



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

TRANSMITTED BY FACSIMILE

MAR 15 2000

Una Ortell, MSc.
Regulatory Products Manager
TAP Holdings Inc.
Bannockburn Lake Office Plaza
2355 Waukegan Rd.
Deerfield, IL 60015

**RE: Prevacid (lansoprazole) Delayed Release Capsules
NDA 20-406
MACMIS # 8796**

Dear Ms. Ortell,

This letter informs you that the 60-second direct-to-consumer (DTC) broadcast advertisement for Prevacid (lansoprazole) submitted by TAP Pharmaceuticals Inc. (TAP), under Form FDA 2253 ("Heartbreak Hotel," #TAP-PRV-A9-1274), violates the Federal Food, Drug, and Cosmetic Act and applicable regulations. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed the advertisement and has determined that the advertisement is misleading and lacks fair balance. Overall, the visuals in the advertisement fail to appropriately communicate Prevacid's indication, efficacy, and side effect information. DDMAC's specific objections follow.

Inadequate Presentation of Indication

The advertisement is misleading because it does not clearly communicate Prevacid's appropriate indication. TAP discloses the indication limitations using a non-prominent super and song lyric that are difficult to comprehend. For example, the super, "frequent, persistent heartburn..." appears faint against distracting visual backgrounds. The information about heartburn persisting despite nonprescription treatments is presented so quickly in the song lyric that the message is difficult to understand. Thus, without adequate presentation of the limitations, the advertisement implies that Prevacid may be used in a broader range of conditions than approved. Specifically, the advertisement implies that Prevacid may be used to treat any type of heartburn, rather than the approved indication for short-term treatment of heartburn and symptoms associated with gastroesophageal reflux disease (GERD).

Overstatement of Efficacy

The advertisement is misleading because it implies that Prevacid is more effective than has been proven in clinical trials. The impact of the benefit presentation, given by the graphics and song lyrics, is not sufficiently qualified by the small, faint, hard-to-read supers of "individual results may vary." Thus, the advertisement's overall impression implies that Prevacid will provide relief for everyone all of the time.

Lack of Fair Balance

The advertisement lacks fair balance because it fails to present the information relating to the side effects with sufficient emphasis. The side effect information is presented in the audio portion of the advertisement along with distracting visual presentations. The quantity and pace of the visual presentations interfere with the audience's ability to comprehend the important side effect information.

Requested Response

DDMAC requests that TAP immediately cease using this advertisement and all other promotional materials for Prevacid that contain the same or similar presentations. DDMAC also requests that TAP submit a written response on or before March 27, 2000, describing its intent to comply with the request. Your written response should include a list of promotional materials that were discontinued and the discontinuation date.

If you have any questions, please contact the undersigned by telephone at (301) 827-2828, facsimile (301) 594-6759, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-42, Room 17B-20, 5600 Fishers Lane; Rockville, MD 20857. All communications regarding this matter should reference MACMIS # 8796. DDMAC reminds you that only written communications are considered official.

Sincerely,

/S/

Patricia Kuker Staub, Esq. R.Ph.
Regulatory Counsel
Division of Drug Marketing,
Advertising, and Communications

[]

SCRIPT/COPY

[]

TV **RADIO** **PRINT**

Client: TAP Pharmaceuticals

Date: 3/2/00

Page: 1 of 1

Product: Prevacid

Title: "Heartburn Hotel 60 US News"

Job #/Ad #: TAP-PRV-A9-1274

Code #: ZBKA 9046 Length: :60

Author(s): []

Revision #: Final As Produced

SINGER:

Welcome to a hot spot...
Where pain and discomfort dwell,
It's down at the end of Acid Street...
The Heartburn Hotel.
Well,
Your stomach's a burnin' baby
The acid's a churnin' baby
You're getting heartburn
All the time (all the time).
Well,
You've changed the way you're eating...
You're getting exercise.
You treat it but two days a week or more,
The acid starts to rise.

VO: Ask your doctor about Prevacid. It can mean 24-hour relief from persistent heartburn associated with Acid Reflux Disease. Prevacid turns off tiny pumps that produce acid in your stomach. Prescription Prevacid has a low occurrence of side effects, such as diarrhea, abdominal pain and nausea. Prevacid can provide complete night and day heartburn relief. Ask your doctor if Prevacid's right for you.

