From: Koenig, Michael [mailto:KoenigM@cder.fda.gov]
Sent: Thursday, October 23, 2003 3:57 PM
To: 'dmcenroe@Sidley.com'
Subject: Antiperspirant Testing Guidelines, Docket No. 78N-0064

Dear Ms. McEnroe:

This is in response to your letter sent to FDA via e-mail on September 10, 2003. Your letter requests 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 request 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." You state that there are two interpretations of this statement:

- two sweat collections following a single application of antiperspirant
- one sweat collection 1 hour after application of antiperspirant followed by another antiperspirant application on the next day and sweat collection 24 hours after this second application.

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, last 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 be made after a single, last application of antiperspirant. Your second interpretation of the testing guidelines - each of two sweat collections being made after a different application of antiperspirant - is not supported by the protocols reviewed by FDA.

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.
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301-827-2222

Rachanow, Gerald M

From: McEnroe, Diane C. [dmcenroe@Sidley.com]
Sent: Wednesday, September 10, 2003 11:04 AM
To: 'rachanow@cder.fda.gov'
Subject: Antiperspirant Testing

Hi, at your suggestion, I am putting our question in writing:

In terms of testing for an enhanced duration claim -- please confirm whether there is flexibility in terms of when one can do the sweat collections. We read the guidelines as suggesting that there is some flexibility and that one could, for example, make one collection 1 hour after the 3rd application and the second 24 hours after the 4th application. The guidance says "at least two times during the period of the claim such as" and provides an example.

However, we have been told that some interpret that phrase to mean that the 2 sweat collections must be after the last application, b/c that is the example provided ("such as 1 hour and 24 hours after the last daily treatment for 24 hours claims.")

Please let us know if you agree that there is some flexibility as to when the sweat collections can occur. As I stated, the client hoped to start a test on Monday, so we would appreciate your response as soon as possible.

Thanks again.

Diane C. McEnroe
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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