CPG Sec. 100.200 FDA Jurisdiction Over Products Composed of Interstate Ingredients

BACKGROUND:

This policy guide sets forth the position of FDA with respect to products composed of ingredients which were shipped in interstate commerce and were then used in the manufacture of a finished product. This policy is applicable only when the finished product has not itself been shipped in interstate commerce as defined by Section 20l(b) of the FD&C Act. For oleomargarine see Sec. 407 of the FD&C Act. For devices see 304(a)(2)(D) and Sec. 709 of the FD&C Act. For counterfeit drugs and materials see 304(a)(2)(A), (B) and (C) and 301(i)(2) and (3) of the FD&C Act.

Over the years, the courts have reviewed the question of jurisdiction over products made from interstate components. The defense in these cases has been that the finished product is a new entity and FDA lacks jurisdiction until the "new" product is itself shipped in interstate commerce.

The following court cases involving this question establish that FDA clearly has jurisdiction over finished products made from interstate components.

1. U.S. v. An Article of Drug ... Korleen Tablets

   192 F. Supp. 51 (E.D. Mich., 1961), Affirmed at 330 F. 2nd 78 (C. A. 6, 1964) KK 61-64 at 754

2. U.S. v. 40 Cases ... Pinocchio Brand ... Olive Oil

   289 F. 2nd 343 (C. A. 2, 1961) KK 58-60 at 106 and 35

3. Palmer v. U. S.

   340 F. 2nd 48 (C. A. 5, 1964) KK 61-64 at 809

4. *U.S. v. Dianovin Pharmaceuticals, Inc.

   342 F. Supp. 724(D.P.R. 1972). Affirmed at 475 F. 2nd 100 (C. A. 1, 1973) KKW 69-74 at 369 and 382*

5. *U.S. v. 14 Cases ... Naremco Medimatic

   374 F. Supp. 922 (W. D. Mo., 1974) KKW 69-74 at 168*

POLICY:

The Food & Drug Administration has jurisdiction over all products made from interstate components regardless of the amount present, even though the finished product has not moved in interstate commerce. Action may be taken against the product or the responsible firm when violative finished products are encountered, or when conditions of manufacture result in nonviolative interstate ingredients becoming adulterated or misbranded. The importance and the amount of the ingredient in the product, as well as the seriousness of the violation, will be considered in arriving at the decision to take action.

Material between asterisks is new or revised

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