SINGER:

Check out of the Heartburn Hotel.
Prevacid stops the burnin'...
So leave your heartburn behind.
Yeah!

Legal Approval

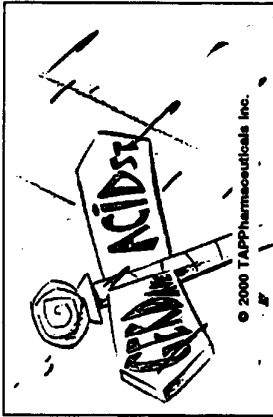
Date

Client Approval

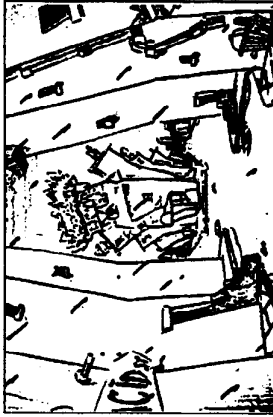
Date

CLIENT: Prevacid
 TITLE: Heartburn Hotel
 LENGTH: 60

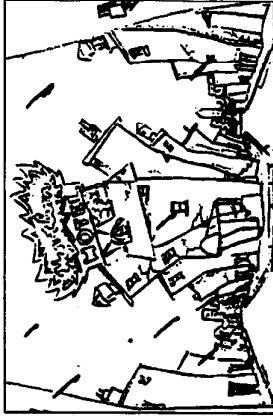
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 PAGE: 1 OF 3



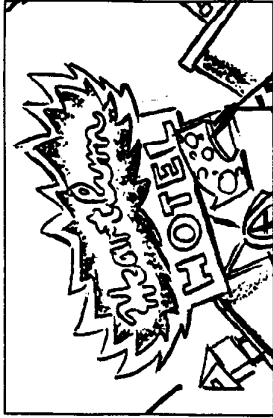
SONG:
 Welcome to a hot spot...
 Open on sign, move away down Acid Street...
SUPER: © 2000 TAPPharmaceuticals Inc.



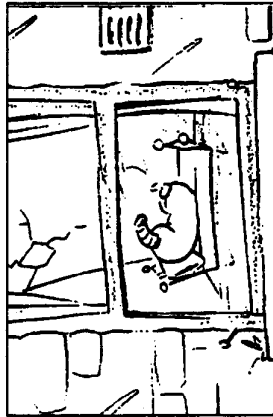
where pain and discomfort dwell,
 towards Heartburn Hotel



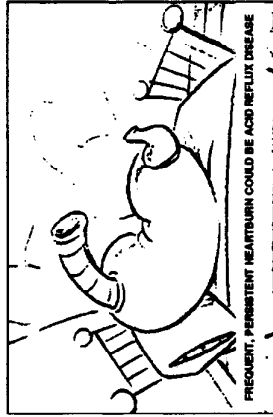
It's down at the end of Acid Street...



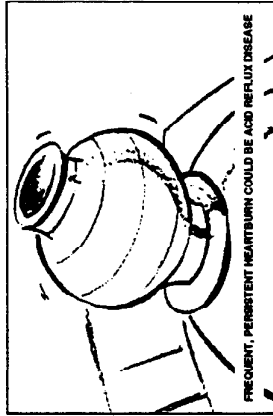
the Heartburn Hotel.



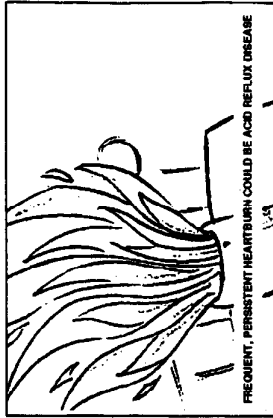
Well,
 See Tummy character in room, Tummy is suffering
 heartburn as indicated by it's movement.



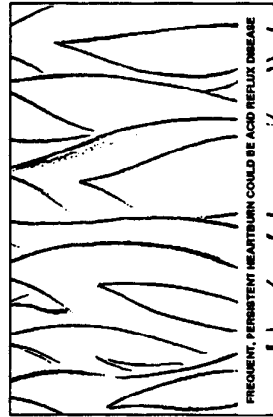
Your stomach's a burmin' baby, the acid's a
 churmin' baby



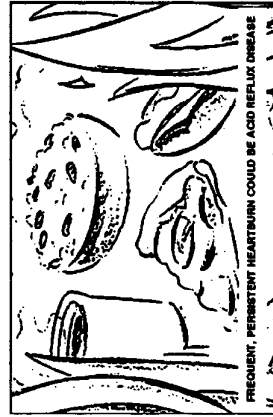
You're getting heartburn...
 See burning glow, representative of reflux pain.



