names of inactive ingredients, but permits certain color components to be designated as "coloring" rather than being specifically named.

organizations, health care professionals, and consumers. A number of comments supported the proposed rule generally or supported certain portions of the proposed rule. Other comments objected to the proposed rule. Several comments raised issues that were outside the scope of the proposed rule and will not be discussed here. A summary of the relevant comments and the agency's responses to the comments follow.

(Comment) One comment requested that FDA not consider cochineal extract and carmine to be major allergens under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).

(Response) Cochineal extract and carmine are not considered to be "major food allergens" nor are they derived from one of the eight foods or food groups identified in FALCPA (i.e., milk, eggs, fish (e.g., bass, flounder, cod), Crustacean shellfish (e.g., crab, lobster, shrimp), tree nuts (e.g., almonds, walnuts, pecans), peanuts, wheat, and soybeans).

(Comment) One comment stated that cochineal extract and carmine are allergens and should be listed under the allergen information on food labels.

(Response) FDA disagrees. Cochineal extract and carmine are allergens for a small subset of the allergic population (71 FR 4839 at 4841 through 4843), but they are not "major food allergens" under FALCPA. However, because these additives are allergens, FDA is requiring that they be labeled by name in the ingredient list.

(Comment) One comment stated that carmine or cochineal extract could be present in food by virtue of having been an ingredient in a component of that food. The comment argued that when the color additive has no technical or functional effect in the food, carmine or cochineal extract is an incidental additive and should be exempt from labeling under § 101.100(a) (21 CFR 101.100(a)).

(Response) FDA disagrees. Cochineal extract and carmine are allergens for a small subset of the allergic population. Section 403(x) of the act (21 U.S.C. 343(x)) provides FDA the authority to establish labeling requirements through rulemaking for the disclosure of any food allergen (other than a major food allergen) that is found in a spice, flavoring, coloring, or incidental additive. Therefore, because this regulation requires that cochineal extract and carmine be declared on labels, these color additives are not exempt from labeling under § 101.100(a).

(Comment) Several comments stated that cochineal extract and carmine

should be banned. One comment argued that these color additives are not safe under 21 CFR 70.3(i) because the evidence did not establish with reasonable certainty that no harm would result from its intended use. Therefore, the comment stated, FDA is required by section 721(b)(8)(C) of the act (21 U.S.C. 379e(b)(8)(C)) to take into account the availability, if any, of other color additives suitable and safe for one or more of the uses allowed for cochineal extract and carmine. The comment also argued that the impact on the general population is no longer the test in the case of allergens because FALCPA was passed even though only a small percentage of the population then suffered from food allergies.

(Response) FDA disagrees. Cochineal extract and carmine have both been determined to be safe when used as specified by the color additive regulations in part 73 (see 71 FR 4839 at 4845). The comment did not submit any data demonstrating that this conclusion is incorrect. Therefore, FDA is not required to take into account the availability of alternative color additives as a justification for a ban. Section 721(b)(8)(C) applies when, with regard to the aggregate quantity of a color additive likely to be consumed in the diet or applied to the human body, FDA finds that the data fail to show that it would be safe or otherwise permissible to list a color additive for all proposed uses and at the levels of concentration proposed. Further, FALCPA applies only to the eight major food allergens and thus does not bear on the safety of cochineal extract or carmine, which are not major food allergens.

(Comment) One comment requested that FDA ban cochineal extract and carmine because doing so would protect those consumers who are not aware that they are allergic to these ingredients.

(Response) As discussed in the previous paragraphs, FDA has determined that these additives are safe when used as specified by the color additive regulations under part 73, and this comment did not submit any data demonstrating that this conclusion is incorrect. FDA has concluded that the labeling requirements established by this regulation will provide consumers adequate information that will enable them to avoid carmine and cochineal extract. While FDA recognizes that people who have not been diagnosed with an allergy to these color additives will not know to avoid these ingredients, as is the case with any allergen, this fact does not change our conclusion that these color additives are safe when used as specified by the color additive regulations under part 73. The

labeling required by this regulation will help consumers and health professionals more quickly identify people with sensitivities to these color additives.

(Comment) Several comments requested that FDA not require labeling of cochineal extract and carmine by name in the ingredient list of foods. The comments argued that there is inadequate scientific support for finding sensitivity to cochineal extract and carmine.

(Response) FDA disagrees. Cochineal extract and carmine are allergens for a small subset of the allergic population. The adverse event reports and published studies clearly demonstrate that a person may become sensitized and reactive to cochineal extract and carmine from ingestion, inhalation, or topical exposure to the color additives. The data also show evidence of immunoglobulin E (IgE)-mediated allergic reactions to these color additives, including anaphylaxis or other serious health outcome (71 FR 4839 at 4843). The agency has therefore concluded that requiring label declaration for these color additives in foods is necessary so that sensitive individuals may avoid products containing these color additives.

(Comment) One comment expressed concern that focusing on a single color additive in a negative manner will confuse consumers and cause the industry to use artificial color additives that will adversely affect consumers.

(Response) FDA disagrees that the label declaration of these color additives would be confusing or intimidating to consumers or would portray these color additives distastefully. The comment did not provide information to support its position. The use of another listed color additive in accordance with the listing regulations would not adversely affect the public health because such color additives have been found to be safe.

(Comment) Several comments stated that the proposed labeling changes for cosmetics are unwarranted due to inadequate scientific evidence showing allergic sensitization or hypersensitivity reactions to these color additives in cosmetics. Other comments stated that the labeling changes would dilute the impact of truly necessary labeling statements or may cause consumers to avoid the product.

