December 22, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Comments of members of the Patient, Consumer, and Public Health Coalition on the proposed order on Reclassification of Iontophoresis Devices Intended for Any Other Purposes

Docket No. FDA-2000-N-0158

As members of the Patient, Consumer, and Public Health Coalition, we strongly oppose the down classification of iontophoresis devices intended for any other purposes from Class III to Class II (special controls). This down classification could needlessly expose patients to harm, and would eliminate essential safeguards.

On February 21 of this year, a member of our coalition, the National Research Center for Women & Families (which subsequently changed its name to the National Center for Health Research (NCHR)), testified at the advisory committee meeting of the Orthopedic and Rehabilitation Devices Panel in opposition to down classification of these devices. While this federal register notice states that "FDA is proposing this reclassification on its own initiative based on new information,"[1] we challenge that statement. The FDA has not provided evidence that there is sufficient new information to justify this down classification since the date of the advisory committee meeting, or since the original Class III designation of these devices in 1979.

At the time of the February meeting, several safety issues had previously been reported to the FDA through the Manufacturer and User Facility Device Experience (MAUDE) database for

iontophoresis devices intended for other uses. As stated at the February FDA meeting, NCHR researchers found 40 adverse event reports in MAUDE in the previous five years; it is widely recognized that MAUDE reports represent a small fraction of adverse events. Even so, the 40 reports include 12 burns, including 6 patients with third degree burns. In the Federal Register notice, the FDA identified several other risks to health, including electric shock, insufficient or excessive delivery, interference with other medical devices, adverse tissue reactions, infection, and ear trauma. Device malfunction is a potential cause cited by the FDA for several of these serious risks.

The Federal Register notice states that the FDA seeks to down-classify these devices because "general controls and special controls are sufficient to provide a reasonable assurance of safety and effectiveness."[1] We strongly disagree. Device malfunction has been implicated in several of the identified risks to health, and that won't necessarily be prevented with special controls such as performance testing. Manufacturing inspections prior to marketing would help ensure that these devices are constructed properly and therefore be less likely to cause third degree burns and other injuries. Unfortunately, down classification to Class II will eliminate such inspections, which are only conducted for Class III devices approved through the PMA process.
Another risk mitigation strategy proposed by the FDA is a labeling warning about adverse systemic effects. As clinicians and patients may not see or read the label, this safeguard is not sufficient to protect patients from dangerous doses due to misuse or malfunction of these devices. We do feel a label warning of potential systemic side effects should be directly affixed to these devices, rather than being placed on either a loose informational sheet or on the packaging, as both these can easily be misplaced.

A critical difference between Class III and Class II devices is that for companies making new models of Class II devices will never have to demonstrate safety or effectiveness. They will only have to show that their devices are substantially equivalent to other devices currently or previously on the market. In this situation, it would be possible for a new iontophoresis device to be cleared even if it is substantially equivalent to the worst iontophoresis device previously on the market. Without the more thorough safety data required for Class III devices through the PMA process, we will never have comparative safety research to determine which of these devices are most likely to harm patients. By not requiring proof that a new device is itself safe and effective, FDA is asking patients to take unnecessary risk.

Conclusion

After examining the adverse event reporting, risks associated with these devices, and proposed mitigation strategies, we strongly oppose the down-classification of iontophoresis devices "intended for any other purposes" to Class II. Patients deserve such devices to be tested for safety and effectiveness, as well as inspected to make sure they were manufactured correctly. Retaining Class III status and approving the device through the more rigorous PMA process is the best way to protect patients from preventable injuries from these devices. In addition, we feel that a labeling warning from the FDA about adverse systemic effects should be included by direct attachment to such devices.

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[1] Federal Register Volume 79, Number 183 (Monday, September 22, 2014). Proposed order on Reclassification of Iontophoresis Devices Intended for Any Other Purposes [Docket No. FDA-2000-N-0158].