

NUMARK

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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Re: **Docket No. 1978N-0064**
Antiperspirant Drug Products for Over-the-Counter Human Use; Final
Monograph; Partial Stay; Reopening of the Administrative Record
Response to FDA Request for Comments (Federal Register: October 15, 2004)

Dear Sirs:

Reference is made to the Federal Register Notice of October 15, 2004 regarding the reopening of the administrative record for the Over-the-Counter antiperspirant drug products and the request for comments related to the claims of enhanced antiperspirant duration. Further reference is made to the Numark Laboratories' submission of April 12, 2005 which included preliminary information in response to the FDA request for comments, and communicated the unexpected difficulties encountered in conducting the study with Numark's Certain Dri[®] (aluminum chloride 12%) antiperspirant product. This submission is an amendment of the original April 12, 2005 communication and contains the completed clinical study report supporting enhanced duration of effectiveness claims for the Certain Dri[®] antiperspirant product.

The study entitled, "Clinical Efficacy Evaluation of an Antiperspirant Formulation After Four Daily Applications and Perspiration Collections at Baseline, Day Four, Day Six and Day Seven to Support Claims for Enhanced Duration of Effect (Protocol No.: NPHH-002)", incorporated the following conditions:

- The study was performed in accordance with the testing guidelines as set forth in "Guidelines for Effectiveness Testing of Over-The-Counter Antiperspirant Drug Products", as referenced in 21 CFR 350.60;
- The test material being evaluated is formulated with an active ingredient and strength (aluminum chloride 12%) listed in 21 CFR 350.10;
- The study was a randomized, controlled clinical trial;
- The subjects enrolled into the study reflect consumer demographics, with comparable numbers of men and women.

78N-0064

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Mailing Address: P.O. Box 6321, Edison, New Jersey 08818

Thirty-two subjects were enrolled into the study; all subjects completed the study. There was one report of moderate itching and burning in one subject on Day 2 at the application site; the event resolved and the subject completed the study.

The results of the study demonstrate that on Days 4, 6, and 7, the amount of perspiration at the treated axillae was significantly less than the amount of perspiration at the untreated control axillae. The mean percent reduction in perspiration at the Certain Dri[®]-treated axillae was significantly less than the amount of perspiration at the untreated axillae as presented in the following table. The Wilcoxon Signed Rank Test was used to test the null hypothesis that the median reduction in perspiration was less than or equal to 30% at Days 4, 6, and 7. The null hypothesis was rejected in each case and the corresponding p-value is presented.

Day	Percent Reduction	p-Value
4	42%	< 0.05
6	38%	<0.001
7	43%	< 0.025

If there are any questions or comments associated with this submission, please contact Wayne Brozynski at (732) 417-1870.

Sincerely,



Wayne V. Brozynski
Vice President, Operations



EST. 1975

Consumer Product Testing Co.

FINAL REPORT

CLIENT: Numark Laboratories, Inc.
164 Northfield Avenue
Edison, NJ 08818-6321

ATTENTION: Wayne B. Brozynski
Vice President, Operations

TEST: Clinical Efficacy Evaluation of an Antiperspirant
Formulation After Four Daily Applications and Perspiration
Collections at Baseline, Day Four, Day Six and Day Seven to
Support Claims for Enhanced Duration of Effect.
Protocol No.: NPHH-002

TEST MATERIAL: Certain Dri

**EXPERIMENT
REFERENCE NUMBER:** C05-0409.01



Michael Traudt, Ph.D.
Senior Director, Clinical Evaluations



Joy Frank, R.N.
Executive Vice President, Clinical Evaluations

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Consumer Product Testing Co.

QUALITY ASSURANCE UNIT STATEMENT

Study No.: C05-0409.01

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of clinical laboratory studies. These studies have been performed with adherence to the applicable ICH Guideline E6 for Good Clinical Practice and requirements provided for in 21 CFR parts 50 and 56 and in accordance to standard operating procedures and applicable protocols. The QAU maintains copies of study protocols and standard operating procedures and has inspected this study. All data pertinent to this study will be stored in the Consumer Product Testing Company archive, unless specified otherwise, in writing by the Sponsor.

