the levels of brand awareness as long as it is linked to well-publicized images.

In Australia, the percentages of children in four different States between the ages of 12 and 14 who smoked were similar. However, their cigarette brand purchases mirrored the brands that had sponsored sporting events in their respective States. For example, more than 44 percent of children in New South Wales and Queensland smoke Winfield, the sponsor of the Queensland Rugby League, whereas, in South Australia, about 44 percent of children smoke Escort, which sponsors the South Australia's Australian Rules Escort Cup. This study demonstrates the effectiveness of sports sponsorship in influencing children's choice of cigarettes.228

Finally, a study was conducted in which approximately 100 boys in a secondary school were shown a 15minute videotape containing an advertisement promoting a cigarette company's sponsorship of a sporting event while another 100 boys were shown the same video with an advertisement of a non-tobacco company's sponsorship of a sporting event. Exposure to the advertisement for the tobacco-sponsored event did not significantly change the boys' general attitudes to smoking. However, nonsmoking students who saw the tobacco sponsorship advertisement had a significantly higher level of agreement with the statement that "smoking doesn't harm people if they play sports" than did nonsmokers who were not exposed to this advertisement. According to the study's authors: "Our study suggests that advertising of sponsorships reinforces existing behaviors, and has the potential to increase the rate at which young males smoke by negating the ill-effects associated with smoking. We also conclude that these promotions do affect those under the age of 18 by creating associations with events, teams or personalities with whom they identify." 229

The proposed rule is intended to break the link between tobacco company-sponsored events and use of tobacco. These provisions are intended to reduce the so-called "friendly familiarity" that sponsorships and items generate among young people.

iii. Established name and intended use. Proposed § 897.32(b) would require each piece of advertising for cigarettes, cigarette tobacco, or smokeless tobacco products, permitted under § 897.30(a), to state the product's established name and give a statement of its intended use. Section 502(r)(1) of the act requires, for

any restricted device, that all advertising or other descriptive printed material contain "a true statement of the device's established name * * * printed prominently and in type at least half as large as that used for any trade or brand name thereof." The agency has determined that the established names for these products are the common and usual names: "cigarettes," "cigarette tobacco," "loose leaf chewing tobacco," "plug chewing tobacco," "twist chewing tobacco, "moist snuff," and "dry snuff." (These names would be codified at proposed § 897.24.)

The product's established name would be followed by the words, "a Nicotine-Delivery Device." Under section 502(r)(2) of the act, a restricted device is misbranded unless all advertising contains "a brief statement of the intended uses of the device." The agency finds that it is necessary to require that the product's established name and intended uses be placed on all advertising, under section 520(e) of the act, as a measure which affirmatively identifies the products to persons reading the advertising.

iv. The brief statement. Under proposed §897.32(c), cigarette advertising (permitted under § 897.30(a)) would contain information regarding relevant warnings, precautions, side effects, and contraindications. This brief statement is required under section 502(r)(2) of the act. Section 502(r)(2) does not require that labeling contain a brief statement and the agency does not intend to place such a requirement on labeling (e.g., vehicles, entries or teams in sponsored events). Because of the products' serious "potentiality for harmful effect," the proposal would specify the text of the brief statement. This would ensure that all advertisements contain the same, required information in a manner that is consistent, readable, clear and conspicuous, and not misleading to the reader.

FDA is generally responsible for approving information in the brief statement to ensure that the appropriate risks and benefits are communicated. In this case, the risks associated with cigarettes are much greater than those for any other consumer product on the market, and hundreds of different cigarette brands exist. The proposed rule, therefore, would provide, as an example, the following text for one of the brief statements to ensure that important information is communicated in an informative manner to young people and that the information is consistent for all cigarette brands:

"ABOUT 1 OUT OF 3 KIDS WHO BECOME SMOKERS WILL DIE FROM THEIR SMOKING."

FDA will include in the final rule the exact language for any and all brief statements to ensure that this important information is conveyed accurately and effectively. In addition, the agency requests comment on what other information should be included in the brief statements concerning relevant warnings, precautions, side effects, and contraindications.

Support for the proposed brief statement comes from the European Union's report on the labeling of tobacco products. The report states that "[t]he warnings which are perceived as being the most credible are, in general, those which draw attention to the risk of death, the risk of illness and to the addiction caused by smoking. Credibility is reinforced when the message is felt to apply personally to the reader or which describes a risk which may be felt by the reader to concern them personally." ²³⁰

During the comment period for this proposed rule, FDA intends to perform extensive focus group testing on the proposed brief statement[s]. The testing will evaluate the content and various formats for the brief statement[s] to determine if the warnings are communicated effectively. The agency will base the design, the format and content of the brief statement[s] on the results of this testing and the comments received to the proposed rule.

FDA is not proposing that advertising list cigarette ingredients, but FDA is aware that several surveys and studies show that cigarette users would like to know more about the ingredients in, or the chemical constituents of, smoke delivered by cigarettes. In a survey of 2,345 adults, 93 percent agreed that tobacco companies should be required to list additives on package labels the way food and drug companies are required to list ingredients.²³¹ Those surveyed believed that in order to inform consumers about the risks involved in smoking, more comprehensive information about cigarette ingredients and combustion by-products should be provided to the consumer.

Section 502(r)(2) of the act (21 U.S.C. 352(r)(2)) states that "in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health," a restricted device shall be misbranded unless its advertising and other descriptive printed matter include "a full description of the components of