



TRANSMITTED BY FACSIMILE

Una Ortell, MSc, RAC
Assistant Director, Regulatory Affairs
TAP Pharmaceutical Products Inc.
675 North Field Drive
Lake Forest, IL 60045

RE: **NDA# 20-406**
Prevacid (lansoprazole) Delayed Release Capsules
MACMIS# 10893

Dear Ms. Ortell:

This letter objects to TAP Pharmaceutical Products Inc.'s (TAP) dissemination of promotional materials for Prevacid that are in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. Specifically, as part of its routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has identified a 60-second direct-to-consumer (DTC) television broadcast advertisement ("TV Ad") for Prevacid entitled "Get Serious" that is misleading. Our specific objections follow:

Misleading Communication of Indication

This TV Ad is misleading because it fails to clearly communicate to the typical consumer the definition and limitations of the approved indication for Prevacid, the short-term treatment of symptomatic gastroesophageal reflux disease ("GERD")(referred to in the TV Ad as "acid reflux disease"). The symptoms that are used to define and diagnose GERD, or acid reflux disease, include persistent heartburn for two or more days a week despite treatment and diet change. The typical consumer needs to be aware that these symptoms, which define and limit Prevacid's symptomatic GERD indication, signify more than occasional heartburn. This basic premise is also essential to the typical consumer's understanding that, over time, these symptoms could lead to erosive esophagitis, a more serious GERD condition that is also promoted in this TV Ad.

The TV Ad's communication of the symptoms/definition of GERD to consumers is interfered with by the simultaneous presentation of competing visual, graphic, and auditory distractions. The ad opens with vignettes of several GERD "sufferers" and a simultaneous subtitled SUPER on a black background describing symptomatic GERD as "Persistent heartburn 2 or more days a week despite treatment & diet change may be acid reflux disease." However, this subtitled presentation does not adequately communicate the definition of symptomatic GERD because a variety of competing visual, graphic, and auditory distractions draw the consumers' attention away, thereby interfering with the processing of this critical subtitled information. Specifically, "strobe-light" flashing graphics and more prominent moving SUPERS, such as "HARD TO IGNORE" and "WHO NEEDS THE PAIN?," next to and combined with actors portraying GERD sufferers speaking to the camera, along with music, sound

effects, and vivid "eye-catching" images of "sufferers" splitting wood with an ax and hitting a bullseye with an arrow, draw the consumers' attention away from the subtitled information.

Consequently, the totality of attention-drawing and other distracting opening elements combine to interfere with, and indeed undermine, a typical consumer's reading and comprehension of the text in the SUPER of the TV Ad. Therefore, notwithstanding the subtitled SUPER, the critical information describing the symptoms of GERD, which defines and limits the indication, is not adequately communicated to the typical consumer. A prescription drug advertisement is misleading, and therefore in violation of Section 502(n) of the Act, if it uses headline, subheadline, or pictorial or other graphic matter in a way that is misleading, 21 C.F.R. §202.1(e)(6)(xviii). DDMAC previously notified TAP of objections to a prior Prevacid broadcast TV Ad that, among other problems, was misleading because it also failed to convey the limitations of the symptomatic GERD indication (March 15, 2000, DDMAC untitled letter to TAP).

Requested Action

TAP should immediately cease distribution of this broadcast ad, and all other promotional materials for Prevacid that contain the same or similar claims or presentations. TAP should submit a written response to DDMAC, on or before August 16, 2002, describing its intent and plans to comply with the above. In its letter to DDMAC, TAP should include a list of all promotional materials that were discontinued, and the discontinuation date.

TAP should direct its response to me by facsimile at (301) 594-6771, or write to me at the Division of Drug Marketing, Advertising, and Communications, HFD-42; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. DDMAC reminds TAP that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS #10893 and NDA 20-406.

Sincerely,

{See appended electronic signature page}

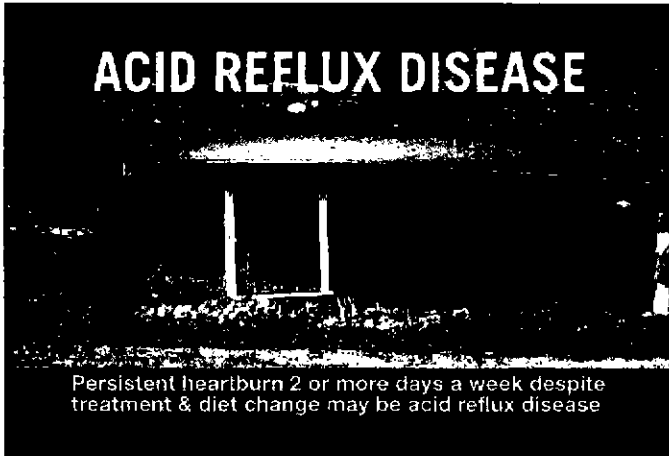
Joan Hankin, J.D.
Consumer Promotion Analyst
Division of Drug Marketing,
Advertising, and Communications

