CPG Sec. 325.100 Karaya Gum Powder and Related Devices for Use by Ostomates

BACKGROUND:

Karaya gum powder and devices made from karaya gum powder intended for use by ostomates have been the subject of recalls because the devices contained opportunistic pathogens.

Efforts to sterilize some of these devices by ethylene oxide and irradiation were unsuccessful. Ethylene oxide sterilization of karaya gum is generally not effective. Irradiation sterilization of consumer size containers of karaya gum powder is effective if the irradiation dose is intense. However, the performance of karaya gum powder and devices sterilized in this way is considered unsatisfactory as the irradiation destroys the qualities of the karaya gum and renders these products useless for their intended purpose.

In November 1976, information letters were sent to all known manufacturers of karaya gum devices, advising the firms that these devices should be labeled as nonsterile and that their use on reddened, abraded or excoriated skin is contraindicated. Sterile karaya gum powder was excluded from this labeling requirement. This policy was based on the fact that karaya gum is an essential accessory to ostomy appliances, and we are aware of no satisfactory substitutes available on the market.

Subsequent information indicates to us that this labeling requirement has caused confusion in the profession and in the opinion of medical experts this labeling may cause ostomates to discontinue the use of karaya gum products, thereby causing other problems in attempting successful management of the ostomies. Additionally, FDA has not seen any documented evidence of infection due to the use of karaya ostomy products. Thus, the *Center for Devices and Radiological Health* reconsidered the significance of microorganisms in non-sterile karaya products in terms of use of the product, the nature of the product, and the potential hazard to the user and concluded that the benefits to be derived exceed the potential hazards.

Consequently by memorandum of May 5, 1977, the *Center for Devices and Radiological Health* requested the districts to send a followup letter to all firms who received the November 1976, information letter advising the firms of our new position as stated in the prior paragraph.

POLICY:

The requirement that nonsterile karaya gum devices be labeled as nonsterile and that their use on reddened, abraded, and excoriated skin be contraindicated will not be mandatory, provided the devices meet the "Microbiological Attributes of Non-Sterile Pharmaceutical Products" as specified in the United States Pharmacopeia, XXI, page 1329.

Material between asterisks is new or revised

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