Koenig, Michael

From: Koenig, Michael
Sent: Thursday, October 23, 2003 3:57 PM
To: 'jo-annejubinville@hill-top.com'
Subject: Antiperspirant Testing Guidelines, Docket NO. 78N-0064

Dear Ms. Jubinville:

This is in response to the telephone conversation you had with Dr. Matthew Holman and myself on September 10, 2003. During that conversation, you requested clarification of the Guidelines for Effectiveness Testing for OTC Antiperspirant Drug Products (testing guidelines) released on June 9, 2003, along with the Final Rule on Antiperspirant Drug Products for Over-the-Counter Human Use (68 FR 34273 at 34292). More specifically, you requested confirmation that the testing guidelines permit some "flexibility" in the testing procedure for making an enhanced duration claim (Sections 4(a)(4) and 7(a)): "the test should be conducted at least two times during the period of the claim, such as 1 hour and 24 hours after the last daily treatment for 24 hour claims."

In the notice of proposed rulemaking (NPR) published on October 10, 1978 (43 FR 46694 at 46728), the Advisory Review Panel on OTC Antiperspirant Drug Products (the Panel) concluded that there was insufficient data to substantiate antiperspirant claims of enhanced duration of effect. The Panel specified that a modification of the protocol described for determining antiperspirant effectiveness would be required to validate a claim of enhanced duration. Specifically, the Panel determined that the protocol should include sweat collections at "at least two times...which span the period of the claim."

The testing guidelines were proposed initially in the Tentative Final Monograph (TFM) on August 20, 1982 (47 FR 36492 at 36504). Subsequently, FDA published the Final Monograph (FM) on June 9, 2003 (68 FR 34273) with revised testing guidelines. However FDA did not change the enhanced duration testing protocol in the revised testing guidelines. As a result, the enhanced duration testing protocol in the current testing guidelines is based on protocols described in the NPR (43 FR 46694 at 46713-46718) as well as protocols submitted to FDA between publication of the NPR and the TFM. Nearly all of the submitted protocols included multiple sweat collections during the period of the claim following a single application of antiperspirant. Because these protocols are the basis for the testing guidelines, FDA intends that the sweat collections made to support a claim for enhanced duration should be made after a single application of antiperspirant.

FDA encourages you or any other interested party to submit alternative testing protocols and supporting data for enhanced duration claims to the Division of Dockets Management in accordance with 21 CFR 10.30. Please ask that the information be filed in Docket No. 78N-0064. I hope this information clarifies the testing guidelines for OTC antiperspirant products with respect to the procedure to be followed in substantiating claims of enhanced duration.

Sincerely,
Michael Koenig

Michael L. Koenig, Ph.D.
DOTCDP CDER FDA
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301-827-2222

78N-0064 C 50/ANS

10/23/2003

CONVERSATION RECORD

DATE: September 10, 2003	TIME:
CENTER REPRESENTATIVE(S): Matthew Holman; Michael Koenig	
SPONSOR REPRESENTATIVE(S): JoAnne Jubinville	
SPONSOR TELEPHONE NUMBER: 1-480-949-7766	
SPONSOR NAME: Hill Top Research, Inc.	
SUBJECT: Enhanced duration effectiveness testing	

DISCUSSION

A pads are thrown away following 40 min pre-treatment. Hill Top usually tests 32 subjects at a time, but sometimes tests as many as 40. Turn on hotroom 24 hours before testing. Subjects do everything in the same order. Time first and last subject -> last subject is 19-20 minutes. Two day test -> collect baseline on day 1 & do testing on day 2. We told her that her SOP was acceptable. She also wanted to know whether 2 test times required for enhanced duration testing must occur after a single application or whether each test time could occur after one of two applications. We told her that we would find out the answer, and let her know by the end of the week.

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