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this page is the manifestation of the electronic signature.**

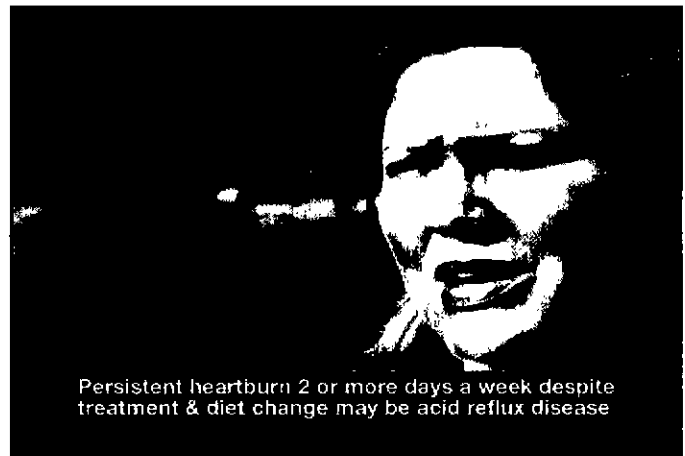
/s/

Christine Smith
8/2/02 10:42:41 AM
Signed for Joan Hankin

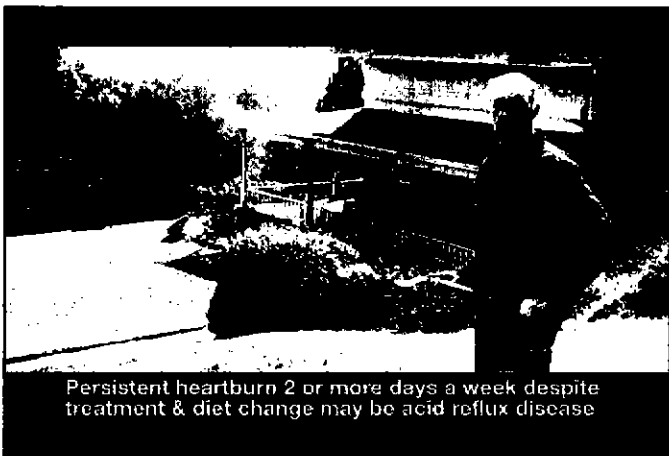
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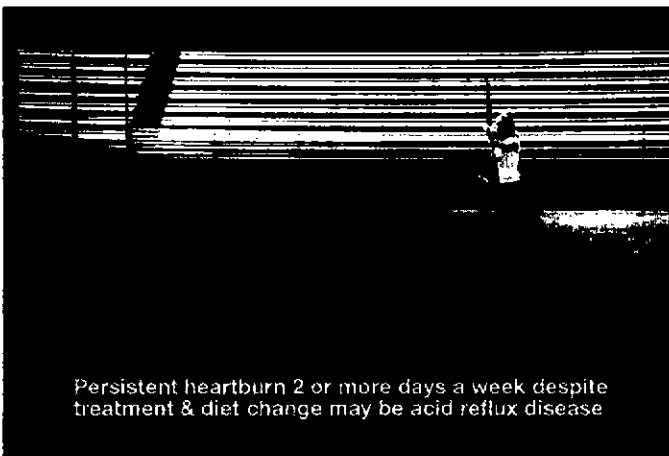
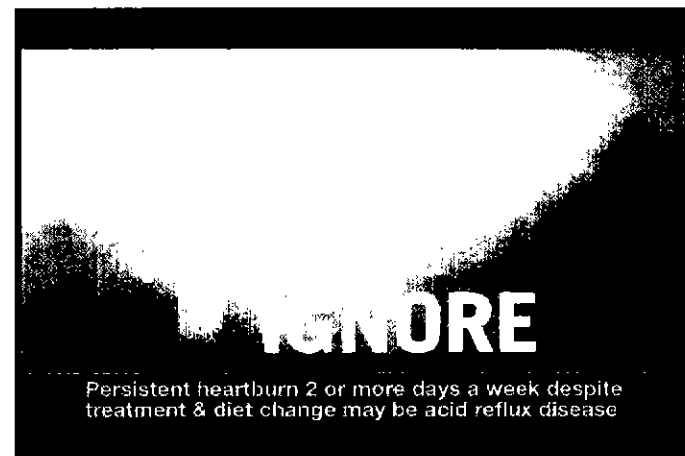
Woman VO: Acid reflux disease