Quality Assurance personnel involved:


Quality Assurance


Date

The representative signature of the Quality Assurance Unit signifies that this study has been performed in accordance with standard operating procedures and study protocol as well as government regulations regarding such procedures and protocols.

Objective: To determine the antiperspirant effectiveness of a test material forty-eight (48) and seventy-two (72) hours after four (4) consecutive applications, exceeding the minimum requirements of the FDA recommended procedure outlined in the Antiperspirant Drug Products for Over-the-Counter Human Use; Final Monograph of Monday, June 9, 2003 (effective date: December 9, 2004).

Participants: Thirty-two (32) male and female subjects, ranging in age from 30 to 65 years, were selected and qualified for this study. All thirty-two (32) subjects completed the study.

Inclusion Criteria:

- a. Approximately thirty (30) male and/or female volunteers, in general good health, between the ages of 18 and 65 years.
- b. History of stable and normal blood pressure (Systolic range = 100 – 160 mm Hg; Diastolic range = 60 – 90 mm Hg) and must not be taking any anti-hypertensive medications.
- c. Must produce at least 100 mg of perspiration under each axilla during each of two (2) twenty (20) minute baseline collection periods.
- d. Females must not be pregnant, lactating, or planning on becoming pregnant during the course of the study.
- e. Absence of any axillary irritation.
- f. Completion of a Medical History Form and the understanding and signing of an Informed Consent Form.
- g. In compliance with all pre-study requirements and considered capable of following directions.

Exclusion Criteria:

- a. Known sensitivity or intolerance to antiperspirants or deodorants (Medical History, Consent).
- b. Frequent user of antihistamines or anticholinergics (Medical History, Consent).
- c. History of heart disease, asthma, diabetes, kidney disease or mastectomy (Medical History, Consent).
- d. Any axillary abnormalities that would preclude participation (Consent, Visual Examination).

Test Material: Certain Dri

Hot Room Conditions: Temperature: 100⁰ F (\pm 2⁰)
Humidity: 30 - 40%

Test Sites: Right and left axillae.

Study Schedule:	<u>Panel #</u>	<u>Initiation Date</u>	<u>Completion Date</u>
	20050223	June 6, 2005	June 12, 2005

Test Procedure:

This study was performed to satisfy the requirements as set forth in "Guidelines for Effectiveness Testing of Over-The-Counter Antiperspirant Drug Products". These guidelines are in accordance with the Final Monograph (final rule) for Over-The-Counter Antiperspirant Drug Products, published in the Federal Register on June 9, 2003 (68 FR 34273).

Pre-test Qualification:

- a. Thirty-two (32) subjects were required to abstain from the use of antiperspirants for seventeen (17) days prior to the start of the study. During this time, deodorants (Original Right Guard Sport Deodorant®) and soaps (Camay® Classic) supplied by Consumer Product Testing Company were to be used exclusively. Use of all other deodorants, antiperspirants and soaps was prohibited.
- b. Subjects did not shave their axillae at least 48 hours prior to the start of the study and through the completion of the study.

Control Collection:

On Day One, a qualifying perspiration collection was conducted, utilizing the following sequence:

- a. Prior to entering the controlled-temperature room, each subject had their blood pressure taken and acclimated for approximately fifteen (15) minutes in an area that was approximately 70°F. Any subject not meeting the blood pressure requirements, (Systolic range = 100 – 160 mm Hg; Diastolic range = 60 – 90 mm Hg), was to be disqualified at this time.
- b. The controlled-temperature room was maintained at a temperature of 100⁰ F (± 2⁰) with a relative humidity of 30 - 40 % (percent) by the Johnson Control Medisys System with a DX-100 controller. Entry of all subjects into the controlled-temperature room was conducted in unison.
- c. Each subject had an envelope bearing his or her name and qualification number. Each envelope contained:

Two (2) loose, unweighed, Webril pads and:

**Test Procedure
(continued):***Control Collection (Continued):*

Four (4) plastic sandwich bags containing pre-weighed Webril pads, each labeled to match the subject's number and either the word "RIGHT" A, "LEFT" A, "RIGHT" B or "LEFT" B.