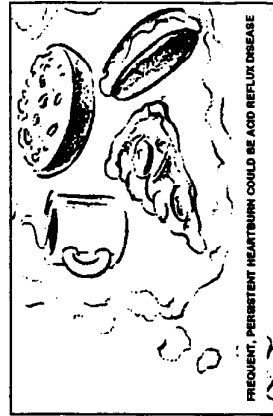
all the time
 Close up of flames that erupt from Tummy's esopha-
 gus.
**SUPER: FREQUENT, PERSISTENT HEARTBURN
 COULD BE ACID REFLUX DISEASE**



Well,
 Flames part to reveal food inside thought bubble.
**SUPER: FREQUENT, PERSISTENT HEARTBURN
 COULD BE ACID REFLUX DISEASE**



Well,
 Flames part to reveal food inside thought bubble.
**SUPER: FREQUENT, PERSISTENT HEARTBURN
 COULD BE ACID REFLUX DISEASE**



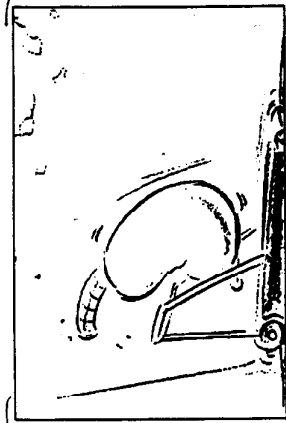
You've changed
**SUPER: FREQUENT, PERSISTENT HEARTBURN
 COULD BE ACID REFLUX DISEASE**



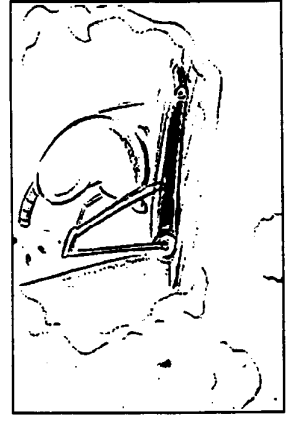
the way you're eating...
 Food pops off.

CLIENT: Prevacid
 TITLE: Heartburn Hotel
 LENGTH: 60

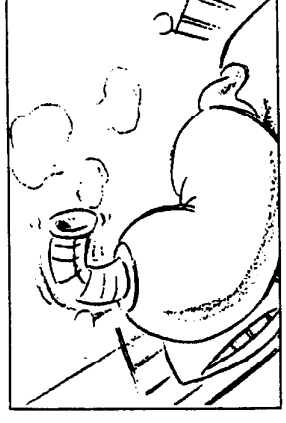
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 JOB NUMBER:
 PAGE: 2 OF 3



You're getting exercise.
 Pull out to reveal tummy running on treadmill.



Pull out further to reveal this as a thought bubble that floats off screen.



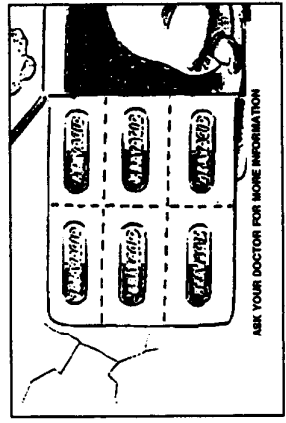
You treat it but two days a week or more, the acid starts to rise.
 Continue to reveal tummy sitting on bed with a smoking esophageus that is burning with reflux pain.



ASK YOUR DOCTOR FOR MORE INFORMATION

AVO:
 Ask your doctor about Prevacid.
 Rise up to focus on pack.

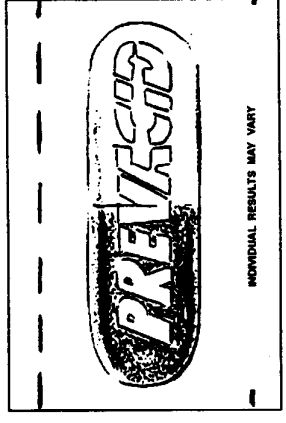
SUPER: ASK YOUR DOCTOR FOR MORE INFORMATION



ASK YOUR DOCTOR FOR MORE INFORMATION

It can mean
 Foil slides out of box.

