Food and Drug Administration, HHS

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has been evaluated on the basis of limited conditions of use, the agency will describe in the regulation that affirms the GRAS status of the indirect ingredient, one or more of these limited conditions of use, which may include the category of food-contact surface(s), technical effect(s) or functional use(s) of the indirect ingredient, and the level(s) of use. If the ingredient is used under conditions that are significantly different from those described in the regulation, such use of a substance may not be GRAS. In such a case, a manufacturer may not rely on the regulation as authorizing that use but shall independently establish that the use is GRAS or shall use the ingredient in accordance with a food additive regulation. Persons seeking FDA approval of an independent determination that a use of an ingredient is GRAS may submit a GRAS petition in accordance with §170.35 of this chapter.

(2) If the ingredient is affirmed as GRAS with specific limitation(s), it shall be used in food-contact surfaces only within such limitation(s), including the category of food-contact surface(s), the functional use(s) of the ingredient, and the level(s) of use. Any use of such an ingredient not in full compliance with each such established limitation shall require a food additive regulation.

If the ingredient is affirmed as GRAS for a specific use, prior to general evaluation of use of the ingredient, other uses may also be GRAS.

Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

§ 186.1256 Clay (kaolin).

(a) Clay (kaolin) \( \text{Al}_{2}\text{O}_{3}.2\text{SiO}_{2}.n\text{H}_{2}\text{O} \), Cas Reg. No. 1332–58–7) consists of hydrated aluminum silicate. The commercial