(Response) FDA disagrees that requiring the labeling of carmine on cosmetic products is unwarranted. Review of consumer adverse event data supports the comment's contention that these reports do not provide definitive proof of sensitization to carmine

through the skin. However, there is clear evidence in FDA's Voluntary Cosmetics Registration Program database (discussed in 71 FR 4839 at 4843) that several carmine-sensitive individuals had used carmine-containing cosmetics previously and had noted or reported reproducible allergic-type reactions at the site where these products were applied. FDA believes that consumers should be alerted to the presence of carmine in all cosmetic products because of the allergenicity of the color additive. Labeling of carmine by name on most cosmetics has been a requirement for many years under § 701.3 and the agency has no evidence, nor was any submitted, demonstrating that consumers have been confused or have avoided these products because they were labeled as containing carmine.

(Comment) Several comments requested FDA to require disclosure that cochineal extract and carmine are "insect (or animal) derived." Many of these comments stated that persons who wish to avoid consuming animal products need this information in order to avoid such products and that labeling cochineal extract and carmine by name is not sufficient.

(Response) FDA disagrees that declaring these color additives by name provides insufficient information to consumers who choose to avoid products containing these additives. The origins of cochineal extract and carmine are clearly described in the color additive regulations. If consumers desire to avoid products containing these color additives, they will be able to identify such products by reading the ingredient list.

(Comment) One comment, which urged FDA not to require that the color additives are insect-derived, stated that this information is "not a material fact of the type that would be required to be declared on a label or in labeling" under section 201(n) of the act (21 U.S.C. 321(n)).

(Response) FDA agrees that this information is not material under section 201(n) of the act. Section 201(n) of the act states that, in determining whether labeling is misleading, the law takes into account the extent to which the labeling fails to reveal facts material to consequences which may result from the use of the product as it is labeled or customarily used. The agency has required special labeling in cases where information is necessary to ensure that consumers are aware of special health risks associated with consumption of a particular product. Because the origin of these color additives has no bearing on consequences that may result from the

use of foods containing them, information regarding their origin is not considered “material”; therefore, declaration on the label is not required.

(Comment) FDA received several comments about the effective date for the final rule. A few comments recommended that it be sooner than proposed, and several comments suggested that FDA use the current uniform effective date, January 1, 2010. Another comment favored using the current uniform effective date for food, but only if it provided at least 2 years for compliance. One comment requested that the effective date be 36 months after the date that the final rule is published.

(Response) FDA is adopting the proposed effective date of 24 months after date of publication for compliance with the final rule. Many manufacturers may have significant inventories of labels. Some manufacturers may incur costs, including those related to loss and disposal of obsolete packaging inventories, product in obsolete packages, and new printing plates, which would be passed on to consumers. For the reasons discussed in section IV.C.3 of this document, the agency has concluded that 24 months will minimize these labeling costs and, at the same time, avoid unnecessarily delaying the benefits of this final rule to the public health.

Although the effective date of the final rule is some time away, FDA encourages manufacturers to have new labels printed that are in compliance with these final rules so they may be used as soon as current inventories are exhausted to ensure a smooth and timely changeover. The agency will not object to voluntary compliance immediately upon publication of the final rule.

Given the absence of convincing evidence or information submitted in response to the proposed rule, FDA is adopting the proposed rule, without change, to require that all food and cosmetic products disclose the presence of cochineal extract and carmine by name.

### III. Legal Authority

The legal authority for the regulations prescribing the safe use of color additives in foods, drugs, and cosmetics comes from section 721(b) of the act. Under section 721(b) of the act, FDA has the authority to prescribe conditions, including labeling requirements, under which a color additive may be safely used. Products containing color additives that are not used in compliance with the color additive regulations are adulterated under sections 402(c) (foods), 501(a)(4) (drugs),

or 601(e) (cosmetics) of the act (21 U.S.C. 342(c), 351(a)(4), and 361(e), respectively). FDA has concluded that cochineal extract and carmine may cause potentially severe allergic responses in humans. Thus, the agency has determined that label information about the presence of these color additives in all foods and cosmetics is necessary to ensure their safe use. We note that, with respect to OTC drugs, declaration of inactive ingredients is already required under 21 CFR 201.66(c)(8), and FDA plans to initiate rulemaking to implement the FDAMA provisions that require declaration of inactive ingredients for drugs, including prescription drugs.

Additional legal authority for requiring disclosure of a coloring that is, or that bears or contains, a food allergen comes from section 403(x) of the act. Under that section, a coloring determined by regulation to be, or to bear or contain, a food allergen must be disclosed in a manner specified by regulation.

Finally, the provisions of section 701(e) of the act (21 U.S.C. 371(e)) apply to the issuance, amendment, or repeal of any regulation listing a color additive or the certification of a color additive for foods, drugs, and cosmetics, subject to the provisions of section 721(b)(5)(C) of the act. Under section 721(d) of the act, the provisions of section 701(e) of the act apply to §§ 73.100 and 73.2087. Section 701(e) of the act directs the Secretary of Health and Human Services to initiate through proposed rulemaking the issuance, amendment, or repeal of such regulation that is based on a petition of any interested persons showing reasonable grounds. Any person who is adversely affected by the final rule may file within 30 days of the issuance of the final rule, objections with FDA, specifying with particularity the provision of the final rule deemed objectionable, stating the grounds for the objections, and requesting a public hearing upon such objections.

### IV. Analysis of Economic Impacts

#### A. Final Regulatory Impact Analysis

FDA has examined the impacts of the final rule amending 21 CFR 101.22, which is not subject to formal rulemaking, under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). The amendments to part 73 that are subject to formal rulemaking are exempt from review under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory

alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. We find that this final rule may have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

#### B. Need for Regulation

We did not receive any comments on the discussion of the need for this regulation in our analysis of the proposed rule (71 FR 4839 at 4846).

#### C. Regulatory Options

We considered the following regulatory options in the analysis of the proposed rule: (1) Take no action; (2) take the proposed action; (3) take the proposed action, but make the effective date later; (4) take the proposed action, but make the effective date sooner; and (5) ban cochineal extract and carmine.

