Koenig, Michael

From: Koenig, Michael

Sent: Thursday, October 23, 2003 3:56 PM

8542 '03 NOV 20 19:38

To: 'jo-annejubinville@hill-top.com'

Subject: Telephone conversation of 10/15/03: pedal effectiveness testing

Dear Ms. Jubinville,

Thank you for your call the week before last. You had several questions regarding testing the effectiveness of antiperspirant products on the feet (rather than on the axillae). In response to my request, you sent me a FAX of a pilot protocol designed to evaluate the pedal effectiveness of antiperspirants. The protocol was prepared by your company.

With respect to testing pedal effectiveness, to date FDA has not received sufficient data to classify claims for the use of antiperspirant products on hands and feet as Category I (generally recognized as safe and effective). The advisory review panel for OTC antiperspirant products (the Panel) declared that claims of "antiperspirancy on the hands and feet" were Category III (insufficient data to determine safety and efficacy) (43 FR 46694 at 46728). The Panel indicated that tests conducted to support reclassification of pedal effectiveness claims to Category I status should do the following: (1) include a user perception test and (2) demonstrate a 20% reduction in sweat production in an objectively measured test (43 FR 46694 at 46728).

Test data to support claims of antiperspirant effectiveness on feet was provided to FDA during the comment period following publication of the tentative final monograph for OTC antiperspirant products on August 20, 1982 (47 FR 36492). Data was submitted requesting Category I status for 25% aluminum chlorohydrate solution used to control foot perspiration (68 FR 34273 at 34279). FDA found that the user perception of sweat reduction in these studies was not statistically significant. Numark Laboratories submitted a protocol for testing claims of effectiveness in reducing foot perspiration. FDA found the protocol to be acceptable, but Numark Laboratories did not submit any test data (68 FR 34273 at 34279).

The final monograph for OTC antiperspirant products published on June 9, 2003, does not include claims of pedal antiperspirant efficacy (68 FR 34273). In addition, the testing guidelines released with the final monograph do not include procedures for testing any parts of the body other than axillae. You are welcome, at any time, to submit data to support claims for antiperspirant effectiveness on feet. Should you wish to do so, please submit all documentation to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The documentation should be filed in Docket No. 78N-0064. All of the referenced rulemakings published in the *Federal Register* may be viewed on the "Industry Information" link on the webpage for the Division of OTC Drug Products: http://www.fda.gov/cder/Offices/OTC/default.htm.

Sincerely,

Michael L. Koenig

Michael L. Koenig, Ph.D.
DOTCDP CDER FDA
5600 Fishers Lane, HFD-560
Rockville, MD 20857
301-827-2222

78N-0064

CSI / ANS

CONVERSATION RECORD

DATE: October 15, 2003	TIME: 9:35 AM
CENTER REPRESENTATIVE(S): Michael Koenig	
SPONSOR REPRESENTATIVE(S): Jo-Anne Jubinville	
SPONSOR TELEPHONE NUMBER: 1-480-949-7766	
SPONSOR NAME: Hill Top Research, Inc.	
SUBJECT: Antiperspirant effectiveness testing - feet	

DISCUSSION

Ms. Jubinville called to ask if we had an answer for her Sept. 9 question regarding claims of enhanced duration. I told her that we had prepared a formal response to her question following discussion with others in the division - that the two tests should be made following a single application of antiperspirant. She then asked about studies of pedal (foot) efficacy based on an FDA protocol(?) sent by Hill Top to one of its clients. I asked that she FAX me a copy of the protocol, so that we could review it. She raised several issues: 1) Gender-specific testing. I told her that we are formulating a response to this question (asked earlier by Ms. Oddo) but that the consensus seemed to be that gender-specific products should be tested in the appropriate gender. 2) No antiperspirant under arms during 21 day conditioning period (for foot tests)? 3) Does the collection have to be 60 min. or can it be 2 x 30 min.? 4) Can minimal sweat collection for feet be 100 mg or does it have to be 150 mg? I told Ms. Jubinville that I would check into these things and get back to her as quickly as possible.

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: November 14, 2003

FROM: Michael L. Koenig, IDS, DOTCDP

SUBJECT: Material for Docket No. 78N-0064

TO: Division of Dockets Management (HFA-305)

☒ The two attached documents should be placed on public display as two separate items under the above referenced Docket No.

☒ Each item should be cross-referenced to the Guidelines for Effectiveness Testing of OTC Antiperspirant Drug Products (GDL2), and the two items should be cross-referenced with each other.

Michael L. Koenig, Ph.D.
301-827-2283

Attachments