Each "RIGHT" bag contained a Webril pad identified by red dots in each of two corners.

Each "LEFT" bag contained a Webril pad without identifying marks.

The combined plastic bags and pads were weighed prior to the subsequent perspiration collection.

- d. Following instructions from study personnel, all subjects placed the unweighed pads in the axillary areas for a forty (40) minute warm-up period. During this time, subjects were allowed to move freely while seated in their chairs.
- e. At the end of the forty (40) minute warm-up period, a clinical technician removed and discarded the unweighed pads and placed the pre-weighed "RIGHT" A and "LEFT" A pads into the appropriate axillary vault. The subjects sat erect with both feet on the floor and arms at their sides. After the twenty (20) minute collection period, the clinical technician removed the "A" collection pads and placed them in the appropriate plastic bags. The process was then repeated with the pre-weighed "RIGHT" B and "LEFT" B pads. After completion of collection "B", both bags were then placed into the appropriate envelope and carried out of the controlled-temperature room by the subjects and placed in a designated location.
- f. Upon exiting the controlled-temperature room, subjects were dismissed.
- g. Post-weights of the pads were then calculated to determine the eligibility of each subject to meet the minimum required perspiration output (100 mg) in both axillae. Subjects not meeting inclusion criteria for perspiration production were excluded from the study phase at this time.

**Test Procedure
(continued):**Test Phase:

- a. Subjects who met all the qualifying requirements had a:
 1. Supervised washing of the axillary vault utilizing 4"x4" gauze pads placed in a solution of mild soap (Camay® Classic) and tepid water. Subjects used one pad for each axilla, then discarded and moved to the next station and rinsed each axilla with plain tepid water. A different rinse pad was used for each axilla. A paper towel was then placed in each axilla to blot the area dry. There was no rubbing. The paper towels were left in place until application of the test material.
 2. Randomized test material/untreated control application was made to both axillae. Half of the subjects received the test material application in the right axillae and the left axillae remained untreated. The remaining subjects had the reverse test material/untreated control allocation.
 3. One (1) hour wait post-application, then the subjects were dismissed.
- b. On Days Two and Three, only application of the test material/untreated control were conducted, utilizing the following sequence:

Acclimation, as previously described.

Supervised axillary wash, as described previously.

Test material/untreated control application, as described previously.

One (1) hour wait post-application, then subject dismissal.
- c. On Day Four, test material/untreated control application and perspiration collection were conducted, utilizing the following sequence:

Acclimation, as described previously.

Supervised axillary wash, as described previously.

Test material/untreated control application, as described previously.

**Test Procedure
(continued):**

Test Phase:

One (1) hour wait post-application.

Subjects entered the controlled-temperature room for a forty (40) minute warm-up and two (2) subsequent twenty (20) minute perspiration collection periods, as described previously.

Dismissal from the controlled-temperature room.

- d. On Days Six (6) and Seven (7), perspiration collection was performed, utilizing the following sequence:

Acclimation, as described previously.

Subjects entered the controlled-temperature room for a forty (40) minute warm-up and two (2) subsequent twenty (20) minute perspiration collection periods, as described previously.

Dismissal from the controlled-temperature room.

- e. The study was completed on Day Seven (7).

Product Application:

The test material/untreated control was applied according to the randomization schedule (Table 2) by a clinical technician to ensure complete coverage of the axillary vault.