The comments on the proposed rule suggested a number of other regulatory options. We add those options as follows: (6) Take the proposed action, but also require labeling of the origin of cochineal extract and carmine and (7) take the proposed action, but do not change the labeling requirements for cosmetics.

##### 1. Option One: Take No Action

We did not receive any comments on this option.

##### 2. Option Two: Take the Proposed Action.

###### a. Costs

(Comment) One comment suggested we set the effective date to be the next uniform compliance date for labeling regulations.

(Response) Setting the effective date to be the next uniform compliance date for labeling regulations would result in firms having between 12 months and 36 months to make the proposed labeling changes, depending on the date of the publication of the final rule. In the analysis of the proposed rule, we found that changing the effective date from 24 months to 12 months decreased net benefits. We also found that we had insufficient information to determine if changing the effective date from 24 months to 36 months would increase or decrease net benefits. Therefore, we cannot determine the effect on net benefits of changing the effective date from 24 months to the next uniform compliance date for labeling regulations.

b. *Benefits*

(Comment) Some comments noted that some consumers might prefer not to consume food containing cochineal extract or carmine even if they are not allergic to those color additives. These comments specified various groups of consumers who might wish to avoid these color additives for non-health reasons, including vegetarians, Jews, Muslims, and Jains. One comment suggested there was some controversy about the acceptability of consuming these color additives within the kosher Jewish community. Other comments were from individuals who did not belong to any of these groups but who simply preferred not to consume food containing these color additives.

(Response) In the analysis of the proposed rule, we did not account for the value of the proposed labeling changes for consumers who wish to avoid cochineal extract and carmine for non-health reasons. A significant number of consumers belong to the groups identified in the comments as potentially wishing to avoid cochineal extract and carmine for non-health reasons. Therefore, the value of labeling cochineal extract and carmine for these consumers represents a potentially significant addition to the benefits we estimated in the analysis of the proposed rule.

A recent nationwide poll concluded that 2.3 percent of adults in the United States over the age of 18 were vegetarians in 2006 (Ref. 1). This poll defined a vegetarian as someone who never eats meat, chicken, or fish. In 2005, there were 215,246,449 consumers over the age of 18 living in the United States, excluding those living in institutions, college dormitories, and

other group quarters (Ref. 2). The population in 2006 was larger than in 2005, and some adults living in group quarters are probably vegetarian. Therefore, the poll we cited previously in this paragraph suggests there were probably at least 4,950,668 vegetarians over the age of 18 living in the United States in 2006. One study estimated that 5,764,000 Jews; 4,745,200 Muslims; and 7,700 Jains lived in the United States in 2005 (Ref. 3). We do not know how many Jews, Muslims, or Jains are also vegetarians. Therefore, we assume that the rate of vegetarianism in these groups is similar to that in the general population, or 2.3 percent. We also do not know how many consumers in the specified groups also wish to avoid cochineal extract and carmine for health reasons. However, few consumers in the general population are sensitive to these color additives. Therefore, we assume that only a very small percentage of consumers in these groups also wish to avoid these color additives for health reasons. Adding these numbers after subtracting 2.3 percent from each of the religious groups to avoid double counting with vegetarians, we estimate that up to approximately 15 million adult consumers in the United States may wish to avoid cochineal extract and carmine because they are vegetarian or for religious reasons. However, these comments did not provide information establishing that these groups actually have policies in place to encourage their members to avoid these substances, nor did they provide information establishing that every member of these groups follows such policies, if they exist. Therefore, the full range of the number of adults who wish to avoid these substances because they are vegetarian or for religious reasons is 0 to 15 million. In addition, some consumers who are not vegetarian and who do not belong to any of the specified religious groups may also wish to avoid cochineal extract and carmine for non-health reasons. However, we do not have sufficient information to estimate the potential number of such consumers.

We do not know how much these consumers would be willing to pay for the proposed labeling changes. However, any benefit accruing to these consumers would recur annually and, given the number of consumers involved, would probably represent significant additional benefits beyond the quantified benefits involving people who wish to avoid cochineal extract and carmine for health reasons.

(Comment) One comment said that we made an error in our analysis of the proposed rule. According to this

comment, we said there were 14 adverse events over a 10-year period, and we assumed that only one percent of adverse events are reported. The comment said that this implies an estimate of 140 adverse events per year, but we estimated only 31 adverse events per year.

(Response) In our discussion of Option Two in the analysis of the proposed rule, we identified three adverse events over an approximately 10-year period that involved products containing carmine or cochineal extract in which those color additives did not or probably did not appear on the ingredient list. We based our benefit estimate on these three cases because the proposed labeling changes could only eliminate cases in which cochineal extract or carmine did not already appear on the product label, and the other 11 cases either did not contain information on how the product that caused the reaction was labeled or involved products that were labeled as containing carmine or cochineal extract. We applied a reporting rate of 1 percent to this figure to obtain our estimate of 31 adverse events per year.

We addressed the remaining 11 adverse events, which involved products that probably already listed carmine or cochineal extract on the product label, in our discussion of Option Five in the analysis of the proposed rule. We noted that it would be easier for consumers or health care personnel to identify carmine or cochineal extract as the potential cause of an adverse event in these cases than in cases in which these color additives did not appear on the product label. Therefore, we assumed a reporting rate of 10 percent for those cases.

(Comment) One comment said we did not explain why we assumed that only 1 percent of adverse events are reported rather than assuming that 0.1 percent or 10 percent of adverse events are reported.

(Response) In the analysis of the proposed rule, we cited studies that found adverse event reporting rates for various products and reporting systems ranging from less than 1 percent to 10 percent. Estimating the reporting rate for any particular product, adverse event, and reporting system is difficult because many factors can affect adverse event reporting rates, including the severity of the adverse event, whether the adverse event is unusual or unexpected, the amount of media attention the cause of the adverse event has received, and the details of the reporting system involved. We discussed our bases for assuming an adverse event reporting rate of 1 percent for products in which cochineal extract

and carmine do not appear on the label. The comment did not provide sufficient information for us to revise that assumption.

