

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000N-1409]

Medical Devices; Revision of the Identification of the Iontophoresis Device; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the proposed rule the agency issued in the **Federal Register** of August 22, 2000 (65 FR 50949) (the August 2000 proposed rule). In that document, FDA proposed to amend the physical medicine devices regulations to remove the class III (premarket approval) iontophoresis device identification. In response to the comments received on the proposed rule, FDA is withdrawing the proposed rule and considering and other courses of action. Elsewhere in this issue of the **Federal Register**, FDA is announcing an opportunity to submit information and comments concerning FDA's intent to initiate a proceeding to reclassify those iontophoresis devices currently in class III into class II (special controls).

DATES: The proposed rule is withdrawn on [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-827-2974.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 23, 1983 (48 FR 53032), FDA issued a final rule classifying the iontophoresis device into class II (performance standards before the Safe Medical Devices Act of 1990 and now special controls) and class III (premarket approval), depending on its intended use. An iontophoresis device is a device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for diagnostic or other uses. If the iontophoresis device is intended for use in the diagnosis of cystic fibrosis or another intended use and the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug, the device is categorized as class II. An iontophoresis device that is intended to introduce ions of soluble salts or other drugs into the body for other purposes is categorized as class III.

In the August 2000 proposed rule, FDA proposed regulations to amend the physical medicine devices regulations to remove the class III (premarket approval) iontophoresis device identification. FDA proposed this action because it believed that there were no preamendments iontophoresis devices marketed for uses other than those described in the class II identification. FDA expected that manufacturers of those devices currently in class III would be able to relabel their devices to meet the class II identification.

II. Withdrawal of the Proposed Rule

FDA received substantial comment in response to the August 2000 proposed rule. Several comments disagreed with FDA's assertion that no class III preamendments iontophoresis devices existed. In response to these comments, FDA is considering other courses of action and is withdrawing the August 2000 proposed rule.

III. Alternative Action

Elsewhere in this issue of the **Federal Register**, FDA is providing interested persons with an opportunity to submit new information concerning the safety and effectiveness of the iontophoresis device. After FDA reviews any information that it receives in response to this notice, the agency will decide

whether it should go forward with a reclassification of those iontophoresis devices currently in class III and whether a panel meeting is necessary before taking any action.

Dated: October 25, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S