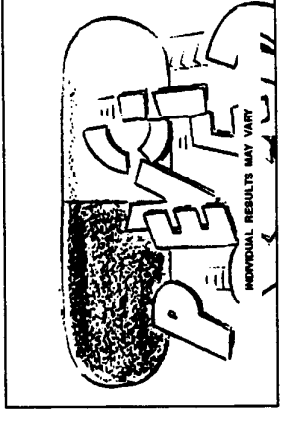
SUPER: ASK YOUR DOCTOR FOR MORE INFORMATION



INDIVIDUAL RESULTS MAY VARY

24-hour relief from persistent heartburn

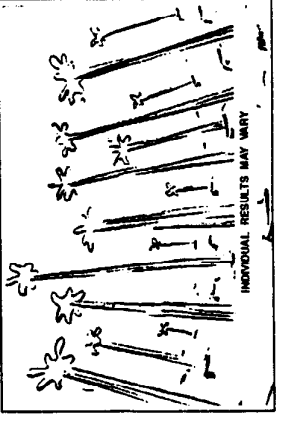
SUPER: INDIVIDUAL RESULTS MAY VARY



INDIVIDUAL RESULTS MAY VARY

associated with Acid Reflux Diseases.
 Close in on tablet as lettering falls off and out of screen.

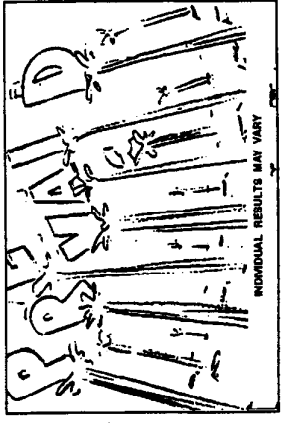
SUPER: INDIVIDUAL RESULTS MAY VARY



INDIVIDUAL RESULTS MAY VARY

Prevacid
 Pull back through spurting acid streams.

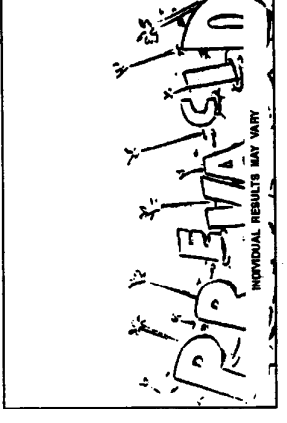
SUPER: INDIVIDUAL RESULTS MAY VARY



INDIVIDUAL RESULTS MAY VARY

turns off tiny pumps that produce
 To see the letters fall into screen and land on the top of the fountains.

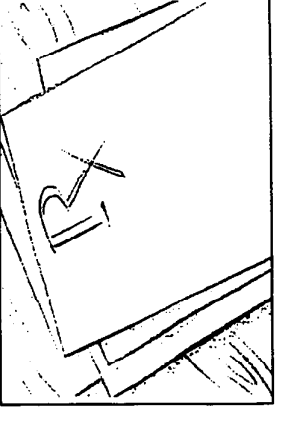
SUPER: INDIVIDUAL RESULTS MAY VARY



INDIVIDUAL RESULTS MAY VARY

acid in your stomach.
 The acid settles down (25% left) and the letters drop to spell Prevacid.

SUPER: INDIVIDUAL RESULTS MAY VARY



INDIVIDUAL RESULTS MAY VARY

Prescription Prevacid
 A prescription comes into view.

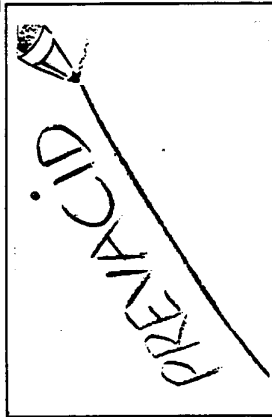


INDIVIDUAL RESULTS MAY VARY

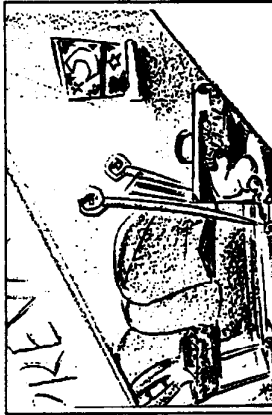
has a low occurrence

CLIENT: Prevacid
 TITLE: Heartburn Hotel
 LENGTH: 60

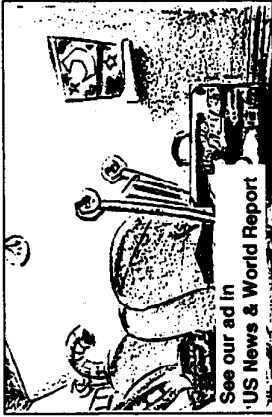
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of side effects, such as diarrhea,