(Comment) One comment was from an organization that said it had received reports that 32 people had suffered adverse events caused by products containing carmine or cochineal extract between August 1998 and April 2006. The comment noted that applying a 1 percent reporting rate to this number of adverse events results in an estimate of approximately 400 adverse events per year.

(Response) As we discussed elsewhere in this section, we estimated the number of adverse events reported annually based on the number of adverse events involving products containing carmine or cochineal extract in which those color additives did not or probably did not appear on the label. This comment does not indicate whether any of the adverse event reports it received involved products that contained carmine or cochineal extract and did not or probably did not declare those color additives on product labels. Based on these considerations, we have not revised our analysis to reflect the information provided in this comment.

(Comment) Some comments noted that labeling would not prevent allergic reactions that a consumer experiences before he or she identifies carmine or cochineal extract as the cause of the allergic reaction. Some comments were from people who said it had taken them up to 10 years to identify cochineal extract or carmine as the cause of their allergic reactions.

(Response) In the analysis of the proposed rule, we acknowledged that the proposed labeling changes would not prevent adverse events involving people who do not yet know that they are sensitive to these color additives. We do not have an estimate of how many people are allergic to these color additives but are not aware of it. To reflect this, we assumed that the proposed labeling changes would eliminate between 10 percent and 90 percent of the adverse events. These comments did not provide sufficient information for us to revise this estimate.

#### *c. Distributive Impacts*

(Comment) One comment argued that the proposed labeling changes could reduce demand for cochineal extract and carmine. This comment noted that a drop in the demand for these color additives would reduce the incomes of people who produce and collect cochineal. The comment said that 20,000 families in the poorest rural zones of Peru depend exclusively on the

production and collection of cochineal for their livelihood.

(Response) We discussed potential distributive impacts in the analysis of the proposed rule under Option Five, which involved banning cochineal extract and carmine. However, we did not discuss distributive impacts in the context of Option Two. The proposed labeling changes may have some effect on the demand for cochineal extract and carmine. However, any distributive impacts generated by the proposed labeling changes would be significantly smaller than those generated by a ban because consumers who wish to avoid products containing cochineal extract and carmine probably represent only a small fraction of the total number of consumers of such products. Therefore, we have revised our discussion of the impacts of this option to add the potential for a small distributive impact on producers of cochineal extract and carmine.

#### *d. Summary*

The revised estimated costs and benefits of this option are the same as the original estimated costs and benefits of this option in the analysis of the proposed rule except for the following changes. We revised our earlier health benefit estimate of \$1 million to \$26 million to include the value of the proposed labeling changes for consumers who wish to avoid cochineal extract and carmine for non-health reasons. We do not have sufficient information to estimate this benefit, but it may be significant based on the number of consumers that might be involved and the fact that any benefit would recur annually. In addition, we revised the analysis of this option in the proposed rule to include potential distributive effects on producers of cochineal extract and carmine due to a possible decline in the demand for those color additives. These distributive effects would probably be small because relatively few consumers probably wish to avoid these substances.

We have not revised the estimate of the costs that we presented in the analysis of the proposed rule, which consisted of relabeling costs of \$0 million to \$3 million plus some small but permanently recurring costs associated with the loss of otherwise free label space. Therefore, we estimate total net benefits of -\$2 million to \$26 million, plus the recurring benefit to consumers who wish to avoid carmine or cochineal extract for non-health reasons, minus the recurring costs associated with the loss of otherwise free label space.

3. Option Three: Take the Proposed Action, but Make the Effective Date Later

(Comment) One comment suggested we make the effective date 36 months after publication of the final rule because this would avoid problems caused by a large number of firms trying to change their labels within 24 months.

(Response) In the analysis of the proposed rule, we discussed the option of setting the effective date at 36 months after publication of the final rule. We noted that this would reduce costs to a range of \$0 million to some amount less than \$3 million. The high end of this range would be lower than the high end of the range that we estimated for the proposed effective date of 24 months after publication of the final rule, which was \$3 million.

In the analysis of the proposed rule, we also noted that setting the effective date at 36 months after publication of the final rule would eliminate the \$0 million to \$2 million in health benefits that would have occurred in months 24 to 36 under Option Two, which would make total quantified benefits approximately \$1 million to \$24 million. Reducing the recurring annual stream of benefits that led to the estimated present value of \$1 million by the small amount per year that rounds to \$0 million did not change the overall estimated value of this stream of recurring benefits, which remained \$1 million after rounding. However, reducing the recurring stream of annual benefits that led to the estimated present value of \$26 million by \$2 million in months 24 to 36 reduced the overall estimated value of this stream of recurring benefits from \$26 million to \$24 million. We said that we were unable to make any conclusions about the effect on net benefits of choosing this option rather than Option Two because of the overlapping changes in quantified costs and benefits. The revisions to the benefits that we discussed under Option Two also apply to this option. Therefore, we now estimate that the benefits that would have occurred in months 24 to 36 under Option Two are \$0 million to \$2 million plus the recurring benefits to consumers who wish to avoid cochineal extract and carmine for non-health reasons. Therefore, total net benefits would be -\$2 million to \$24 million, plus the recurring benefits to consumers who wish to avoid cochineal extract and carmine for non-health reasons, minus the recurring costs associated with the loss of otherwise free label space. This range overlaps with the range that we estimated for Option Two, so we are

again unable to draw any conclusion about whether this option would generate greater net benefits than Option Two.