The test material was applied directly from the container by the study coordinator to the right or left axilla (randomized). The container was weighed prior to and post-application to ensure that approximately 400 mg of the material had been applied. The opposite axilla remained untreated (control site). An average amount of 0.470 g of test material, Certain Dri, was applied.

Axillary examinations for adverse effects were conducted by qualified Consumer Product Testing Company personnel prior to each test material application and prior to the final collection using the following evaluation key:

**Test Procedure
(continued):**Product Application (Continued):**Evaluation Key:**

0	=	None
+	=	Barely Perceptible
1	=	Mild
2	=	Moderate
3	=	Marked
4	=	Severe

Adverse Events:

Subject #26- Moderate itching and burning sensations experienced reported on Day 2 only, five minutes after product application to the left axillae. Sensations lasted approximately 12 minutes. Product application was not interrupted at any time. No irritation or abnormalities were noted

Protocol Deviation:

The protocol indicated that the test product would be compared to a placebo control product. However, the Sponsor elected to test the product against untreated axillae (memo on file).

Statistics:

Antiperspirant data were submitted to John C. Thornton, Ph.D. for analyses. (See attached Antiperspirant Evaluation statistical report Appendix I).

Descriptive statistics were calculated for the amounts of test product used and the amounts of perspiration collected. Descriptive statistics for the amount of perspiration were calculated for treated and untreated control axillae at each evaluation. The percent reduction in perspiration at the treated axillae was calculated for each subject as:

$$\text{Percent Reduction} = 100 * \frac{((\text{UntreatedControlAmount}) - (\text{TreatedAmount}))}{\text{UntreatedControlAmount}}$$

Descriptive statistics were calculated for the percent reduction in perspiration.

The efficacy of the antiperspirant was determined as described in the "Guidelines for Effectiveness Testing of OTC Antiperspirant Drug Products" using the Wilcoxon Signed Rank Test.

For Antiperspirant Efficacy Claims:

The percent reduction in perspiration was calculated for each subject. The Wilcoxon Signed Rank Test was used to test the null hypothesis that the median reduction in perspiration was equal to or greater than twenty percent.

Statistics:
(continued)*For Extended Duration of Effect Claims:*

Required a minimum of one (1) application and two (2) controlled collections post-application (i.e. one (1) hour post-application and then forty-eight (48) and seventy-two (72) hours post-application for seventy-two (72) hour effectiveness claims, respectively).

The percent reduction in perspiration was calculated for each subject. The Wilcoxon Signed Rank Test was used to test the null hypothesis that the median reduction in perspiration was equal to or greater than thirty percent.

The level of significance for all statistical tests was $P < 0.05$. All statistical calculations were performed using the STATA statistical software package for personal computers.

Results:

Perspiration collection amounts and randomizations are presented in Table 1.

Individual product usage weights are presented in Table 2.

Subject demographics are presented in Table 3.

Analyses of data for all qualified subjects are presented in the appended statistical report.

Summary:

Under the test conditions described, on Days Four (4), Six (6) and Seven (7), the amount of perspiration at the treated axillae was significantly less than the amount of perspiration at the untreated control axillae. The mean percent reduction in perspiration using the test material, Certain Dri, on Day Four (4) was 42%, on Day Six (6) 38% and Day Seven (7) 43%.

The Wilcoxon Signed Rank Test was used to test the null hypothesis that the median reduction in perspiration was less than or equal to thirty percent at Days Four (4), Six (6) and Seven (7). The null hypothesis was rejected at Day Four (4) ($p < 0.05$), at Day Six (6) ($p < 0.001$) and at Day Seven (7) ($p < 0.025$); therefore, the results are consistent with a greater than thirty percent reduction in perspiration on Days Four (4), Six (6) and Seven (7) using the test product. The test product does qualify as an extra effective antiperspirant with enhanced duration.

See the attached Antiperspirant Statistical Report for details.

