CPG Sec. 525.850 Whole Plant (Unprocessed) Oregano, Crushed Oregano & Ground Oregano - Adulteration by Insect & Rodent Filth; Mold; Mammalian Excreta

REGULATORY ACTION GUIDANCE:

- 1. The following represents 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*:
- 2. Whole Plant (Unprocessed) Oregano:
 - a. Insect Filth and Mold:

The spice contains an average of 5% or more insect infested and/or moldy pieces by weight.

or

b. Mammalian Excreta:

The spice contains an average of 1 milligram or more of mammalian excreta per pound (mammalian excreta should be identified as to source when possible).

- 3. The following represents the criteria for recommending legal action to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605).
 - a. Ground Oregano

The ground oregano contains an average of 1250 or more insect fragments and/or an average of 5 or more rodent hairs per 10 gram subsample.

b. Crushed Oregano

The crushed oregano contains an average of 300 or more insect fragments and/or an average of 2 or more rodent hairs per 10 gram subsample.

NOTE: Determinations for all defects are made on a minimum of six (6) ten (10) gram subsamples for ground and crushed oregano. See Macroanalytical Procedures Manual for number of grams of subsamples used in analyses of whole spices.

REMARKS:

Since the majority of spices are imported, determine that the lot in question has not been previously examined and released by FDA as an import. If the lot has been examined and released previously, submit all available facts to CFSAN/Office of *Compliance*/Division of Enforcement (HFS-605) for seizure consideration in the usual manner.

SPECIMEN CHARGES (for all including leafy spices):

Article (whole plant unprocessed/crushed/ground oregano) adulterated (when introduced into and while in interstate commerce) (while held for sale after shipment in interstate commerce) within meaning of 21 U.S.C. 342(a)(3), in that it consists wholly or in part of a filthy substance by reason of presence therein of (insects), (insect fragments), (insect webbing), (insect excreta), (insect damaged oregano), (mammalian excreta) and (rodent hairs); and that it consists in part of a decomposed substance by reason of the presence therein of (moldy, decomposed oregano) (mold).

NOTE: Only use direct citation authority when prosecution is anticipated and evidence to support a prosecution is included with the adulteration charge. Evidence necessary to support a prosecution is specified in existing regulatory procedures issuances.

Material between asterisks is new or revised.

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