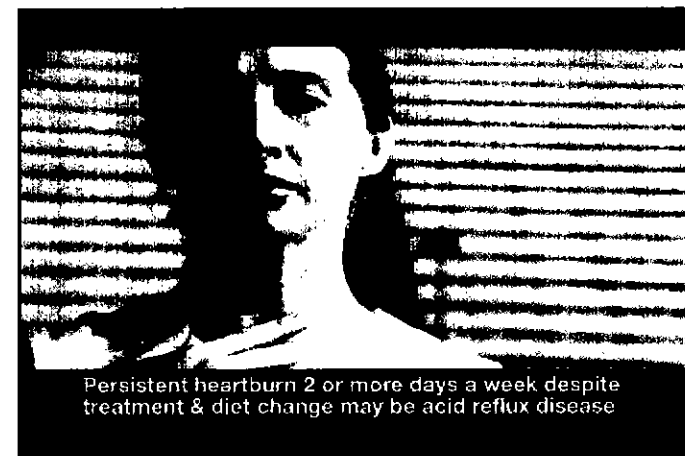
Woman OC: can really upset your plans.



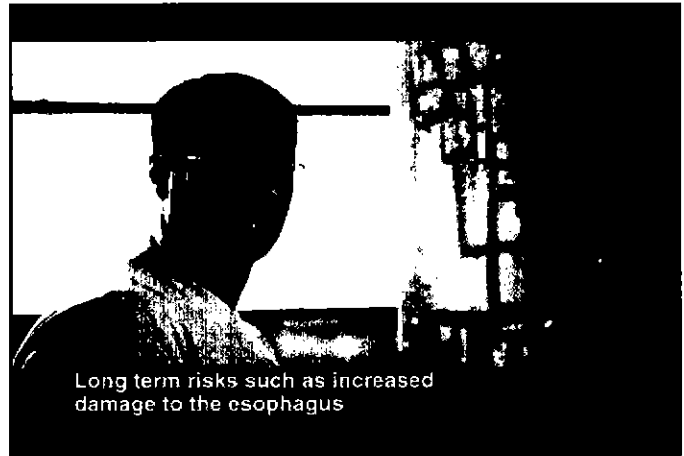
Man OC: You never know when to expect it.



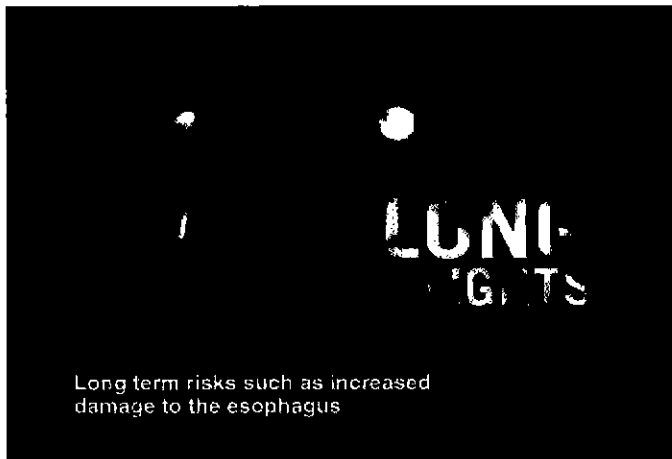
Woman VO: The burn can



Woman OC: stop you in your tracks.



Man OC: You worry about the risk of long-term problems.



Woman OC: I got help. Learned to handle the disease and the risks



Woman VO: in ways that make sense for me.



Announcer VO: Call this number now for information and a free kit from Prevacid.



Announcer VO: A handbook on managing acid reflux disease and its risks.



Announcer VO: A Risk Alert Profiler.



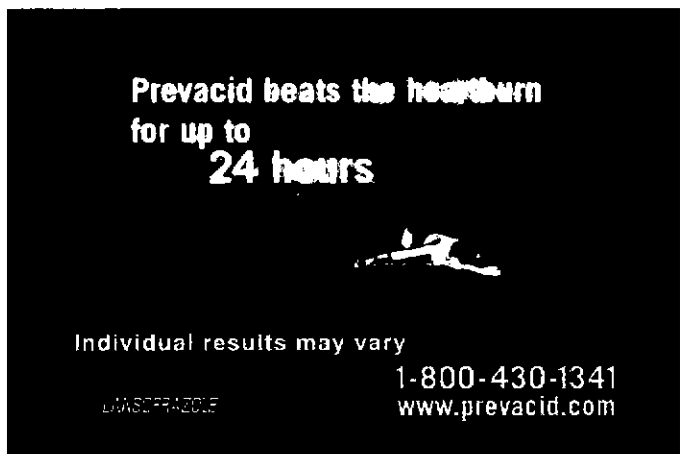
Announcer VO: A guide to making the most of your next doctor visit.