Table 1
Panel #20050223

Perspiration Collection (g)
Day 1 (Pre-Treatment)

Subject Number	Collection A				Collection B			
	Left		Right		Left		Right	
	Rando	Weight	Rando	Weight	Rando	Weight	Rando	Weight
1	A	0.307	B	0.745	A	0.400	B	0.514
2	B	1.233	A	0.829	B	0.672	A	0.323
3	A	0.153	B	0.111	A	0.227	B	0.169
4	B	3.357	A	0.505	B	0.361	A	7.796
5	B	0.411	A	0.137	B	0.216	A	0.237
6	A	0.833	B	0.898	A	0.956	B	1.140
7	B	0.916	A	0.481	B	0.366	A	4.264
8	A	0.286	B	0.290	A	0.400	B	0.185
9	A	0.291	B	0.220	A	0.330	B	0.270
10	A	0.290	B	0.266	A	0.174	B	0.232
11	B	0.203	A	0.114	B	0.133	A	0.143
12	B	0.607	A	0.437	B	0.503	A	0.427
13	A	0.576	B	0.740	A	1.152	B	0.841
14	A	0.694	B	1.083	A	0.329	B	0.604
15	A	0.388	B	0.340	A	0.410	B	0.388
16	B	0.860	A	0.738	B	0.430	A	0.686
17	A	0.166	B	0.263	A	0.692	B	0.925
18	A	0.739	B	0.707	A	0.846	B	0.647
19	A	1.040	B	1.315	A	0.996	B	1.313
20	B	0.125	A	0.178	B	0.269	A	0.375
21	B	0.371	A	0.494	B	0.486	A	0.674
22	A	0.142	B	0.182	A	0.159	B	0.177
23	B	0.302	A	0.276	B	0.192	A	0.242
24	B	0.116	A	0.158	B	0.154	A	0.329
25	A	0.450	B	0.675	A	0.614	B	0.738
26	B	0.436	A	0.320	B	0.514	A	0.709
27	B	0.424	A	0.573	B	0.420	A	0.549
28	B	0.354	A	0.304	B	0.428	A	0.415
29	A	0.598	B	0.707	A	0.728	B	1.018
30	B	0.627	A	0.602	B	0.480	A	0.562
31	A	0.981	B	1.124	A	1.089	B	1.125
32	A	0.105	B	0.100	A	0.152	B	0.131

A = Certain Dri

B = Untreated

Table 1
(continued)
Panel #20050223

Perspiration Collection (g)
Day 4 (1 Hour Post-Treatment)

Subject Number	Collection A				Collection B			
	Left		Right		Left		Right	
	Rando	Weight	Rando	Weight	Rando	Weight	Rando	Weight
1	A	0.035	B	0.176	A	0.031	B	0.510
2	B	0.675	A	0.138	B	0.728	A	0.272
3	A	0.133	B	0.201	A	0.173	B	0.197
4	B	0.693	A	0.158	B	0.260	A	0.100
5	B	0.102	A	0.030	B	0.285	A	0.080
6	A	0.164	B	0.496	A	0.280	B	0.998
7	B	0.545	A	0.299	B	0.689	A	0.340
8	A	0.049	B	0.165	A	0.064	B	0.266
9	A	0.053	B	0.093	A	0.051	B	0.157
10	A	0.071	B	0.119	A	0.119	B	0.176
11	B	0.119	A	0.088	B	0.134	A	0.066
12	B	0.359	A	0.435	B	0.178	A	0.192
13	A	0.180	B	0.727	A	0.253	B	0.737
14	A	0.201	B	1.274	A	0.334	B	2.106
15	A	0.129	B	0.190	A	0.193	B	0.275
16	B	0.555	A	0.099	B	0.424	A	0.106
17	A	0.192	B	0.278	A	0.448	B	0.670
18	A	1.549	B	1.427	A	1.494	B	1.264
19	A	0.824	B	0.968	A	0.772	B	1.068
20	B	0.144	A	0.092	B	0.182	A	0.084
21	B	0.096	A	0.194	B	0.319	A	0.288
22	A	0.052	B	0.076	A	0.081	B	0.160
23	B	0.219	A	0.095	B	0.232	A	0.098
24	B	0.024	A	0.046	B	0.188	A	0.138
25	A	0.443	B	0.379	A	0.258	B	0.322
26	B	0.163	A	0.200	B	0.203	A	0.207
27	B	0.284	A	0.080	B	0.419	A	0.119
28	B	0.248	A	0.129	B	0.469	A	0.251
29	A	0.148	B	0.810	A	0.232	B	1.428
30	B	0.801	A	0.794	B	0.691	A	0.883
31	A	0.294	B	0.663	A	0.388	B	1.106
32	A	0.039	B	0.034	A	0.066	B	0.077

