

November 20, 2000

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Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20862

RE: Docket Number: 00N-1409; Proposed Rule on Physical Medicine Devices;
Revision of the Identification of the Iontophoresis Device

Dear Sir or Madam:

On behalf of patients with cystic fibrosis (CF), the Cystic Fibrosis Foundation (CFF) is concerned about the potential negative impact of the proposed rule to revise the identification of the iontophoresis device for the use of this device to diagnose patients with cystic fibrosis (CF).

The sweat test using the iontophoresis device has been the standard test to diagnose CF for more than 40 years. As a physician who has treated patients with CF for many years, I can assure you that sweat testing is essential for the diagnosis of these patients. Because of this, the CF Foundation routinely site visits all of its accredited centers and, during this visit, it documents that the center is in compliance with the NCCLS guidelines for sweat testing. For more information, we have enclosed a recent memorandum to the CFF Care Centers from September 21, 2000 and the consensus document entitled "Sweat Testing: Sample Collection and Quantitative Analysis; Approved Guideline- Second Edition" from NCCLS (C34-A2, (ISBN 1-56238-407-4)).

We believe that the requirement in the proposed rule for labeling of the pilocarpine for use with the iontophoresis device could inadvertently halt the use of this test for CF diagnostic purposes. Since the makers of this device have no control over the plans of the manufacturers of pilocarpine to obtain labeling, and this device and drug combination is essential for the sweat test to diagnose CF, this rule could undermine the ability of our physicians to properly diagnose CF via an accurate method, which is free from adverse reactions.

It is not clear from the information in the Federal Register (August 22, 2000, Volume 65, Number 163, page 50949) whether or not the proposed rule impacts the use of the iontophoresis device for diagnosis of cystic fibrosis or if it only impacts non-CF uses. In outlining the existing rule, the notice states that "the regulation defines a class II device as a device intended for use in the diagnosis of cystic fibrosis or for other uses, if the labeling of the drug intended for use with the device bears adequate directions for the

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National Office

6931 Arlington Road Bethesda, Maryland 20814

(301) 951-4422 (800) FIGHT CF (800) 344-4823 Fax: (301) 951-6378 Internet: www.cff.org E-mail: info@cff.org

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device's use with that drug.... A class III iontophoresis device is intended for uses other than those specified for the class II device.”

The proposed revision states that FDA is “revoking the class III identification. Any device that is not substantially equivalent to the class II device would be considered a postamendment device that is automatically classified in class III...” This could be interpreted to state that the proposed rule does not affect the classification of the device as a class II device for use in diagnosing patients with CF. Alternatively, it could require that, in order to properly be classified as a class II device, further labeling of the associated drug products for CF diagnostic purposes would be necessary.

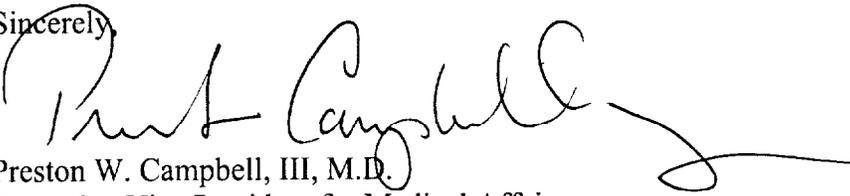
If the proposed rule is intended to impact the use of the device in diagnosing CF, we respectfully request that you revisit this issue. We believe it would be best to continue classifying the iontophoresis device as a Class II device for purposes of CF diagnosis to enable continued use of the device.

The CF Foundation hopes to play a proactive role in proper classification of the iontophoresis device for use in diagnosing CF, because the impact of new regulations on this classification could make it more difficult to identify manufacturers to make this device for CF diagnostic testing. If the bar is raised further, the use of this device in diagnosing CF with the sweat test may no longer be feasible.

Therefore, we respectfully request clarification on the impact of this proposed rule on the use of iontophoresis devices for diagnosing CF with the sweat test. We want to work with you to identify the best means to appropriately classify and label this device to ensure the use of this device for diagnosing patients with CF. It would be a tremendous disservice to patients and families if the sweat test were no longer available.

Please contact us at 301-951-4422 to identify ways in which we can work together to address this issue.

Sincerely,



Preston W. Campbell, III, M.D.
Executive Vice President for Medical Affairs