Compliance Policy Guide
Sec. 335.300 Hypnotherapy Devices - Self Hypnotic Tape Recordings

Guidance for FDA Staff

This document supersedes Sec. 335.300, Hypnotherapy Devices – Self Hypnotic Tape Recordings, previously revised on 02/1995.

Issued by:
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Food and Drug Administration
Center for Devices and Radiological Health
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I. Introduction:

This CPG provides guidance to FDA staff on the submission of regulatory action recommendations for self-hypnotic tape recordings which are misbranded because of false or misleading medical claims in the accompanying promotional literature, and the lack of adequate directions for lay use on these prescription devices.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background:

FDA has both seized self-hypnotic tape recordings and issued regulatory letters to manufacturers concerning such recordings because the intended use of the tapes

(gathered from both the tapes and their labeling) made them devices within the Federal Food, Drug, and Cosmetic Act's definition of a device. The Center's position is that the tapes are misbranded because of false or misleading medical claims in the accompanying promotional literature. Furthermore, the center *affirms* that these tapes are prescription devices and adequate directions for lay use cannot be written for these devices.

Hypnotherapy is a recognized medical modality useful for diagnostic and therapeutic purposes. Tape recordings used in conjunction with hypnotherapy which are intended for use in the mitigation, treatment, and cure of disease and other medical conditions are "devices" as that term is defined in Section 201(h) of the act.

Tape recordings labeled only for behavior modification, self-improvement, habit correction, learning techniques, and simple relaxation are not considered to be devices unless they are also labeled for medical or therapeutic use.

III. Policy:

The Agency will not object to the distribution of tape recordings provided the labeling and the text of the recordings do not contain claims for specific disease conditions or therapeutic use. The intended use of the tape recordings as medical devices can be established from the labeling and statements made in the tapes themselves that the tapes have therapeutic and medical usefulness.

Tape recordings, the labeling and text of which claim that the tapes are effective as a form of hypnotherapy (including self-hypnosis) and are intended for use in the mitigation, treatment or cure of a specific disease or medical condition, will be regarded as misbranded devices when sold for lay use.

Examples of objectionable claims for lay use are listed below:

Acne and skin problems
Birth Control
Control of Allergies
Emotional health
Enuresis
Hair loss
Hearing Loss
High blood pressure
Hyperactive children *or Adults*
Improving vision
Insomnia
Menstrual Control
Migraine headaches
Pain Control
Psychic healing
Wart Removal

IV. Regulatory Action Guidance:

Refer to Compliance Policy Guide *120.500*, Health Fraud - Factors in Considering Regulatory Action. Please Note: The Health Fraud definition includes the "... promotion, advertisement, distribution or sale of articles, intended for human or animal use ...") for guidance. The district should consider submitting a recommendation for misbranding to the *Center for Devices and Radiological Health (CDRH), Office of Compliance* when tapes with such claims are offered for lay use.

V. Specimen Charges:

The appropriate charges are 502(a), in that the labeling is false or misleading because the articles are not effective for such use and 502(f)(1) in that the articles fail to bear adequate directions for use since adequate directions for use cannot be written for use by laymen of the articles for the purposes for which the devices are intended and they are not exempt from the requirements of section 502(f)(1) of the act and 21 CFR 801.109.

For Rx use, district offices should contact the CDRH, Office of Compliance for guidance before submitting a recommendation.

Material between asterisks is new or revised

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