

# CPG Sec. 515.100 Confectionery - Use of Non-Nutritive Substances as Ingredients

## BACKGROUND:

Widespread publicity about use in candy of non-nutritive fillers, poisonous colors, narcotics, and alcoholic liquors helped arouse support for passage of the Food and Drugs Act of 1906. That act included a provision that a confectionery was deemed to be adulterated if it contained "terra alba, barytes, talc, chrome yellow, or other mineral substance or poisonous color or flavor, or other ingredient deleterious or detrimental to health, or any vinous, malt or spirituous liquor or compound or narcotic drug."

In 1910, the Circuit Court of Appeals for the Second Circuit ruled that the prohibition against "mineral" substances applied only if the "mineral" was used to deceive or was detrimental to health. (*French Silver Dragee Co. v. U.S.*, 179 Fed. 824). The Federal Food, Drug, and Cosmetic Act of 1938 included a provision under which a confectionery was deemed to be adulterated "if it bears or contains any alcohol or non-nutritive article or substance except authorized coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 percentum, natural gum, and pectin."

Contrary to the finding in *French Silver Dragee Co. v. U.S.*, this section of the act was strictly construed by the FDA to prohibit use in a confectionery of any non-nutritive substance other than those named, even when the substance was safe and performed a technological function.

This concept was litigated in the case of *U.S. v. 1200 Candy Bars, More or Less, Labeled in Part "Sta-Trim."* The candy bars were seized on charges of misbranding and adulteration, the latter charge being based on use of non-nutritive artificial sweeteners. The court condemned the candy on the misbranding charges but ruled that it was not adulterated because the non-nutritive sweeteners were not harmful or deceptive. It cited the case of *French Silver Dragee Co., v. U.S.* \*The government appealed the decision, but \* the Court of Appeals for the Ninth Circuit, in January 1963, vacated the judgement insofar as it dealt with adulteration because the candy bars had been destroyed as a result of the misbranding charge (313 F. 2d 219).

In June 1966, Congress amended section 402(d) to provide that the prohibition against non-nutritive substances "shall not apply to a safe non-nutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this Act."

For many years, FDA interpreted this provision as allowing only those non-nutritive substances that had a technical effect in the production of a confectionery, i.e., that affected the candy in some way in attaining or maintaining certain physical characteristics, to be used in candy. This interpretation led FDA to not permit the use of non-nutritive sweeteners in a confectionery for the purpose of caloric reduction and sweetening because neither use was considered to have a technical effect in the confectionery.

FDA reexamined this position in 1992 and concluded that Congress did not intend to exclude the use of non-nutritive sweeteners in a confectionery. The purpose of the 1966 amendment was to "place the confectionery industry on the same basis as other segments of the food industry and permit that industry to use in the manufacture of candy, food additives cleared for safety under the Food Additives Amendment of 1958 [Section 409]." 21 CFR 170.3(o) defines the terms used to describe the physical or technical functional effects for which food additives are added to food. "Non-nutritive sweetener" is listed in 21 CFR 170.3(o) (19) as a technical effect.

#### POLICY:

Non-nutritive substances may be used in a confectionery if they meet all of the following criteria:

1. They must be safe. They may be used if listed by FDA as generally recognized as safe for the proposed use, if subject to a prior-sanction or interim listed for such use, or if they are food additives or color additives used in accord with a regulation establishing safe conditions of use. If there is any question about the safety of a proposed use, this should be resolved by submitting a petition for a regulation to establish safe conditions of use.
2. The non-nutritive substances must be used for a practical functional purpose. 21 CFR 170.3(o) defines those terms that describe a practical functional purpose. The non-nutritive substance should be used in the minimal amount needed to achieve its purpose, and its use should otherwise be in accord with good manufacturing practice.
3. The use of a non-nutritive substance must not promote deception and must not result in adulteration as defined in section 402(b) of the Act. As long as the confectionery is properly labeled, the use of non-nutritive sweeteners in a confectionery is not considered to promote deception. However, the use of any \*non-nutritive\* substance, including cheap fillers, such as talc, which would promote deception, is still prohibited.

The agency advises that this CPG represents its current position regarding the interpretation of Section 402(d) of the Federal Food, Drug, and Cosmetic Act as it applies to the use of non-nutritive sweeteners and other non-nutritive substances in a confectionery. This CPG may be useful to FDA Field Officers when interpreting the agency's policy on the use of non-nutritive sweeteners in a confectionery. Furthermore, this CPG does not bind the agency, and it does not create or confer any rights, privileges, or benefits for or on any person.

\*Material between asterisks is new or revised\*.

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