

CPG Sec. 555.550 Foods, Standardized; Enriched or Fortified - Adulteration Involving Misbranding - Potency

REGULATORY ACTION GUIDANCE:

The following represents the criteria for direct reference seizure *requests to the Office of Human and Animal Food Operations (OHAFO) in consultation with the Office of Enforcement and Import Operations (OEIO) and CFSAN, and for direct citation by the appropriate Field Office within the Human and Animal Food Program*:

The article is an enriched or fortified food for which a standard of identity has been established, and is more than 20% deficient in one or more of the vitamins or minerals required to be present by the standard of identity.

SPECIMEN CHARGES:

The article is adulterated while held for sale after shipment in interstate commerce, within the meaning of 21 U.S.C. 342(b)(1) in that a valuable constituent, namely riboflavin, has been wholly or in part omitted, or abstracted therefrom.

The article is misbranded while held for sale after shipment in interstate commerce, within the meaning of 21 U.S.C. 343(g)(1), in that it purports to be and is represented as enriched noodles, a food for which a definition and standard of identity has been prescribed by regulations (21 CFR 139.155) promulgated pursuant to 21 U.S.C. 341, and it fails to conform to such definition and standard since paragraph 139.155(a)(1) of such definition and standard prescribes, among other things, that enriched noodles contain in each pound not less than 1.7 milligrams of riboflavin; whereas the article contains less than 1.7 milligrams of riboflavin in each pound.

Material between asterisks is new or revised.

Issued: 11/21/79

Reissued: 10/1/80

Revised: 2/1/89