#### 4. Option Four: Take the Proposed Action, but Make the Effective Date Sooner

The revisions to the benefits that we discussed under Option Two also apply to this option. In the analysis of the proposed rule, we discussed the option of setting the effective date at 12 months after publication of the final rule rather than the proposed 24 months after publication of the final rule. We estimated that this option would increase costs relative to Option Two by \$3 million to \$52 million, which means that the total cost of this option relative to the baseline would be \$3 million to \$55 million. We also estimated that this option would increase benefits relative to Option Two by \$0 million to \$2 million, which means that the total benefits of this option relative to the baseline would be \$1 million to \$28 million. Under the revisions to the benefits that we discussed under Option Two, we now estimate that the total benefits of this option would be \$1 million to \$28 million plus the recurring benefits to consumers who wish to avoid cochineal extract and carmine for non-health reasons. Therefore, we now estimate net benefits of -\$54 million to \$25 million plus the recurring benefits to consumers who wish to avoid cochineal extract and carmine for non-health reasons minus the recurring costs associated with the loss of otherwise free label space. This range overlaps with the range that we estimated for Option Two. Therefore, we are unable to determine if the net benefits of this option would be greater than those of Option Two.

#### 5. Option Five: Ban Carmine or Cochineal Extract

In the analysis of the proposed rule, we estimated that the costs of banning cochineal extract and carmine would be \$3 million to \$1,390 million and that the total value of the resulting annual stream of health benefits would be \$9 million to \$36 million. The revisions to the benefits that we discussed under Option Two also apply to this option. Our revised estimate of the benefits of this option is \$9 million to \$36 million plus the recurring benefits to consumers who wish to avoid cochineal extract and carmine for non-health reasons. Therefore, we estimate net benefits of -\$1,381 million to \$33 million plus the recurring benefits to consumers who wish to avoid cochineal extract and carmine for non-health reasons minus

the recurring costs associated with the loss of otherwise free label space. This range overlaps with the range that we estimated for Option Two. Therefore, we are unable to determine if the net benefits of this option would be greater than those of Option Two.

(Comment) One comment said that we ignored the availability of potential alternative color additives. Another comment argued that firms would have difficulty using alternative synthetic color additives to reproduce the colors produced by cochineal extract and carmine.

(Response) We addressed the potential use of alternatives in the analysis of the proposed rule. The comments did not provide information that would allow us to revise that analysis.

(Comment) One comment argued that we overestimated the cost of reformulating products that would result from banning the use of cochineal extract and carmine. This conclusion was based on two factors: (1) The modest number of foods that contain carmine or cochineal extract and (2) the assertion that some foods already contain alternative color additives.

(Response) The analysis of the proposed rule addressed the fact that only a modest number of foods contain carmine or cochineal extract. In addition, the model we used to estimate reformulation costs addressed the potential use of alternatives. Therefore, we have not revised our analysis in response to this comment.

(Comment) Some comments argued that no color additives currently on the market are acceptable replacements for carmine or cochineal extract.

(Response) In the analysis of the proposed rule, we noted that potential substitute color additives have technical and functional characteristics that differ from those of cochineal extract and carmine. The comment did not provide information establishing that there are no acceptable substitutes after considering changes in product formulation that address differences in technical and functional characteristics.

(Comment) One comment suggested that alternative synthetic color additives might have genotoxic, teratogenic, or carcinogenic properties.

(Response) In the analysis of the proposed rule, we did not address potential genotoxic, teratogenic, or carcinogenic properties of alternative color additives. Adverse health effects generated by alternative color additives would represent a cost of banning cochineal extract and carmine. However, listed color additives are safe when used for their intended purposes.

#### 6. Option Six: Take the Proposed Action, but Also Require Labeling of the Origin of Cochineal Extract and Carmine

(Comment) A number of comments suggested that we take the proposed action but also require labeling indicating that cochineal extract and carmine are derived from insects or, more broadly, from animals. One comment argued that consumers who want to avoid eating ingredients derived from animals, including insects, would not think to look up the source of cochineal extract and carmine.

(Response) This option would generate the same costs and benefits as Option Two plus some additional costs and benefits. This option would result in additional costs because it would require a more complicated type of label change than the change in the ingredient list that we discussed under Option Two. In addition, this option would generate additional loss of otherwise free label space beyond the amount that we discussed under Option Two.

This option would result in additional benefits because consumers who are interested in avoiding ingredients derived from insects or animals would have all the information they need to accomplish their objective on the product label, so they would not need to learn that cochineal extract and carmine are derived from insects. Learning that cochineal extract and carmine come from insects is a one-time cost for individuals. However, some people would enter the pool of people trying to avoid ingredients derived from insects or animals every year, so these learning costs would be an annual cost. Education costs would probably be relatively low because one can get information on ingredients derived from animals from a variety of sources such as books or Web sites dealing with vegetarianism, health, and religious eating restrictions. We do not have sufficient information to estimate the number of people who might wish to avoid carmine and cochineal extract for various reasons, nor do we know how much it would cost them to learn that cochineal extract and carmine are derived from insects. Therefore, we cannot estimate the net benefits of this option or determine if this option would generate greater net benefits than Option Two.

#### 7. Option Seven: Take the Proposed Action, but Do Not Change the Labeling Requirements for Cosmetics

(Comment) One comment said that we lacked support for our claim that cosmetics containing carmine have

caused adverse reactions. This comment also discussed some studies that ostensibly showed that cosmetics containing this color additive do not cause allergic reactions. Another comment was from a manufacturer of cosmetics that contain carmine that said it had never received a documented adverse event report involving this color additive in these cosmetics in 40 years of selling these products in various countries. One comment suggested we take the proposed action with respect to food but not cosmetics.

(Response) The estimated cost of taking the proposed action but not changing the labeling requirements for cosmetics is approximately \$0 million to \$3 million, which is the same as the cost we estimated for Option Two, plus

the recurring costs associated with the loss of otherwise free label space. This option would also generate the same benefits as Option Two. The cost of changing cosmetic labels did not contribute significantly to the total estimated cost of changing labels in Option Two in the analysis of the proposed rule.

