Koenig, Michael

From: Koenig, Michael
Sent: Thursday, October 23, 2003 3:56 PM
To: 'loddo@hill-top.com'
Subject: AP monograph question - gender of subjects

Dear Ms. Oddo:

This message is in response to your e-mail message (to Mr. Gerald Rachanow) dated October 2, 2003. In that message, you questioned whether antiperspirant products targeted to a specific gender should be tested in a gender-specific population.

If you wish to target an antiperspirant product to a gender-specific population, the antiperspirant product should be tested in a panel made up of subjects of that gender. The advisory review panel on OTC antiperspirant drug products (the Panel) found that, because of *sex differences*, sweat rate, and other factors, "unidentified antiperspirant materials or specific active ingredients cannot be generalized to apply to all other antiperspirant materials" (emphasis added) (43 FR 46694 at 46716). Thus, the Panel concluded that antiperspirant test results for one gender are not necessarily valid for the other gender. Further, in defining the basis for making a claim of effectiveness, FDA has stated that a drug must provide clinically significant relief of the type claimed "in a significant proportion of the *target* population" (emphasis added) (21 CFR 330.10(a)(4)(ii)).

In your message, you also stated that, historically, your company has "used a lot of female panels." As indicated in the discussion above, data collected from these panels would support effectiveness claims for women but could not be extrapolated to make effectiveness claims for men. Therefore, testing of antiperspirant products to be used by both genders should be tested in panels comprised of approximately equal numbers of men and women.

I hope this information is helpful.

Sincerely,

Michael Koenig

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

78N-0064

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10/23/2003

Rachanow, Gerald M

From: Linda Oddo [LODDO@hill-top.com]

Sent: Thursday, October 02, 2003 4:25 PM

To: rachanow@cder.fda.gov

Subject: AP monograph question

Gerald,

Hill Top Research has received several questions regarding the gender of the population selected for studies. The question asked concerns running a monograph study with a product targeted to a specific gender. Does the qualifying study need to be conducted with a gender specific population? Since we have not seen differences in efficacy between male and female groups, and female panels are more accessible we have historically used a lot of female panels, even occasionally to test male oriented products. So that we can accurately direct our clients, I welcome your advice.

Linda Oddo

Technical Director

Hill Top Research, Inc.

480-949-7766

loddo@hill-top.com

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