A = Certain Dri

B = Untreated

Table 1
(continued)
Panel #20050223

Perspiration Collection (g)
Day 6 (48 Hours Post-Treatment)

Subject Number	Collection A				Collection B			
	Left		Right		Left		Right	
	Rando	Weight	Rando	Weight	Rando	Weight	Rando	Weight
1	A	0.049	B	0.234	A	0.039	B	0.293
2	B	1.242	A	0.390	B	1.804	A	0.513
3	A	0.139	B	0.103	A	0.311	B	0.434
4	B	0.703	A	0.133	B	0.670	A	0.164
5	B	0.180	A	0.069	B	0.183	A	0.069
6	A	0.264	B	0.726	A	0.419	B	0.919
7	B	0.124	A	0.253	B	0.049	A	0.138
8	A	0.043	B	0.153	A	0.040	B	0.234
9	A	0.049	B	0.123	A	0.039	B	0.200
10	A	0.113	B	0.234	A	0.218	B	0.297
11	B	0.140	A	0.077	B	0.165	A	0.079
12	B	0.328	A	0.210	B	0.233	A	0.177
13	A	0.267	B	0.828	A	0.639	B	1.789
14	A	0.107	B	0.503	A	0.167	B	0.856
15	A	0.195	B	0.269	A	0.188	B	0.428
16	B	0.339	A	0.065	B	0.707	A	0.150
17	A	0.536	B	0.787	A	0.532	B	0.517
18	A	1.325	B	0.990	A	1.166	B	0.953
19	A	1.133	B	2.200	A	1.364	B	2.527
20	B	0.103	A	0.058	B	0.098	A	0.083
21	B	0.597	A	0.519	B	0.621	A	0.616
22	A	0.073	B	0.135	A	0.118	B	0.360
23	B	0.174	A	0.139	B	0.176	A	0.108
24	B	0.182	A	0.024	B	0.236	A	0.163
25	A	0.089	B	0.117	A	0.325	B	0.312
26	B	0.283	A	0.445	B	0.388	A	0.517
27	B	0.407	A	0.123	B	0.464	A	0.134
28	B	0.414	A	0.213	B	0.549	A	0.316
29	A	0.170	B	0.677	A	0.785	B	2.325
30	B	0.282	A	0.243	B	0.324	A	0.353
31	A	0.540	B	1.193	A	0.590	B	1.221
32	A	0.117	B	0.103	A	0.131	B	0.186

A = Certain Dri

B = Untreated

Table 1
(continued)
Panel #20050223

Perspiration Collection (g)
Day 7 (72 Hours Post-Treatment)

