

Guidance for Industry

SMALL ENTITY COMPLIANCE GUIDE DECLARING COLOR ADDITIVES IN ANIMAL FOODS

Submit comments on this guidance at any time. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. All written comments should be identified with Docket No. FDA-2013-D-1088.

For further information regarding this document, contact Charlotte Conway, Division of Animal Feeds (HFV-220), Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-276-8649, Email: charlotte.conway@fda.hhs.gov.

Additional copies of this guidance document may be requested from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either <http://www.fda.gov/AnimalVeterinary/default.htm> or <http://www.regulations.gov>.

**U.S. Department of Health and Human Services
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Guidance for Industry

Small Entity Compliance Guide

Declaring Color Additives in Animal Foods

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. BACKGROUND

On November 17, 2011, FDA published a final rule in the Federal Register (76 FR 29701) that amended its regulations regarding the declaration of certified color additives on the labels of animal food including animal feeds and pet foods. FDA issued the regulation in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), which, among other things, amended Section 403(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA has prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. INTRODUCTION

This document is intended to provide guidance to small businesses on the requirements of the final rule (cited above) which implements a portion of the 1990 amendments. The 1990 amendments, among other things, provided for the declaration of certified color additives on the labels of human and animal food, including animal feeds and pet foods. The 1990 amendments also provided for the listing on food labels of the common or usual names of all color additives required to be certified by FDA. This regulation deals with the requirements associated with animal food only.

Contains Nonbinding Recommendations

Before passage of the 1990 amendments, the FD&C act provided that colorings could be declared collectively on food product labels using the term “colorings.” This regulation requires that certified color additives be declared on labeling of animal food by their common or usual name, but color additives exempt from certification (e.g., caramel, paprika, and beet juice) may still be declared collectively. This rule makes these animal food regulations consistent with the regulations regarding the declaration of certified color additives on the labels of human food. The rule also suggests appropriate terminology for the declaration of noncertified color additives on the labels of animal food.

The FDA enforces the laws governing color additives used in foods. These laws include the FD&C Act, the Fair Packaging and Labeling Act, as well as the Public Health Security and Bioterrorism Preparedness and Response Act, and the FDA Food Safety Modernization Act. These statutes, among other things, require domestic and foreign manufacturers of color additives used as ingredients in foods to register with FDA.

The FD&C Act defines “food” as any article used for food or drink for man or other animals. FDA lists new color additives or new uses for listed color additives that have been shown to be safe for their intended uses in the Code of Federal Regulations (CFR). The FDA conducts a certification program for batches of color additives that are required to be certified before sale and monitors the use of color additives in products in the U.S., including product labeling.

Color additives used in foods must comply with individual listing regulations issued by FDA. The use of an unlisted color additive, the improper use of a listed color additive, or the use of a color additive that does not conform to the purity and identity specifications of the listing regulation may cause a product to be adulterated according to the provisions of the FD&C Act. FDA has established regulations for color additives in Title 21 of the CFR, parts 70-82. The regulations in 21 CFR parts 73, 74, and 82 identify each listed color additive, provide chemical specifications for the color additives, and identify uses and restrictions, labeling requirements, and the requirement for certification.

The following question and answer section provides information that will help you comply with this new regulatory requirement.

III. QUESTIONS AND ANSWERS

1. Which color additives are affected by this rule?

All color additives required to be listed by FDA are affected by this rule. Therefore, the label of an animal food product to which any coloring has been added must declare the coloring in the statement of ingredients in the manner specified in the new paragraph (k) of section 501.22 of the 21 CFR.

Contains Nonbinding Recommendations

Color additives fall into two categories: those that are subject to FDA's certification process and those that are exempt from the certification process. Color additive certification is the process by which FDA assures that newly manufactured batches of color additives meet the identity and specification requirements of their listing regulations. Color additives subject to batch certification are synthetic organic dyes, lakes, or pigments. Color additives exempt from certification generally include those derived from plant or mineral sources.

2. Is your firm affected by this rule?

All firms that manufacture animal food products containing color additives must comply with this rule.

3. What you need to do to comply with this rule. When does this rule become effective?

You must revise your animal food labels to ensure that color additives are properly declared in the ingredient statement. FDA encourages all animal food manufacturers to begin to comply with this rule as soon as possible. The effective date is November 18, 2013.

4. What specific changes have been made to the color additive labeling regulations?

The rule adds paragraph (k) to the animal food labeling regulations at section 501.22 of the 21 CFR. This paragraph explains how certified color additives used in animal foods must be declared in the ingredient list and sets out the various ways that manufacturers may collectively declare certification-exempt color additives in the ingredient list.

A color additive or the lake of a color additive subject to certification must be declared by the name of the color additive listed in the applicable regulation in part 74 (Subpart A – Foods) or part 82 (Subpart B) of the 21 CFR, except that it is not necessary to include the “FD&C” prefix or the term “No.” in the declaration. For example, a certified color additive may be listed by a specific or abbreviated name such as “FD&C Blue No. 1” or “Blue 1.” However, the term “Lake” shall be included in the declaration of the lake of the certified color additive (e.g., Blue 1 Lake). You may parenthetically declare an appropriate alternative name of the certified color additive following its common or usual name as specified in part 74 or part 82 of the 21 CFR.

Color additives not subject to certification and not otherwise required by applicable regulations in part 73 of the 21 CFR 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 the 21 CFR.