



TRANSMITTED BY FACSIMILE

Leslie Rogers, MD
Director, Regulatory Affairs
GlaxoSmithKline
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

RE: NDA 20-132
Imitrex (sumatriptan succinate) Tablets
MACMIS ID#: 10795

Dear Dr. Rogers:

This letter notifies GlaxoSmithKline (GSK) that the Division of Drug Marketing, Advertising, and Communications (DDMAC) has identified a direct-to-consumer television (TV) advertisement (ad) that is in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. Specifically, the 60 second DTC TV ad "Hospital Nursery" (submitted on FDA Form 2253) makes an unsubstantiated and hence misleading comparative claim about Imitrex Tablets.

Misleading Comparative Claim

The TV ad is misleading because it suggests that Imitrex is more effective than has been demonstrated by "substantial evidence" (generally, two adequate and well-controlled head-to-head clinical trials). The beginning of the ad portrays a nurse migraine sufferer looking at a stout amber prescription medicine bottle in conjunction with her voiceover "...a migraine my medicine just dulled the pain. So I talked to my doctor. He prescribed Imitrex. Imitrex targets your total migraine." The stout amber bottle is likely to be identified by consumers as containing a prescription medicine (i.e., her regular pain reliever). As you know, there are several competing prescription pain relievers sold in this type of container. This video portrayal referring to another prescription medicine, combined with the "medicine just dulled the pain" claim, implies that Imitrex is superior to another prescription pain reliever(s), in the absence of substantial evidence. See 21 CFR § 202.1(e)(6)(ii). FDA is not aware of any studies comparing Imitrex to other prescription pain relievers. Therefore, this presentation is in violation of the Act because it makes an unsubstantiated and hence misleading comparative claim.

Requested Action

GSK should immediately discontinue this ad and all other promotional materials and activities for Imitrex that contain the same or similar violative presentations. GSK should submit a written response to DDMAC on or before May 28, 2002, describing its intent and plans to comply with the above. In its letter to DDMAC, GSK should include the date on which this and other similarly violative materials were discontinued.

Leslie Rogers, MD
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GSK should direct its response to Lisa L. Stockbridge, Ph.D., by facsimile at (301) 594-6771, or by written communication at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications HFD-42, Rm. 17-B-20, 5600 Fishers Lane, Rockville, Maryland 20857.

In all future correspondence on this matter, please refer to MACMIS ID# 10795 as well as the NDA number. DDMAC reminds you that only written communications are considered official.

Sincerely,

{See appended electronic signature page}

Joan Hankin, JD
Consumer Promotion Analyst
Division of Drug Marketing,
Advertising, and Communications

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Joan Hankin

5/13/02 04:57:53 PM

3/21/02

VIDEO

OPEN ON NURSE IN HOSPITAL NURSERY CARRYING BABY. MANY INFANTS IN BASSINETS BEHIND HER. SHE RUBS HER TEMPLE.

SUPER: NURSE DRAMATIZATION

3 seconds 1



AUDIO

NURSE (VO): How was I supposed to do my job?

CLOSE-UP OF CRYING BABY.

1.5 seconds 2



15 newborns...

CLOSE-UP OF HER SUFFERING FROM MIGRAINE. NURSE RUBS HER TEMPLE.

SUPER: DIAGNOSIS: MIGRAINE

1.5 seconds 3



and a migraine

MEDICINE CABINET POINT-OF-VIEW OF NURSE READING MEDICINE LABEL.

2 seconds 4



my medicine just dulled the pain.

WIDE SHOT OF NURSE
CONSULTING WITH DOCTOR.

SUPER:
PRESCRIPTION:
IMITREX®
SUMATRIPTANSUCCINATE

1.5 seconds 5

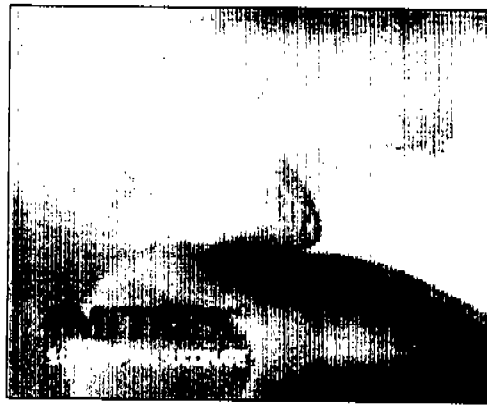


So I talked to my doctor.

CLOSE-UP OF IMITREX
TABLET.

SUPER:
IMITREX®
SUMATRIPTANSUCCINATE

2 seconds 6



He prescribed Imitrex.

DOCTOR TALKS TO CAMERA.

SUPER:
DOCTOR DRAMATIZATION

2 seconds 7



DOCTOR: Imitrex targets
your *total* migraine.

FLASHBACK TO NURSE IN
PAIN. NURSE RUBS HER
TEMPLE.

1 second 8



The pain,

FLASHBACK TO NURSE
SUFFERING NAUSEA.

.5 second 9



nausea...

FLASHBACK TO NURSE
REACTING TO BRIGHT
LIGHT IN NURSERY.

2 seconds 10



sensitivity to light and sound.

CUT TO WOMAN'S SILHOU-
ETTE WITH DIFFERENT
AREAS OF PAIN THROB-
BING. "IMITREX" RISES UP
FROM BOTTOM OF
SCREEN.

2 seconds 11



ANNCR (VO): Some pain
relievers are made for general
kinds of pain.

