

their degree of effectiveness. One comment requested a hearing on this subject.

To prove the validity of comparative claims, two comments submitted both gravimetric and perceptual data (Refs. 4 and 5). Another comment submitted gravimetric data only (Refs. 6 and 7) and stated that one study showed that a 10 percent difference in antiperspirant effectiveness can be measured with currently marketed antiperspirant products. This comment stated that adequate data (Ref. 8) had been submitted to the Panel (43 FR 46694 at 46715) to show that as differences in antiperspirant performance levels increase, larger numbers of consumers perceive the difference. These data included a chart plotting differences in sweat reduction against the percentage of subjects who noted variations in axillary wetness. The chart shows that at 20 percent sweat reduction, approximately 45 to 50 percent of the subjects noticed a difference; at 35 percent sweat reduction, approximately 60 percent noticed a difference; and at 50 percent sweat reduction, approximately 75 percent noticed a difference. The comment contended that this study confirmed the Panel's determination that the user can perceive a shift of at least 10 percent in antiperspirant effectiveness and that a product providing a 30 percent or greater sweat reduction is perceived as more effective than a standard antiperspirant. The comments requested monograph status for "extra strength" and "extra effective" claims, as qualified by gravimetric studies.

The agency has determined that some of the studies (Ref. 4) meet the Panel's "guidelines for user perception test to be done for claims of 'extra-effective' to be classified as Category I" (43 FR 46694 at 46730). In these studies, two solid stick antiperspirant products (containing either 10 percent or 25 percent aluminum chlorohydrate) were compared by both a gravimetric and a user perception test. In the gravimetric test, 91 female subjects used the 10-percent product, and 88 used the 25-percent product. A 17-day conditioning period with no antiperspirant use was followed by four daily applications of one of the products to a randomly selected axilla (armpit or underarm). The opposite axilla received no treatment and served as the control. Baseline sweat production was determined the first day of the test. On days two and three, the antiperspirant was applied and 1 hour later a sweat production sample was collected. On day five, 24 hours after the fourth application, a sweat production sample

was collected. Both the 10- and 25-percent products were more effective than the no treatment control for all time periods according to the statistical methods (Wilcoxon signed rank test) in the agency's guidelines for effectiveness testing of OTC antiperspirant drug products (Ref. 9). Evaluation of the Z values for the two 1-hour test days and the 24-hour test day showed that both products were statistically (Wilcoxon test) at least 20 percent better than the control axilla for all time periods ( $p < 0.001$  for all three cases). Thus, both products met the requirements for standard effectiveness, i.e., a minimum of 20-percent reduction in underarm perspiration. Applying the same statistical methods to a 30-percent reduction in underarm perspiration on the last 24-hour data showed that the 25-percent product was more effective than no treatment ( $p < 0.001$ ) and, thus, met one of the extra effective criteria.

The same study design was used in the user perception test except that the subjects applied the 10-percent product under one axilla and the 25-percent product under the other axilla. On day five, 24 hours after the fourth application, the 100 female subjects were asked "Under which arm do you feel drier?" All subjects had a preference: 33 favored the 10-percent product and 67 favored the 25-percent product. A statistically significant number of the subjects were able to perceive that the 25-percent product was more effective than the 10-percent product ( $p = 0.0005$  one-sided). This result exceeded the Panel's requirement that 58 out of 100 subjects have a preference for the test antiperspirant (43 FR 46694 at 46731). Thus, these studies showed that the 25-percent aluminum chlorohydrate met the Panel's criteria (gravimetric measurements and user perception) for an extra effective claim.

The agency has determined that the studies indicate that gravimetric testing shows an adequate difference between a standard antiperspirant (with a 20-percent reduction in sweat) and an antiperspirant with at least a 30-percent reduction in sweat, as required by the Panel, to support an "extra effective" claim. The agency stated in the tentative final monograph (47 FR 36492 at 36499) that once the level of activity that is perceivable by users has been established using the Panel's recommended guidelines, it will not be necessary to perform user perception testing on individual products. Accordingly, the agency concludes that no further user perception testing is necessary for an "extra effective" claim, which is being included in the monograph for those antiperspirant

products that reduce underarm perspiration by 30 percent or more using the guidelines for effectiveness testing of antiperspirant drug products referred to in § 350.60.

The Panel placed "extra-strength" claims in Category II because it concluded that "the presence of more active ingredient in an antiperspirant product cannot be used as a basis for a claim of added effectiveness because additional amounts of antiperspirant active ingredient do not necessarily result in improved product effectiveness" (43 FR 46694 at 46724). The Panel also stated that "the term 'extra-strength' normally refers to increased concentration of the active ingredient which would normally mean added effectiveness." Several comments agreed that more active ingredient may not yield more effectiveness. Thus, a product containing 20 percent of an active ingredient (compared to 15 percent) that did not provide 30 percent or more sweat reduction could not claim "extra strength" or "extra effective."

The agency does not believe that for antiperspirants the claim "extra strength" is as informative to consumers as the claim "extra effective." The agency considers "extra effective" to be the key information that consumers want to know to select an appropriate antiperspirant product. The agency is including this new labeling claim in § 350.50(b)(4) of this final monograph. Based on this discussion, the agency concludes that a hearing is not needed on this subject.

(Comment 12) Several comments objected to the Panel's Category III classification of claims for enhanced duration of effect, such as "24-hour protection," "one spray keeps you comfortably dry all day," "prolonged protection," etc. (43 FR 46694 at 46728). One comment stated that if an antiperspirant product can be shown to provide the required 20-percent reduction in perspiration under hotroom conditions for 24, 48, etc. hours after application, then duration claims have been substantiated.

Three manufacturers submitted gravimetric studies (Refs. 4, 7, 10, and 11) that used a hotroom to induce sweating and measured sweat collected in cotton pads twice over a 24-hour period. The tested ingredients showed a 20-percent or more reduction in sweat production for both collection times, which the comments contended satisfied enhanced duration claims such as "24 hour protection" and "all day protection." One comment added that its data (Ref. 11) support a variety of product forms (cream, roll-on, solid