None of the three adverse events involving products that contained carmine or cochineal extract but did not list those substances on the product label, which we used to estimate benefits for Option Two, involved cosmetics. However, some small number of adverse events involving unlabeled carmine in cosmetics probably occur because some consumers have reported having adverse reactions

to cosmetic products containing carmine and some cosmetic products containing carmine do not list those substances on the product label. We do not have sufficient information to estimate the number of such cases. Therefore, we cannot estimate the net benefits of this option or determine if this option would generate greater net benefits than Option Two.

8. Summary

In table 1 of this document, we summarize the quantified costs and benefits and compare the estimates from our analyses of the proposed and final rules. We discuss the nonquantified costs and benefits after table 1.

TABLE 1.

Option	Final Rule Cost (millions of dollars)	Final Rule Benefit (millions of dollars)	Proposed Rule Cost (millions of dollars)	Proposed Rule Benefit (millions of dollars)
Option One: Take No Action	Baseline	Baseline	Baseline	Baseline
Option Two: Take the Proposed Action as Revised in This Final Rule	\$0 to \$3	\$1 to \$26	\$0 to \$3	\$1 to \$26
Option Three: Take the Proposed Action, but Make the Effective Date Later	\$0 to < \$3	\$1 to \$24	\$0 to < \$3	\$1 to \$24
Option Four: Take the Proposed Action, but Make the Effective Date Sooner	\$3 to \$55	\$1 to \$28	\$3 to \$55	\$1 to \$28
Option Five: Ban Carmine or Cochineal Extract	\$3 to \$1,390	\$9 to \$36	\$3 to \$1,390	\$9 to \$36
Option Six: Take the Proposed Action, but Also Require Labeling of the Origin of Cochineal Extract and Carmine	\$0 to \$3	\$1 to \$26	Not applicable (NA)	NA
Option Seven: Take the Proposed Action, but Do Not Change the Labeling Requirements for Cosmetics	\$0 to \$3	\$1 to \$26	NA	NA

In addition to quantified costs and benefits, we also have nonquantified costs and benefits. One nonquantified benefit, which we discussed in the analysis of the proposed rule, is the value of the various potential regulatory alternatives that consumers who are sensitive to cochineal extract and carmine gain from being able to consume some foods and use some cosmetics that they might currently avoid because these consumers are uncertain as to whether the products contain these substances. This benefit occurs under Options Two through Seven. It is greatest under Option Five (Ban Carmine or Cochineal Extract). Among the options that involve labeling, this benefit is somewhat smaller under Option Seven than under the other relevant options because

Option Seven does not apply to cosmetics. Another nonquantified benefit, which we have introduced in this analysis of the final rule, is the value to consumers who wish to avoid cochineal extract and carmine for non-health reasons. This benefit occurs under Options Two through Seven. It is greatest under Option Five (Ban Carmine or Cochineal Extract). Among the options that involve labeling, this benefit is also somewhat greater under Option Six because this option requires declaration of information on the origin of these substances and somewhat smaller under Option Seven because this option does not apply to cosmetics. The one nonquantified cost is a small but permanently recurring cost from the loss of otherwise free label space. This nonquantified cost occurs under

Options Two through Four and Six through Seven. This cost is somewhat greater under Option Six because this option requires additional information to be declared and somewhat less under Option Seven because this option does not apply to cosmetics.

D. Small Entity Analysis

We have examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. We find that this final rule may have a significant economic impact on a substantial

number of small entities. The discussion in this section of the final rule, as well as data and analysis contained in this rule's regulatory impact analysis, constitutes our final regulatory flexibility analysis in compliance with section 604 of the Regulatory Flexibility Act.

The Regulatory Flexibility Act requires that we present a succinct statement of a rule's objectives. As stated previously in this analysis and unchanged from the proposed rule, the intent of this rule is to enable individuals with sensitivities to cochineal extract and carmine to avoid products containing these color additives, as well as to enable consumers and healthcare professionals to more quickly identify sensitivities to these additives.

The Small Business Administration (SBA) publishes definitions of small businesses by North American Industry Classification System (NAICS) code. We presented a list of relevant NAICS codes in the preliminary regulatory impact analysis (71 FR 4839 at 4847). For most of the relevant NAICS codes, SBA defines a small business as a business with 500 or fewer employees. The exceptions are NAICS codes 311821 and 312140, for which the cutoff is 750 employees, and 311422, for which the cutoff is 1,000 employees. We used the 1997 Economic Census to check the number of firms that would be classified as small businesses under the SBA definitions. We found that virtually all (98 percent) of the firms in the relevant NAICS code categories are small businesses according to the SBA definitions.

Total costs potentially incurred by small businesses will be virtually equal to the social costs estimated in the initial and final regulatory impact analyses because the vast majority of the affected firms discussed in the cost benefit analysis are small businesses. These costs may or may not be borne by small businesses because firms may be able to pass on some or all of these costs to consumers in the form of higher prices, depending on market conditions. If the total costs accruing to small businesses are proportional to the number of affected food and cosmetic firms that are small businesses, and if these firms are unable to pass on any costs to consumers, then we estimate that the one-time costs accruing to small businesses from taking the proposed action would be \$0 million to \$3 million, plus some small but permanently recurring costs associated with the loss of otherwise free label space. We described these costs and our method for estimating these costs in the

initial and final regulatory impact analyses.

