Use of the Terms "Brown King Crab" and "Golden King Crab" in the Labeling of Human Food Products: Guidance for Industry

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I. Introduction

The purpose of this guidance is to advise manufacturers who have labeled crabmeat products derived from the species known as *Lithodes aequispina* as "Brown King crabmeat," consistent with our regulations at 21 CFR 102.50, of our intent to exercise enforcement discretion with regard to the name of the crabmeat. Specifically, because a recently enacted Federal law establishes "golden king crab" as the "market name" for *Lithodes aequispina*, we intend to exercise enforcement discretion by not taking action against products derived from *Lithodes aequispina* where the label for such products bears the "Brown King crabmeat" name until January 1, 2020, the next Uniform Compliance Date applicable to food labeling regulations issued in calendar years 2017 and 2018 (see 81 FR 85156 (November 25, 2016)). We are taking this action to allow companies flexibility in implementing this labeling change.

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. Background

Under section 403(i)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(i)(1)), a food² is deemed misbranded unless its label bears "the common or usual

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

² Section 201(f) of the FD&C Act (21 U.S.C. 321(f)) defines the term "food" to mean articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article.

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name of the food, if any there be." FDA assists industry to determine the appropriate name for seafood by providing <u>Guidance for Industry: The Seafood List - FDA's Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce</u>. The Seafood List is intended to provide guidance to industry about what FDA considers to be acceptable market names for seafood sold in interstate commerce and to assist manufacturers in labeling seafood products. In addition, our regulations, at 21 CFR 102.50, which predate the Seafood List, more specifically establish the common or usual name of crabmeat derived from several species of crabs. Those regulations indicate that the common or usual name for the species of crab known as *Lithodes aequispina* is "Brown King crabmeat."

In 2017, the Consolidated Appropriations Act, 2017 (Public Law 115-31) became law. Section 774 of the Consolidated Appropriations Act, 2017, states that, "Notwithstanding any other provision of law, for purposes of applying the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the acceptable market name of *Lithodes aequispinus* is 'golden king crab.'" In response to this legislation, FDA has modified our *Seafood List* (found on the Web at https://www.accessdata.fda.gov/scripts/fdcc/?set=seafoodlist). We intend to revise § 102.50 accordingly.

III. Discussion

Under section 774 of the Consolidated Appropriations Act, 2017, the acceptable market name of *Lithodes aequispinus* is now "golden king crab." Further, because "golden king crab" is now the only name allowed by Federal law, the common or usual name of *Lithodes aequispinus* is also "golden king crab," notwithstanding § 102.50, which has been superseded by section 774 of the Consolidated Appropriations Act, 2017. However, we recognize that some manufacturers of products containing *Lithodes aequispinus* meat may still have labeled food products or unused label inventory that refer to "Brown King crabmeat," and that these manufacturers may be concerned that FDA would consider such products to be misbranded or that labels referring to "Brown King crabmeat" must be corrected before they could be used. Through this guidance, we are announcing that we do not intend to take enforcement action against products containing *Lithodes aequispina* meat whose labels or labeling refers to "Brown King crabmeat" until January 1, 2020, the next Uniform Compliance Date applicable to food labeling regulations issued in calendar years 2017 and 2018. See 81 FR 85156 (November 25, 2016).

In addition, FDA is also clarifying that because the acceptable market name of *Lithodes aequispinus* is now "golden king crab," manufacturers of food products may use the term "golden king crab" for products that contain *Lithodes aequispinus*, despite § 102.50.