DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Commissioner
Room 14-105 (HF-7)
5600 Fishers Lane
(301) 443-1306

Food and Drug Administration
Rockville MD 20857

June 8, 1992

Orlando Cordova
Quality Assurance Manager
Medi-Flex Hospital Products, Inc.
19 Butterfield Trail Boulevard
El Paso, Texas 79906

Re: Compound Benzoin Tincture
Our File RFD 92(I)-13

Dear Mr. Cordova:

We have completed our review of your letters of March 30, 1992, and May 5, 1992, concerning the jurisdictional status of the referenced product.

Based on the decision of Medi-Flex to relabel the product for use as a non-antiseptic adhesive applicator, we have determined that Compound Benzoin Tincture should be regulated under the medical device provisions of the Federal Food, Drug and Cosmetic Act. In addition, we have determined that the Center for Devices and Radiological Health will have primary jurisdiction for the review and regulation of the product.

The premarket notification for the product should be submitted to the Document Mail Center, Food and Drug Administration, Center for Devices and Radiological Health, 1390 Piccard Drive, Rockville, MD 20850. If you have any questions concerning the premarket notification, please contact the Director of the Division of Product Surveillance, Leighton W. Hansel at (301) 427-1311.

If you have any other questions concerning this matter, please do not hesitate to telephone me, or the Acting Deputy, Mr. Steve Unger at (301) 443-1306.

Sincerely yours,

Amanda B. Pedersen

Amanda B. Pedersen
Product Jurisdication Officer