All of the regulatory alternatives that we discussed in the initial regulatory impact analysis would change the potential impact of this rule on small businesses. Taking no action (Option One) would eliminate all potential impacts on small businesses. However, it would also eliminate all potential benefits of this rule. Taking the proposed action but increasing the compliance period from 24 months to 36 months (Option Three) would reduce the potential impact on small businesses to between \$0 million and some amount less than \$3 million, plus some small but permanently recurring costs associated with the loss of otherwise free label space. However, as we discussed in the initial regulatory impact analysis, extending the compliance period from 24 months to 36 months would also reduce benefits by the amount that would otherwise have been generated in the first 12 months. Taking the proposed action but decreasing the compliance period from 24 months to 12 months (Option Four) would substantially increase the potential impact on small businesses to between \$3 million and \$55 million, plus some small but permanently recurring costs associated with the loss of otherwise free label space. Banning carmine and cochineal extract (Option Five) would significantly increase the potential costs for small food and cosmetic firms to between \$3 million and \$1,390 million. In addition, a ban would also generate significant distributive effects on small businesses that manufacture, import, or process these color additives and do not also handle substitutes. These distributive effects would also be considered costs from the perspective of the affected small businesses. Other firms, including small firms, would benefit from these distributive effects. However, we are unable to consider positive effects on small businesses for purposes of this analysis.

We did not receive any comments that require us to revise the discussion of the five options that we discussed in the analysis of the proposed rule other than those comments that we have already discussed in the final regulatory impact analysis. However, we must address the additional options suggested in the comments. Taking the proposed action but also requiring labeling of the origin of cochineal extract and carmine (Option Six) would increase costs for small entities relative to Option Two because it would require a more complicated type of label change than the change in the ingredient list that we

discussed under Option Two. Therefore, the range of costs for this option would be greater than the \$0 to \$3 million that we estimated for Option Two. In addition, this option would generate additional loss of otherwise free label space beyond the amount that we discussed under Option Two. We do not have sufficient information to determine how much this option would increase costs for small entities relative to Option Two. Taking the proposed action but not changing the labeling requirements for cosmetics (Option Seven) would eliminate costs that would accrue to small cosmetic firms under Option Two. However, costs accruing to cosmetic firms did not contribute significantly to the estimated total costs of Option Two. Therefore, our estimate of the costs of this option rounds to \$0 million to \$3 million plus the recurring costs associated with the loss of otherwise free label space, which is the same as the costs we estimated for Option Two. This option would also eliminate all benefits associated with applying this rule to small cosmetic firms.

## V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to "construe \* \* \* a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute."

Section 403A of the act (21 U.S.C. 343-1) is an express preemption provision. Section 403A(a) of the act provides that: "\* \* \* no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—\* \* \* (2) any requirement for the labeling of food of the type required by section \* \* \* 403(x) that is not identical to the requirement of such section \* \* \*." This final rule, among other things, amends the existing labeling regulations on cochineal extract and carmine by requiring their declaration by name on the label of all food products that contain these color additives. Although this rule has a preemptive effect in that it precludes States from issuing any food labeling requirements for cochineal extract and carmine that are not identical to those required by this final rule, this preemptive effect is consistent with what Congress set forth in section 403A of the act. Section 403A(a)(2) of

the act displaces both State legislative requirements and State common law duties (*Riegel v. Medtronic*, 128 S. Ct. 999 (2008)). In addition, as with any Federal requirement, if a State law requirement makes compliance with both Federal law and State law impossible, or would frustrate Federal objectives, the State requirement would be preempted. See *Geier v. American Honda Co.*, 529 U.S. 861 (2000); *English v. General Electric Co.*, 496 U.S. 72, 79 (1990); *Florida Lime & Avocado Growers, Inc.*, 373 U.S. 132, 142–43 (1963); *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

The preemptive effects are the result of existing law set forth in the statute as interpreted in decisions of the United States Supreme Court. FDA, therefore, has not sought separate comment on the preemptive effect of this action because it is not seeking independently to preempt State law beyond the effects of section 403A(a)(2) of the act or existing case law.

#### VI. Paperwork Reduction Act of 1995

This final rule contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The labeling requirements in this final rule cross-reference labeling requirements in other regulations; therefore, FDA is not estimating the burden of this final rule separately. The burden hours for 21 CFR 70.25 cross-referenced in §§ 73.100(d)(1) and 73.2087(c)(1) have been estimated and approved under OMB Control Number 0910–0016. The burden hours for 21 CFR 101.4 cross-referenced in § 73.100(d)(2) have been estimated and approved under OMB Control Number 0910–0381. The burden hours for § 701.3 cross-referenced in § 73.2087(c)(2) have been estimated and approved under OMB Control Number 0910–0599.

#### VII. Analysis of Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (71 FR 4839). No new information or comments have been received that would affect the agency's previous determination that this action has no significant impact on the human environment and that neither an environmental assessment nor an environmental impact statement is required.

#### VIII. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons

between 9 a.m. and 4 p.m., Monday through Friday.

1. Stahler, Charles. How Many Adults are Vegetarian? *Vegetarian Journal*. 2006. Issue 4.
2. U.S. Census Bureau. 2005 American Community Survey.
3. The 2005 Annual Megacensus of Religions. (2007). *Britannica Book of the Year*, 2006.

#### IX. Objections

This rule is effective as shown in the DATES section of this document; except as to any provisions that may be stayed by the filing of proper objections. Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see ADDRESSES) written or electronic objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register**.

#### List of Subjects

##### 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

##### 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 73 and 101 are amended as follows:

#### PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

■ 1. The authority citation for 21 CFR part 73 continues to read as follows:

**Authority:** 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

■ 2. Section 73.100 is amended by revising paragraph (d) to read as follows:

##### § 73.100 Cochineal extract; carmine.

\* \* \* \* \*

(d) *Labeling requirements.* (1) The label of the color additives and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(2) The label of food products intended for human use, including butter, cheese, and ice cream, that contain cochineal extract or carmine shall specifically declare the presence of the color additive by listing its respective common or usual name, “cochineal extract” or “carmine,” in the statement of ingredients in accordance with § 101.4 of this chapter.

