

products could remain in the marketplace after relabeling occurred. The economic impact of this final rule is discussed in section VI of this document.

#### *B. General Comments on Labeling of OTC Antiperspirant Drug Products*

(Comment 5) Several comments contended that FDA should not incorporate the "exclusivity policy" in the final monograph by prescribing specific labeling terminology to the exclusion of other truthful nonmisleading language.

After these comments were submitted, in the **Federal Registers** of May 1, 1986 (51 FR 16258) and March 17, 1999 (64 FR 13254), the agency published final rules changing its labeling policy for stating the indications for use of OTC drug products. Under § 330.1(c)(2) (21 CFR 330.1(c)(2)), the agency provides options for labeling OTC drug products. The final monograph in this document is subject to the labeling provisions in § 330.1(c)(2). In addition, the monograph labeling follows the format and content requirements of § 201.66 (21 CFR 201.66).

(Comment 6) One comment objected to limiting the terms proposed in § 350.50(b)(1), (b)(2), and (b)(3) to "reduces," "decreases," "diminishes," and "lessens." The comment stated that "lower" and "mitigate" are synonyms for "reduce" and other words and phrases state, truthfully and accurately, the effect of antiperspirants.

Several comments disagreed with the agency that words such as "stop," "check," "halt," "end," "eliminate," and "protect" should not be used in the labeling of antiperspirant drug products, even if preceded by the word "helps," because these words imply the ability to stop underarm perspiration totally and would therefore mislead the consumer about the effectiveness of antiperspirant drug products. The comments mentioned the minority Panel position that "The Panel did not see scientific data to indicate that a consumer can differentiate between such words as 'halts,' 'checks,' 'stops,' and 'ends,' as disallowable words versus 'diminishes' and 'reduces' as allowable words," (43 FR 46694 at 46725). One comment agreed with the minority because a review of the entire record of this proceeding found no studies or data to support a decision to disallow "protects," "halts," "checks," and "stops." Another comment requested a hearing on this issue.

One comment disagreed with the Panel's Category II status for the following labeling claims (43 FR 46694 at 46724): "Dry," "dry formula," "super

dry," "helps stop wetness," "completely guards your family," "helps stop embarrassing perspiration wetness," "complete protection," "really helps keep you dry," and "gentle enough for sensitive areas of the body." The comment asked the agency to allow these claims in the final monograph.

The agency has re-evaluated these claims in light of the comments' arguments and its current policy to provide consumer friendly OTC drug product labeling. The agency is deleting one previously proposed word ("diminishes") and adding some more consumer-friendly words ("sweat" and "sweating") to antiperspirant product labeling.

The agency proposed the word "diminishes" in § 350.50(b) as one of the optional terms that could be used as the first word of the indications statement. While the word "diminish" means to "reduce," the agency does not consider it as consumer-friendly as the other optional words "reduces," "decreases," or "lessens." Therefore, the agency is not including "diminishes" in § 350.50(b) of this final monograph as an FDA-approved term. The agency rejected the words "mitigate" and "lower" in the TFM (comment 14, 47 FR 36492 at 36496 to 36497). The agency's position has not changed. While the terms "mitigate," "lower," and "diminishes" are not in the monograph and the agency does not favor their use, manufacturers may use these terms, or other words or phrases that truthfully and accurately express a similar meaning, under the flexible labeling policy in § 330.1(c)(2).

The agency is not changing its position on the use of the word "helps" in conjunction with the words "stop," "halt," "check," "end," and "eliminate." In the TFM (comment 14), the agency stated that these words imply the ability to stop underarm perspiration totally and would therefore mislead consumers about antiperspirant effectiveness. Although neither the Panel nor the agency had any consumer comprehension studies to support a decision to disallow this information, the comments also did not provide any data to support these terms. The agency would consider these terms if data are provided to show that consumers would not be misled about the effect of antiperspirant drug products. The agency is not including "helps protect" before "underarm dampness," "underarm perspiration," or "underarm wetness," because the language is not clear and could confuse consumers.

The agency is not including any "dry" or similar claims ("dry," "dry formula," "super dry," "really helps keep you

dry") in this final monograph because no criteria have been established to define "dry." Thus, what may be "dry" for one manufacturer's product may not be "dry" for another manufacturer's product. The agency would consider including "dry" claims in the monograph if appropriate criteria for such claims are developed.

The agency is not including claims such as "complete protection" or "completely guards your family" in the monograph because there is no evidence that antiperspirant drug products provide "complete" protection. The agency is not including the claim "gentle enough for sensitive areas of the body" because the words "sensitive areas" may imply that the product can be used on other body areas in addition to the underarm. The agency is not including the claim "helps stop embarrassing perspiration wetness" because what is "embarrassing" or "problem" perspiration for one individual may not be "embarrassing" or a "problem" for others. (See section II.C, comment 10 of this document.)

The agency is not including both "perspiration" and "wetness" in the same claim because it considers the duplicative wording unnecessary. The currently allowed claims are "\* \* \* underarm wetness" or "\* \* \* underarm perspiration." The agency would have no objection to "\* \* \* underarm perspiration wetness," but such would have to be done under the flexible labeling provisions of § 330.1(c)(2). The agency is adding the words "sweat" and "sweating" in § 350.50(b) as other ways to describe "wetness" and "perspiration," because consumers regularly use these terms to describe perspiration. Based on the previous discussion, the agency concludes that a hearing is not warranted on these issues.

(Comment 7) Three comments requested that OTC antiperspirant drug products be exempted from the keep out of reach of children and accidental ingestion warnings in § 330.1(g) because these products are not toxic by oral ingestion. One comment noted only one reported ingestion in 30 years of marketing antiperspirant products. Another comment stated that aerosols, in particular, should be exempt from the ingestion warning due to the characteristics of the delivery system and the warnings already required for aerosols pressurized by gaseous propellants under § 369.21 (21 CFR 369.21).

Although the comments did not submit any data to show that antiperspirant drug products are safe if ingested, the agency believes these products should not be toxic by oral