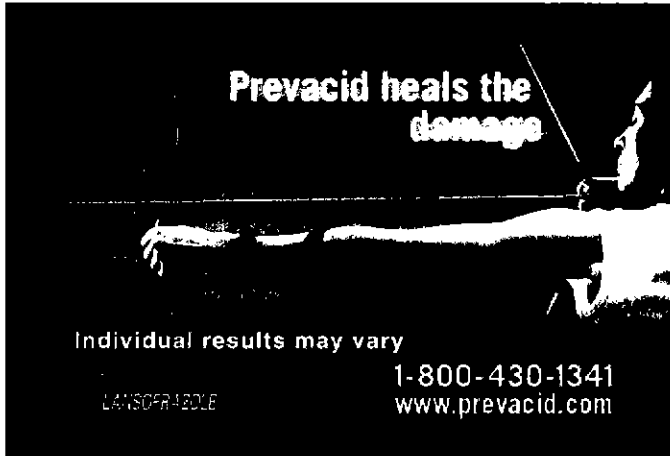
Announcer VO: And a 7-day free trial certificate to use if your doctor decides Prevacid is right for you.



Announcer VO: Prevacid fights acid reflux disease three ways.



Announcer VO: It beats the burn.

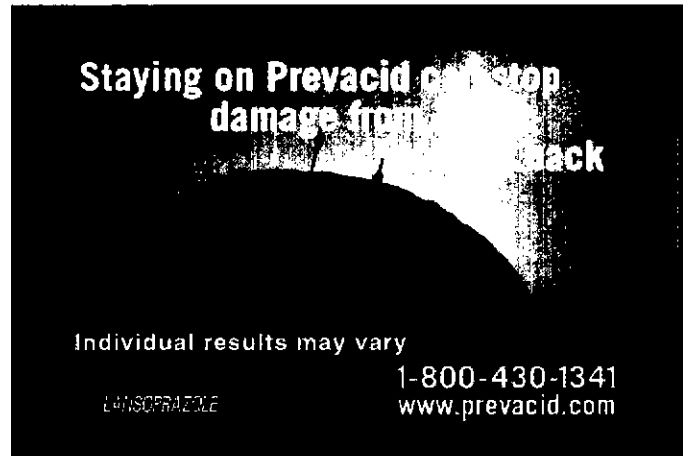


Prevacid heals the damage

Individual results may vary

LANSOPRAZOLE 1-800-430-1341
www.prevacid.com

Announcer VO: Helps heal the damage. And best of all, staying on Prevacid,



Staying on Prevacid can stop damage from coming back

Individual results may vary

LANSOPRAZOLE 1-800-430-1341
www.prevacid.com

Announcer VO: if prescribed, can stop the damage from coming back.



See our ad in Health magazine

LANSOPRAZOLE 1-800-430-1341
www.prevacid.com

Announcer VO: Prevacid has a low occurrence of side effects, such as diarrhea, abdominal pain and nausea.



Ask your doctor for more information

LANSOPRAZOLE 1-800-430-1341
www.prevacid.com

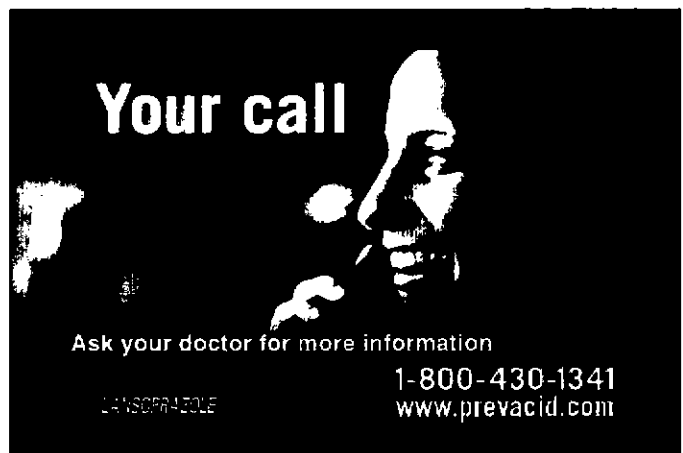
Announcer VO: So if you want the power to manage the risks,



Ask your doctor for more information

LANSOPRAZOLE 1-800-430-1341
www.prevacid.com

Announcer VO: heal the damage, and stay healed,



Your call

Ask your doctor for more information

LANSOPRAZOLE 1-800-430-1341
www.prevacid.com

Announcer VO: call now for your free kit.