

NARB PANEL #152

September 16, 2009

**Appeal of the NAD Final Decision Regarding Advertising for
Extra Strength Excedrin**

Panel Members

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REPORT OF NARB PANEL 152

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Appeal of NAD Final Decision Regarding Advertising for Extra Strength Excedrin

Background

Advertising claims by Novartis for Extra Strength Excedrin were challenged by Wyeth, a manufacturer of competing pain relief products.

The challenged television advertisement showed a woman, clearly suffering from a headache, sitting at a table at an outdoor café. A digital clock rapidly advances below her. When the clock indicates ten minutes has passed, a voiceover asks “What’s the only gel tab with a triple ingredient formula to start relieving your headache in just fifteen minutes?” At the fifteen minute mark, the woman’s facial expression dramatically changes and she gets up, smiling, to greet someone. The voiceover answers the question by stating “Extra Strength Excedrin. Go.”

NAD considered both the express claim stated in the Advertisement – that Extra Strength Excedrin starts relieving headaches in fifteen minutes – as well as an implied claim that Extra Strength Excedrin provides substantial and/or complete relief from headache pain within fifteen minutes.

NAD determined that Novartis did not provide sufficient substantiation for the express claim that Extra Strength Excedrin starts to relieve headache pain in fifteen minutes, and recommended that Novartis either discontinue or substantially modify that claim. Novartis has appealed NAD’s recommendation with respect to the express claim.

NAD further determined that the visual in the challenged advertisement reasonably communicated an implied message that consumers taking Extra Strength Excedrin will typically experience substantial or complete headache pain relief within fifteen minutes. NAD found that Novartis did not provide sufficient substantiation for this claim, and recommended that Novartis discontinue its use of the visual. Novartis did not appeal NAD’s recommendation with respect to the implied claim and instead agreed to take this recommendation into consideration in future advertising.

Findings and Conclusions

This appeal presents a single issue – did Novartis provide sufficient substantiation to support its express claim that Extra Strength Excedrin “Start[s] relieving your headache in just fifteen minutes”?

Message Conveyed by Express Claim

NAD found that the plain language of the challenged express claim conveys the message that the average consumer can reasonably expect to start to feel some relief from headache pain within fifteen minutes after taking Extra Strength Excedrin. On appeal, Novartis argues that the challenged claim does not convey the message found by NAD, but rather conveys an “onset of action” claim that Extra Strength Excedrin begins acting within fifteen minutes.

In the context of the challenged advertisement, which featured a visual showing dramatic improvement in the woman’s expression and activity after fifteen minutes, there is no question that the challenged express claim conveys the message found by NAD -- that typical consumers can reasonably expect some headache relief within fifteen minutes after taking Extra Strength Excedrin. The panel determined that the express claim reasonably conveys the same message even if the visual is removed. Headache relief, from a consumer’s viewpoint, does not start until there is some perceived reduction in headache pain. The panel disagrees with Novartis’ argument that “start[s] relieving your headache” conveys only an “onset of action” message that something is occurring on a pharmacological level – the panel believes that the reasonable message conveyed by promising headache “relief” is that headache pain is perceptibly reduced. The claim that relief will start within a certain time frame conveys the message that typical consumers can reasonably expect some reduction of headache pain within that time frame.

Substantiation

In support of the challenged advertising, Novartis offered a proprietary clinical study that tested Extra Strength Excedrin to determine its efficacy in relieving pain intensity for episodic tension-type headaches. Subjects in the study were asked to report headache pain intensity and headache pain relief at various time intervals – including fifteen minutes – after taking Extra Strength Excedrin. While the study was submitted on a confidential basis, and the exact findings cannot be disclosed, it is clear from the test results that only a very small percentage of subjects indicated at the fifteen minute point that there was less headache pain or that there had been some headache pain relief.¹ While the study showed that Extra Strength Excedrin provided better headache relief than a placebo, it fell far short of showing that typical consumers experienced a reduction in headache pain within fifteen minutes after taking Extra Strength Excedrin.

Novartis argued that the clinical trial was sufficient to support an “onset of action” claim that Extra Strength Excedrin started to work on a pharmacological basis after fifteen minutes. However, that is not the message found by the panel to be reasonably conveyed by “Start[s] relieving your headache in just fifteen minutes.” NAD found, and the panel agrees, that the proffered substantiation does not provide a reasonable basis in support of the reasonably conveyed message that typical consumers can reasonably expect a reduction in headache pain within fifteen minutes after taking Extra Strength Excedrin.

¹ While NAD noted some concern with the basic test methodology used in Novartis’ clinical trial, it determined that the methodology used one of several accepted methods in headache pain relief studies. NAD expressed additional concern over some of the test results that were produced in an analysis that was not part of the original test protocol, but rather resulted from a “new look” at the test data several years after completion of the clinical trial. The panel does not need to address those concerns – even if the panel were to accept the results of the analyses that were not part of the original test protocol, the results are still insufficient to support the claim that typical consumers can reasonably expect a reduction in headache pain within fifteen minutes after taking Extra Strength Excedrin.

Decision

The panel recommends that Novartis discontinue its claim that Extra Strength Excedrin “Start[s] relieving your headache in just fifteen minutes,” or modify the claim to accurately reflect the results of its clinical study in a manner that does not state or imply that typical consumers can reasonably expect a reduction in headache pain within fifteen minutes after taking Extra Strength Excedrin.

Advertiser Statement

Novartis appreciates the opportunity to participate in the self-regulatory process before the NAD and expresses its sincere gratitude to the NARB panel for the time and attention that it devoted to Novartis' appeal. Novartis is pleased that the NAD and NARB acknowledged that the methods employed by Novartis in its substantiation research were a valid and accepted means of substantiating an onset claim. Novartis is disappointed that the NAD and NARB did not agree with its interpretation of its claim that Extra Strength Excedrin starts to relieve your headache in 15 minutes. Novartis will, if it uses a similar claim in the future, take the NAD's and NARB's conclusions and recommendations into consideration in formulating and presenting the claim.