Subject Number	Collection A				Collection B			
	Left		Right		Left		Right	
	Rando	Weight	Rando	Weight	Rando	Weight	Rando	Weight
1	A	0.033	B	0.195	A	0.037	B	0.291
2	B	0.743	A	0.240	B	1.479	A	0.668
3	A	0.110	B	0.406	A	0.129	B	0.523
4	B	0.215	A	0.107	B	0.904	A	0.286
5	B	0.293	A	0.099	B	0.294	A	0.115
6	A	0.137	B	0.212	A	0.181	B	0.293
7	B	0.160	A	0.097	B	0.299	A	0.111
8	A	0.045	B	0.265	A	0.048	B	0.243
9	A	0.036	B	0.219	A	0.081	B	0.281
10	A	0.104	B	0.138	A	0.171	B	0.275
11	B	0.175	A	0.083	B	0.179	A	0.146
12	B	0.224	A	0.161	B	0.101	A	0.108
13	A	0.297	B	0.670	A	0.436	B	1.574
14	A	0.106	B	0.689	A	0.208	B	0.739
15	A	0.274	B	0.402	A	0.184	B	0.347
16	B	0.395	A	0.082	B	0.442	A	0.069
17	A	0.381	B	0.602	A	0.201	B	0.234
18	A	1.031	B	1.112	A	1.880	B	1.763
19	A	0.359	B	0.384	A	0.547	B	0.961
20	B	0.065	A	0.043	B	0.156	A	0.105
21	B	0.561	A	0.714	B	0.519	A	0.572
22	A	0.028	B	0.171	A	0.060	B	0.211
23	B	0.215	A	0.098	B	0.176	A	0.110
24	B	0.082	A	0.168	B	0.689	A	0.683
25	A	0.206	B	0.440	A	0.425	B	0.405
26	B	0.179	A	0.277	B	0.242	A	0.357
27	B	0.278	A	0.160	B	0.438	A	0.212
28	B	0.513	A	0.115	B	0.540	A	0.380
29	A	0.083	B	0.223	A	0.262	B	0.876
30	B	0.625	A	0.457	B	0.424	A	0.490
31	A	0.143	B	0.578	A	0.476	B	1.258
32	A	0.116	B	0.138	A	0.194	B	0.217

A = Certain Dri

B = Untreated

Table 2
Individual Product Usage (g)

Panel #20050223

Subject No.	Axilla Applied	Application 1	Application 2	Application 3	Application 4
1	Left	0.408	0.462	0.403	0.451
2	Right	0.460	0.417	0.458	0.695
3	Left	0.509	0.422	0.582	0.493
4	Right	0.413	0.453	0.426	0.397
5	Right	0.424	0.427	0.418	0.438
6	Left	0.445	0.427	0.523	0.550
7	Right	0.749	0.448	0.488	0.449
8	Left	0.628	0.517	0.568	0.411
9	Left	0.423	0.551	0.413	0.482
10	Left	0.544	0.412	0.461	0.510
11	Right	0.455	0.440	0.402	0.499
12	Right	0.486	0.389	0.395	0.503
13	Left	0.407	0.415	0.479	0.593
14	Left	0.425	0.409	0.581	0.774
15	Left	0.419	0.452	0.435	0.477
16	Right	0.433	0.412	0.504	0.590
17	Left	0.492	0.403	0.473	0.397
18	Left	0.452	0.443	0.506	0.413
19	Left	0.457	0.408	0.531	0.479
20	Right	0.512	0.416	0.386	0.392
21	Right	0.450	0.441	0.466	0.455
22	Left	0.598	0.472	0.584	0.429
23	Right	0.429	0.420	0.443	0.435
24	Right	0.437	0.441	0.446	0.430
25	Left	0.599	0.450	0.481	0.562
26	Right	0.428	0.457	0.507	0.437
27	Right	0.474	0.403	0.413	0.423
28	Right	0.431	0.407	0.580	0.450
29	Left	0.425	0.399	0.532	0.605
30	Right	0.489	0.464	0.439	0.478
31	Left	0.490	0.386	0.485	0.507
32	Left	0.445	0.397	0.536	0.514

An average of 0.470 g of test material, Certain Dri, was applied.