CAMERA CIRCLES AROUND
HER TO HER HEAD, WHERE
A MIGRAINE RAGES. THE
WORD "IMITREX" BENDS,
BONDS ON TO TABLET.

1.5 seconds 12

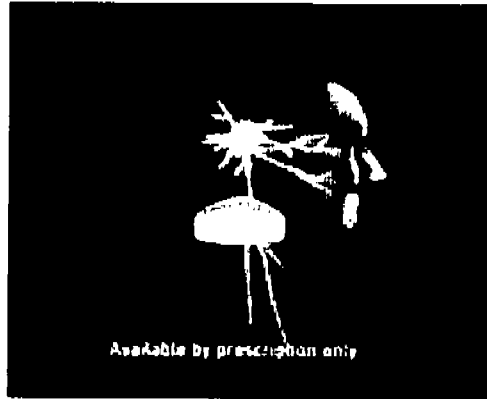


Imitrex is targeted.

TABLET FLIES TOWARD
STORM.

SUPER:
AVAILABLE BY PRESCRIP-
TION ONLY.

1.5 seconds 13



It was the first medicine of its
kind

TABLET DISAPPEARS IN
LIGHTNING EFFECT.

SUPER:
AVAILABLE BY PRESCRIP-
TION ONLY.

2 seconds 14



believed to target the nerves
and blood vessels

STORM DIMINISHES AS
THE WOMAN'S HEAD
TURNS TOWARD CAMERA.

SUPER: INDIVIDUAL
RESULTS MAY VARY.

1 second 15



that can trigger migraine

AND TURNS IN TO A REAL
WOMAN'S HEAD.

SUPER:
INDIVIDUAL RESULTS MAY
VARY.

2 seconds 16

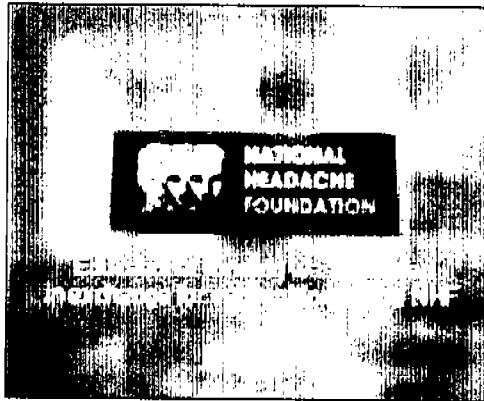


without drowsiness

NHF LOGO APPEARS OVER NOW QUIET NURSERY.

SUPER:
EDUCATIONAL FUNDING WAS PROVIDED IN EXCHANGE FOR RECOGNITION BY THE NHF

3.5 seconds 17



and it's recognized as an effective treatment by the National Headache Foundation.

NURSE PICKS UP QUIET BABY.

SUPER:
SEE OUR AD IN HEALTH 1-800-IMITREX AND PILL

3.5 seconds 18



WOMAN ANNCR (VO):
Imitrex is not right for everyone or every migraine.

NURSE PICKS UP QUIET BABY.

SUPER:
SEE OUR AD IN HEALTH 1-800-IMITREX AND PILL

3.5 seconds 19

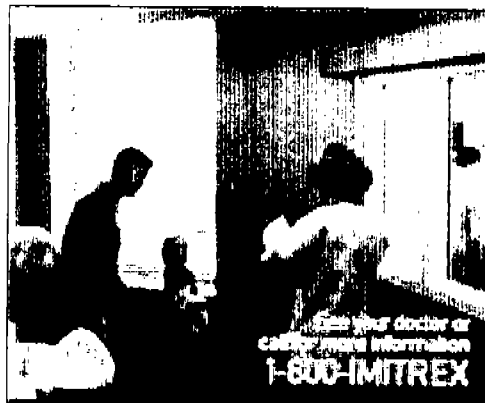


If you have certain types of heart or blood vessel disease or uncontrolled blood pressure

NURSE BRINGS BABY TO BABY'S FATHER AND SISTER.

SUPER:
SEE YOUR DOCTOR OR CALL FOR MORE INFORMATION 1-800-IMITREX AND PILL

3 seconds 20



you shouldn't take Imitrex. Very rarely certain people

FATHER AND SISTER
REACT.

SUPER:
SEE YOUR DOCTOR OR
CALL FOR MORE INFORMA-
TION
1-800-IMITREX AND PILL

3.5 seconds 21



—even some without heart
disease—have had serious
heart-related problems.

SISTER REACTS TO BABY.

SUPER:
www.imitrex.com
1-800-IMITREX AND PILL

3.5 seconds 22



So talk to your doctor,
especially if you have risk
factors for heart disease

FATHER TAKES A PICTURE.

SUPER:
www.imitrex.com
1-800-IMITREX AND PILL

2 seconds 23



such as smoking, high blood
pressure or high cholesterol

NURSE, BABY AND SISTER
POSE FOR PICTURE.

SUPER:
www.imitrex.com
1-800-IMITREX AND PILL

3 seconds 24



or if you are pregnant, nursing
or taking medication.

NURSE TALKS TO CAMERA.

2.5 seconds 25



NURSE: I can't let a migraine call the shots.

DOCTOR TALKS TO CAMERA

SUPER:
GSK LOGO

2 seconds 26



DOCTOR: Talk to your doctor

NURSE AT BASSINET SMILING.

IMITREX TABLET RISES UP
AND FLIES INTO PACKAGING
THAT HAS DISSOLVED ON TO
SCREEN.

SUPER:
TARGET YOUR TOTAL
MIGRAINE

3 seconds 27



and target your total migraine with Imitrex.