COMPLIANCE POLICY GUIDE (CPG)

CPG Sec 587.200 Uncertified or Delisted Colors in Foods for Export - (e.g., FD&C Red #2)

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Final

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BACKGROUND:

The provisional listing and certification of FD&C Red #2 (amaranth) was terminated in Federal Register announcements of February 10 and February 13, 1976. Since that time there have been several inquiries received by FDA concerning the use of FD&C Red #2 in food products for export.

The status of adulterated or misbranded food products for export is found in Section *801(e)* of the Federal Food, Drug, and Cosmetic Act.

POLICY:

Colors such as FD&C Red No. 2, which have been delisted, can be used in lots of food specifically manufactured for export to a country in which its use is legal, provided all the requirements of Section *801(e)* of the Act are followed and provided further, that a control system is followed which insures that there is no possibility of diversion by mistake or otherwise to domestic channels, of the food containing the color. Proper control can be achieved by following the procedure set forth below:

1. Prior to start of production and for each lot produced, a separate order, letter from the purchaser, and letter from an official of the country must be obtained.

The order from the purchaser must state the exact amount desired by the foreign purchaser and must state on the order or be accompanied by a letter from the purchaser stating that he desires that FD&C Red No. 2 or other specific color be used in the lot and that he is aware of its illegality in the United States. The letter from a responsible official of the country to which the lot is to be shipped shall state that the use of the color is legal in his country. Since the law and regulations of countries are subject to change, a continuing order or letter will not be satisfactory.

2. The stock of the color to be used for export production must be kept locked up at all times, except when actually being used. Complete records must be kept accounting for all use.
3. During all stages of production, manufacture, processing and packing the lot must be kept segregated from all other production and must be clearly marked that it is "for export only."

   The outside of each shipping package of the lot must be labeled show it is for export.
4. All records pertaining to such lots, including orders and letters, must be kept for at least three years and made available to any Food and Drug Administration inspector upon oral or written request.

NOTE: This policy only applies to uncertified or delisted colors that have been manufactured in this country, or entered legally into this country prior to being uncertified or delisted, and are intended to be used in foods solely for export.

Material between asterisks is new or revised.

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