\* \* \* \* \*

■ 3. Section 73.2087 is amended by revising paragraph (c) to read as follows:

##### § 73.2087 Carmine.

\* \* \* \* \*

(c) *Labeling.* (1) The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(2) Cosmetics containing carmine that are not subject to the requirements of § 701.3 of this chapter shall specifically declare the presence of carmine prominently and conspicuously at least once in the labeling. For example: “Contains carmine as a color additive.”

\* \* \* \* \*

#### PART 101—FOOD LABELING

■ 4. The authority citation for 21 CFR part 101 continues to read as follows:

**Authority:** 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 5. Section 101.22 is amended by revising paragraph (k)(2) to read as follows:

##### § 101.22 Foods; labeling of spices, flavorings, colorings and chemical preservatives.

\* \* \* \* \*

(k) \* \* \*

(2) Color additives not subject to certification and not otherwise required by applicable regulations in part 73 of this chapter to be declared by their respective common or usual names may be declared as “Artificial Color,” “Artificial Color Added,” or “Color Added” (or by an equally informative term that makes clear that a color additive has been used in the food). Alternatively, such color additives may be declared as “Colored with \_\_\_\_\_” or “\_\_\_\_\_ color,” the blank to be filled in with the name of the color additive listed in the applicable regulation in part 73 of this chapter.

\* \* \* \* \*

Dated: December 24, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8-31253 Filed 1-2-09; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

#### 30 CFR Part 926

[SATS No. MT-028-FOR; Docket ID No. OSM-2008-0018]

#### Montana Regulatory Program

**AGENCY:** Office of Surface Mining Reclamation and Enforcement, Interior.

**ACTION:** Final rule; approval of amendment.

**SUMMARY:** We are approving an amendment to the Montana regulatory program (the “Montana program”) under the Surface Mining Control and Reclamation Act of 1977 (“SMCRA” or “the Act”). Montana proposed revisions to its statute as discussed in **SUPPLEMENTARY INFORMATION, II.** Proposed Amendment, to clarify ambiguities and improve operational efficiency.

**DATES:** *Effective Date:* January 5, 2009.

**FOR FURTHER INFORMATION CONTACT:** Casper Field Office Director Jeffrey Fleischman, Telephone: 307/261-6550, Internet address: [JFleischman@osmre.gov](mailto:JFleischman@osmre.gov).

#### SUPPLEMENTARY INFORMATION:

- I. Background on the Montana Program
- II. Submission of the Proposed Amendment
- III. Office of Surface Mining Reclamation and Enforcement’s (OSM’s) Findings
- IV. Summary and Disposition of Comments
- V. OSM’s Decision
- VI. Procedural Determinations

#### I. Background on the Montana Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, “a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act \* \* \*; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act.” See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Montana program on April 1, 1980. You can find background information on the Montana program, including the Secretary’s findings, the disposition of comments, and conditions of approval in the April 1, 1980, **Federal Register** (45 FR 21560). You can also find later actions at 926.15, 926.16, and 926.30.

#### II. Submission of the Proposed Amendment

By letter dated July 7, 2008, Montana sent us an amendment to its program (Administrative Record No. MT-025-01, under SMCRA (30 U.S.C. 1201 *et seq.*). Montana sent the amendment for changes made at its own initiative. The provisions of the Montana Strip and Underground Mine Reclamation Act that Montana proposed to revise are within MCA 82-4-232, Area mining required—bond—alternative plan.

We announced receipt of the proposed amendment in the August 26, 2008, **Federal Register** 73 FR 50265. In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the amendment’s adequacy (Administrative Record No. MT-25-05). We did not hold a public hearing or meeting because no one requested one. The public comment period ended on September 25, 2008. We received comments from one Federal agency.

#### III. OSM’s Findings

Following are the findings we made concerning the amendment under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17. We are approving the amendment.

##### A. *Minor Revisions to Montana’s Statute*

Montana proposed minor wording changes to the following previously-approved Montana Strip and Underground Mine Reclamation Act: MCA 82-4-232(3) and (4). Area mining required—bond—alternative plan.

Because these changes are minor, we find that they will not make Montana’s statute less stringent than SMCRA.

##### B. *Revisions to Montana’s Statute That Have the Same Meaning as the Corresponding Provisions of SMCRA*

Montana proposed revisions to its statute at MCA 82-4-232(6)(l) requiring detailed written findings when reclamation is not approved. The revised language is similar and corresponds to section 519(d) of SMCRA; and therefore, we approve it.

##### C. *Revision to Montana’s Statute That Is Not the Same as SMCRA*

Montana statute at MCA 82-4-232(5)(k). Requirement to release performance bonds.

MCA at 82-4-232(k)(5) states that the Department may release the bond in whole or in part if it is satisfied the reclamation covered by the bond or portion of the bond has been accomplished as required by this part according to the following schedule:

Montana proposes to replace the existing term “may” in its statute with the more definitive term “shall.” The language in both SMCRA at Section 519 and the Federal regulations at 30 CFR 800.40(c) use the phrase “the regulatory authority may release all or part of the bond \* \* \*.” (Emphasis added). Montana’s proposed statutory change does not alter its existing requirements that all required reclamation must be completed prior to the release of the bond, the public must have been provided with the opportunity to request a hearing to contest the pending release, and the performance bond is released either in whole or in part only when the entire process is completed. With the use of the term “shall”, Montana provides the operator conducting the required reclamation with clear assurance that bond will be released once all the requirements are met including the appropriate request by the operator. The added assurance that bond release will occur is also important to financial institutions providing funds for the reclamation bond. Surety bonds have become more difficult to obtain. Montana’s proposed use of the term “shall” clarifies the terms of the bond. We have, in the past, approved the use of the term “shall” rather than “may” with respect to a State’s decision to release all or part of a reclamation bond. For the reasons discussed above, we are approving Montana’s proposed change to MCA 82-4-232(k)(5) to require bond release with use of the term “shall” in place of the term “may”.