CPG Sec. 345.300 Menstrual Sponges

BACKGROUND:

Natural sea sponges have been promoted as "menstrual sponges," "hygienic sponges," and "sanitary sponges" for use as menstrual tampons. Public interest in these products has grown since the publicity associating toxic shock syndrome with the use of menstrual tampons.

In late 1980, twelve "menstrual sponges" were examined by the University of Iowa Laboratory and found to contain sand, grit, bacteria, and various other materials. The sponges were voluntarily recalled by the distributor. The Centers for Disease Control (CDC) in Atlanta, Georgia also reported one case of TSS associated with the use of a sea sponge, and another case which possibly was associated with the use of a sponge.

During November and December 1980, assignments were issued to all field districts to determine, by inspection, who was packing sea sponges, and to collect samples for FDA analysis. The field offices made forty-one (41) inspections of repackers and visited over 500 retail establishments. These inspections showed the repackers to be small operations which sold limited quantities of sponges, mainly to health food stores. The responsible individuals were informed of the FDA position regarding premarket approval of the sponges, and FDA's concerns about TSS. Most of the repackers elected to go out of the sponge business. A few relabeled them for cosmetic use.

Sponges collected by the districts and analyzed by the Baltimore district laboratory showed that the sponges contained particles of sand, grit, bacteria, yeast, and mold. One sample was confirmed to contain Staphylococcus aureus.

POLICY:

Sea sponges labeled as "menstrual sponges," "hygienic sponges," or "sanitary sponges," intended for use as menstrual tampons, are regarded as significant risk devices requiring premarket approval under Section 515. If a sponsor wishes to conduct a clinical investigation, per 21 CFR 812, it must be approved and a specific IDE number assigned. If districts receive inquiries on the approval process, the Center for Devices and Radiological Health may be contacted:

Investigational Device Exemption Applications
Investigational Device Exemption Staff (HFZ-403)

Premarket Approval Applications
Division of Reproductive, Abdominal, ENT, & Radiological Devices (HFZ-470)

REGULATORY ACTION GUIDANCE:

If evidence is obtained that menstrual sponges are being sold without the required approval, a *Warning Letter should be issued.* If marketing of this device continues, *Office of Compliance (HFZ-300)* in the Center for Devices and Radiological Health should be contacted before submission of a regulatory action proposal.

Material between asterisks is new or revised

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