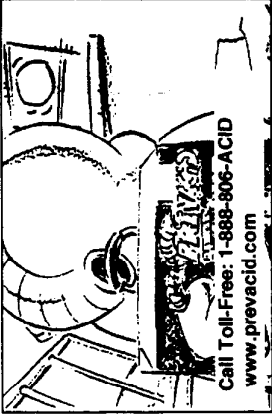
abdominal pain and nausea.
 Prescription opens to reveal tummy in bed and pack shot.



See our ad in
 'US News & World Report

Prevacid can provide complete night and day

SUPER: See our ad in US News & World Report



Call Toll-Free: 1-888-806-ACID
 www.prevacid.com

heartburn relief.
 Tummy climbs out of bed and picks up suitcase.
 Transition from night to day.

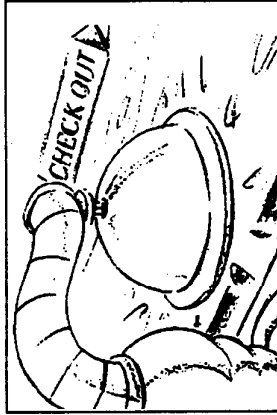
SUPER: Call Toll-Free: 1-888-806-ACID
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 www.prevacid.com

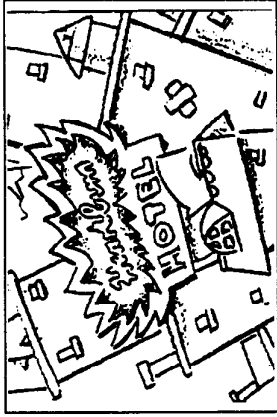
Ask your doctor if Prevacid's right for you.

SUPER: Call Toll-Free: 1-888-806-ACID
 www.prevacid.com

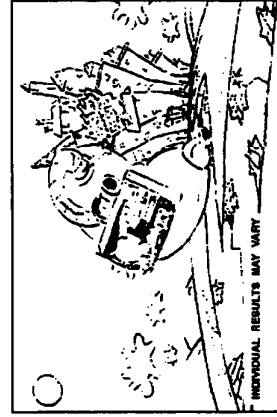


CHECK OUT

SONG:
 Check out of the
 See tummy character checking out of the Heartburn
 Hotel.



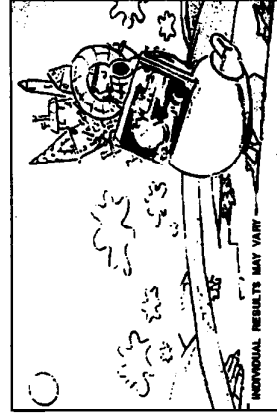
Heartburn Hotel.
 Exterior shot of Hotel



INDIVIDUAL RESULTS MAY VARY

So leave
 ...picks up suitcase and happily walks away.

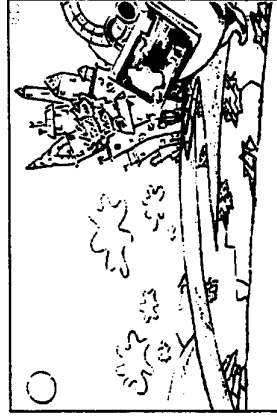
SUPER: INDIVIDUAL RESULTS MAY VARY



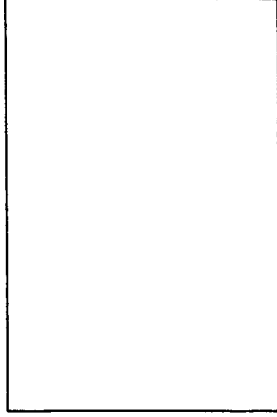
INDIVIDUAL RESULTS MAY VARY

your heartburn behind.

SUPER: INDIVIDUAL RESULTS MAY VARY



Yeah!



Prevacid stops the burnin'...
 Tummy looks back at hotel...