

Guidance for Industry: Colored Sea Salt

*Additional copies are available from:
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<http://www.fda.gov/ForIndustry/ColorAdditives/GuidanceComplianceRegulatoryInformation/ucm153033.htm>

You may submit written comments regarding this guidance at any time. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the title of the guidance document.

**U.S. Department of Health and Human Services
Food and Drug Administration
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This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

This guidance document is intended for manufacturers of colored sea salt products. This document describes the regulatory requirements for the use of color additives to color sea salt.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our 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 FDA guidances means that something is suggested or recommended, but not required.

II. Discussion

Colored sea salt products containing added charcoal or red clay are sometimes referred to as "Hawaiian Sea Salt." These colored sea salt products are being marketed to consumers and industry for food use in the United States.

Under section 201(t) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(t)), a color additive is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction to another substance) of imparting color thereto.² When substances such as charcoal and red clay are added to sea salt, these substances meet the statutory definition of a color additive under the FD&C Act because these substances impart color to the salt.

¹ This guidance has been prepared by the Office of Food Additive Safety, Division of Petition Review in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

² See also 21 CFR 70.3(f).

Contains Nonbinding Recommendations

Section 721(a) of the FD&C Act (21 U.S.C. 379e(a)) defines conditions under which a color additive is deemed unsafe. A color additive used in or on a food will be deemed unsafe unless: (1) there is a regulation listing such color additive; (2) the regulation allows that particular use; and (3) the color additive and its use conform to the regulation. Neither charcoal nor red clay is listed for safe use by FDA under section 721(a) of the FD&C Act. In addition, charcoal and red clay are not otherwise exempt from such listing. Furthermore, neither charcoal nor red clay is listed in FDA's regulations for use in coloring food, including sea salt (see section 721(b) of the FD&C Act (21 U.S.C. 379e(b))).³ Therefore, any food that contains these color additives is adulterated under section 402(c) of the FD&C Act (21 U.S.C. 342(c)). The introduction or delivery for introduction into interstate commerce of any food that is adulterated is a prohibited act.⁴ FDA can take enforcement action against an adulterated food product, consistent with our priorities and resources.

Manufacturers of sea salt that intend to add color additives that are not currently approved for food use to their products, such as charcoal or red clay, must first obtain approval for the use of these substances through the color additive petition process. Color additive petitions must be submitted to FDA's Office of Food Additive Safety, HFS-200, 5001 Campus Drive, College Park, MD 20740. The information required for color additive petitions is outlined in 21 CFR 71.1. There are guidance documents available on our website that address the administrative, chemistry, toxicological, and environmental information that should be included in support of a color additive petition.⁵

³ Charcoal was provisionally listed as a color additive for use in food in 1960, but because no evidence was submitted that scientific investigations were under way to establish safety, the provisional listing was terminated by FDA in 1964 (see 29 FR 17089; December 15, 1964).

⁴ Section 301(a) of the FD&C Act (21 U.S.C. 331(a)).

⁵ <http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/default.htm>.