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Guidance for FDA Staff

Compliance Policy Guide Sec. 540.700 Processed and/or Blended Seafood Products (CPG 7108.16)

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***I. Introduction:**

The purpose of this document is to provide guidance for FDA staff on the proper labeling for processed and/or blended seafood products.

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. Background:

*Surimi is a fish protein consisting primarily of the myofibrillar protein fraction from one or more fish species. Surimi is an intermediate processed seafood product used in the formulation and fabrication of a variety of products that are made to resemble, and be promoted as substitutes for, crabmeat, shrimp, lobster, scallops, and other seafood.

Surimi is made from minced fish meat (usually pollock), which has been washed to remove fat and undesirable matter (such as blood, pigments, and odorous substances), and then mixed with cryoprotectants (such as sugar or sorbitol) to improve its frozen shelf life. In formulating finished seafood products, surimi is thawed and blended with other ingredients such as the seafood being imitated, seafood flavoring, salt, water, and starch or egg white. This mixture is

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then heat processed and extruded to make fibrous, flake, chunk, and composite-molded consumer products. The finished processed seafood products are marketed frozen or unfrozen and may be breaded.

The following guidance is in response to inquiries FDA has received regarding the proper labeling for processed seafood products and current regulations to permit the use of “and/or” labeling for various fish species used in the production of surimi and processed seafood products (21 CFR 101.4(b)(23); 64 FR 50445, 9/17/99).*

III. Policy:

1. *If a processed seafood product purports to be or is represented as a substitute for a specific type of seafood, including shape or form representations, but is nutritionally inferior (as defined in 101.3(e)(4) to that seafood, it must be labeled as imitation in accordance with 21 CFR 101.3(e). For example, a “processed seafood” product that is represented as a substitute for crabmeat and is nutritionally inferior to crabmeat, must be labeled “imitation crabmeat.” An additional statement of product identity may appear on the principal display panel, e.g., “Fish Protein Blended with _____.” The blank is to be filled in with the common or usual name of the specific ingredient, such as snow crab (21 CFR 101.3).
2. A processed seafood product that is not purported or represented to be a specific type of seafood or seafood body part need not be labeled imitation but must bear a name that is appropriately descriptive, e.g., “Fish Protein Blended with Snow Crab.” (21 CFR 101.3(e)(2)(ii))
3. The fish protein ingredient may be declared in the ingredient statement by the collective name “fish protein” followed with a parenthetical listing of the specific common or usual names of each species that may be present, in accordance with 21 CFR 101.4(b)(23), e.g., “fish protein (contains one or more of the following: pollock, cod, and/or Pacific whiting).”
4. The specific common or usual name of any seafood ingredient must appear in the ingredient statement in descending order of predominance by weight in accordance with 21 CFR 101.4(a) and (b). For example, the common or usual name “snow crab” must be used rather than “crab.” (See The Seafood List at <http://www.cfsan.fda.gov/~frf/seaintro.html>, which is a compilation of existing acceptable market names for imported and domestically available seafood as well as scientific names, common names, and known vernacular or regional names).
5. All ingredients must be listed in the ingredient statement of the finished product by their common or usual names in descending order of predominance by weight, in accordance with 21 CFR 101.4, unless exempted from ingredient declaration under 21 CFR 101.100 (a)(3). For example, “Fish protein (contains one or more of the following: pollock, cod, and/or

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Pacific whiting), snow crab, water, sugar, wheat starch, sorbitol, artificial flavor, salt, potassium chloride, sodium tripolyphosphate, tetrasodium pyrophosphate, glucose, artificial color.” However, flavors, colors, or incidental additives that are or contain major food allergens are not exempted from ingredient declaration and must be declared in accordance with section 403(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(w)).*

Material between asterisks is new or revised.

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