

# CPG Sec. 320.100 Ear Piercing Devices

## BACKGROUND:

For the past several years it has been the Food and Drug Administration's position that articles intended to be used for ear-piercing were devices which should be restricted to prescription dispensing in accordance with 21 CFR 801.109. The Food and Drug Administration has attempted to regulate such devices on an ad hoc basis, but this has not resulted in any broad compliance by the industry.

Part of the problem lies in the fact that the states have not uniformly required ear-piercing devices to be restricted to Rx dispensing, and in fact some do not consider piercing of the ears to be a medical procedure. A recent opinion by the California Attorney General states in part, "Since it is concluded that ear-piercing does not constitute the practice of medicine, it follows that \*\*\* there are no circumstances which would prohibit a nurse or any other licensed or unlicensed person from performing earlobe piercing."

Our present ability to enforce the caution legend for Rx devices depends upon the state licensing requirements. Therefore, if the states do not require that ear-piercing devices be restricted to sale by or on the order of a licensed practitioner, we are unable to adequately support our position in the matter.

Ear-piercing devices may eventually be considered for further regulation under Sections 520 and 521 of the Medical Device Amendment as "restricted" devices. If ear-piercing devices are classified as restricted devices, they will be restricted to sale and distribution according to regulations.

## POLICY:

Although we remain of the opinion that ear-piercing devices should be restricted to those qualified to perform this procedure, we have concluded that, because of the absence of documented data establishing that indiscriminate use of ear-piercing devices represents a significant consumer problem, and because of widely varying state and local practices, it would serve no useful purpose at this time to devote our limited resources to this area unless a problem arises which warrants investigation.

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