Table 3

Subject DemographicsPanel #20050223

<u>Subject Number</u>	<u>Initials</u>	<u>Age</u>	<u>Sex</u>
1	AA	62	F
2	CB	65	M
3	PB	48	M
4	RB	54	F
5	TC	58	F
6	RD	57	M
7	RE	40	M
8	CF	54	F
9	SB	53	M
10	FF	45	F
11	EG	53	F
12	MG	39	M
13	SG	65	M
14	NG	62	M
15	DH	47	F
16	AL	50	M
17	CL	53	F
18	JL	54	M
19	TL	53	M
20	RM	55	F
21	RN	30	M
22	DP	33	F
23	SQ	37	F
24	JQ	52	F
25	BR	49	M
26	FR	48	M
27	SS	54	F
28	RS	50	M
29	RT	57	M
30	JT	49	M
31	LT	60	F
32	DW	39	F

ATTACHMENT
STATISTICAL ANALYSES

C05-0409.01

1. Antiperspirant Efficacy

Antiperspirant Evaluation

Study: C05-0409

John C. Thornton, Ph.D.
June 19, 2005

Conclusion:

- The test product does qualify as an extra effective antiperspirant with enhanced duration.

Objective:

The purpose of these analyses is to test the efficacy of an antiperspirant after being used by a panel of subjects.

Data:

Consumer Product Testing Company, Inc. provided the data. The data were provided as Excel data files.

Methods:

Descriptive statistics were calculated for the amount of test product used at each application. Descriptive statistics for the amount of perspiration were calculated for treated and untreated control axillae at each evaluation. The percent reduction in perspiration at the treated axillae was calculated for each subject as

$$\text{Percent Reduction} = 100 * \frac{((\text{ControlAmount}) - (\text{TreatedAmount}))}{\text{ControlAmount}}$$

Descriptive statistics were calculated for the percent reduction in perspiration at days 4, 6, and 7.

The efficacy of the antiperspirant was tested as described in the "Guidelines for Effectiveness Testing of OTC Antiperspirant Drug Products" using the Wilcoxon Signed Rank Test. The adjusted ratio was calculated for each subject using the pretreatment measurements. The Wilcoxon Signed Rank Test was used to test the null hypothesis that the median adjusted ratio was equal to or greater than 0.7 versus the alternative hypothesis that the median adjusted ratio was less than 0.7. If the null hypothesis is rejected, the data are consistent with a median reduction in perspiration of at least thirty percent.

All statistical calculations were performed using the STATA statistical software package for personal computers. The level of significance for the test of hypothesis is 0.05 (one-tailed).

Results:

The panel size was thirty-two. Table 1 gives descriptive statistics for the amount of test product applied each day.

Table 2 gives descriptive statistics for the amount of perspiration for the treated and untreated control axillae at each evaluation. Table 3 gives descriptive statistics for the percent reduction in perspiration with the test product.

The Wilcoxon Signed Rank Test was used to test the null hypothesis that the median reduction in perspiration was less than or equal to thirty percent at days 4, 6, and 7. The null hypothesis was rejected at day 4 ($P < 0.05$), at day 6 ($P < 0.001$), and at day 7 ($P < 0.025$); therefore, the results are consistent with a greater than thirty percent reduction in perspiration on days 4, 6, and 7 using the test product.

Table 1. Descriptive statistics for amounts (g) of test product applied

Day	Number of Subjects	Mean	Standard Deviation
1	32	0.476	0.076
2	32	0.433	0.035
3	32	0.480	0.060
4	32	0.491	0.087

Table 2. Descriptive statistics for amount of perspiration (mg)

Day	Condition	Number	Mean	Standard Deviation
1	Treated	32	650	764
1	Untreated	32	565	392
4	Treated	32	248	298
4	Untreated	32	469	397
6	Treated	32	294	300
6	Untreated	32	553	525
7	Treated	32	255	266
7	Untreated	32	452	316

Table 3. Descriptive statistics for the percent reduction in perspiration using the test product

Day	Number	Mean	Standard Deviation
4	32	42%	34%
6	32	38%	44%
7	32	43%	33%