



The Role of Distraction in DTC Television Ads

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Division of Drug Marketing, Advertising,
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FDA

DTC National -- April 8, 2011 -- Boston, MA



Outline

- Introduction to DDMAC research program
- Description of Distraction study
- Distraction study findings
- Upcoming activities



DDMAC Research Program

Designed to:

- Answer questions of interest to the Agency
- Inform development of policies
- Improve public health



DDMAC Research Program

- Brief summary format
- Distraction
- Efficacy information
- Incentives
- Online
- Quantitative
- Toll-free broadcast



DDMAC Research Program

- Brief summary format
- **Distraction**
- Efficacy information
- Incentives
- Online
- Quantitative
- Toll-free broadcast



Distraction Study

Experimental Evaluation of the Role of
Distraction on Consumer
Understanding of Risk and Benefit
Information in DTC Television
Advertisements

FDA docket No. FDA-2007-N-0451



Distraction Study

- Kathryn (Kit) Aikin, Ph.D.
- Amie O'Donoghue, Ph.D.
- Helen W. Sullivan, Ph.D., M.P.H.
 - DDMAC, FDA
- Nancy Ostrove, Ph.D.
 - Office of the Commissioner, FDA
- Scott B. Douglas, M.P.P.
 - Office of the Assistant Secretary for Planning and Evaluation, HHS



Distraction Study

Purpose

- Role of textual elements in the processing of risk information
- Role of competing, compelling visual information in the processing of risk information
- How text and visuals influence processing of benefit information

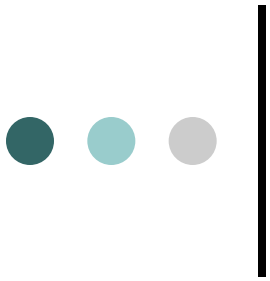


Distraction Study Specific Questions

Superimposed text (“Supers”)

- Shown against black banner
- Select risk words from audio
- 2 sizes of super





Distraction Study

Specific Questions

Emotional Tone Visuals

- Static logo - control
- Mildly positive images
- Strongly positive images



ZINTRIA

metoperiven hydroxylase











Strongly Positive



Strongly Positive



Strongly Positive



Distraction Study

Design 1

3 x 3 (tone by superimposed text)

		SUPER		
		None	Small	Large
TONE	Control			
	Mildly			
	Strongly			



Distraction Study

Specific Questions

Informational Visuals

- Static logo - control
- Consistent with risk information
 - somewhat and very
- Inconsistent with risk information
 - somewhat and very



ZINTRIA

metoperiven hydroxylase



ZINTRIA

metoperiven hydroxylase



- Don't Stop Taking It Suddenly
- Tiredness and Dizziness
- Blurry Vision

Consistent with Risk Information



ZINTRIA
metoperiven hydroxylase

- **Helps Lower Blood Pressure**
- **Can Reduce The Risk of Stroke or Heart Attack**
- **Take Only Once A Month**

Inconsistent with Risk Information



Distraction Study Design 2

5 levels (informational visuals)

Control
Very Consistent
Somewhat Consistent
Somewhat Inconsistent
Very Inconsistent



Distraction Study

Basic Study Parameters

- Internet study
- Sample: 2,134 people 40+
- View ad for fictitious high blood pressure medication, Zintria
 - Multiple experimental conditions
 - Within a “pod” of four ads
- Answer questions about the ad

ZINTRIA
AD VERSION 4
TCAR-MP2



Distraction Study Sample

- N = 2,134
- Men and women
- Approximately half had been diagnosed with high blood pressure
- Mean age = 57
- 30% of sample had high school education or less



Distraction Study

Design 1 Specific Questions

Related to superimposed text:

- Q1: Do *supers* that reinforce the audio risks facilitate risk comprehension?



Distraction Study

Design 1 Specific Questions

Related to emotional tone:

- Q2: Do visuals that vary in degree of positive tone influence how viewers feel about the product?
- Q3: Do visuals that vary in degree of positive tone influence understanding of risk?
- Q4: Does the presence of risk-reinforcing *supers* alter the affects of tonally positive visuals?



Dependent Measures

- Risk Comprehension (range: 0 to 11)
- Benefit Comprehension (range: 0 to 9)
- Attitude toward Drug (range: strongly disagree to strongly agree)
- Product-Related Affect (range: very negative/unpleasant/bad to very positive/pleasant/good)
- Behavioral Intention (no intention/some intention)



Estimated Marginal Means (*SE*) of Dependent Variables, by Super Condition

	No Super	Small Super	Large Super	Test Stat	p
N	462	451	454		
Risk Comprehension (0 to 11)	7.08 (0.20)	7.60 (0.20)	7.49 (0.20)	F(2,1351)= 8.11	<.001
Benefit Comprehension (0 to 9)	6.54 (0.18)	6.49 (0.18)	6.57 (0.18)	F(2,1351)= 0.21	0.81



Estimated Marginal Means (*SE*) of Dependent Variables, by Super Condition

	No Super	Small Super	Large Super	Test Stat	p
N	462	451	454		
Risk Comprehension (0 to 11)	7.08 (0.20)	7.60 (0.20)	7.49 (0.20)	F(2,1351)= 8.11	<.001
Benefit Comprehension (0 to 9)	6.54 (0.18)	6.49 (0.18)	6.57 (0.18)	F(2,1351)= 0.21	0.81



Estimated Marginal Means (*SE*) of Dependent Variables, by Super Condition

	No Super	Small Super	Large Super	Test Stat	p
N	462	451	454		
Attitude toward Drug (0 to 5)	3.03 (0.08)	2.95 (0.08)	2.96 (0.08)	F(2,1351)= 1.37	0.25
Product-Related Affect (0 to 5)	3.36 (0.09)	3.17 (0.09)	3.26 (0.09)	F(2,1285)= 4.85	0.01



Estimated Marginal Means (*SE*) of Dependent Variables, by Super Condition

	No Super	Small Super	Large Super	Test Stat	p
N	462	451	454		
Attitude toward Drug (0 to 5)	3.03 (0.08)	2.95 (0.08)	2.96 (0.08)	F(2,1351)= 1.37	0.25
Product-Related Affect (0 to 5)	3.36 (0.09)	3.17 (0.09)	3.26 (0.09)	F(2,1285)= 4.85	0.01

Percent of Participants who Expressed Some Behavioral Intention, by Super Condition

	No Super	Small Super	Large Super	Test Stat	p
N	462	451	454		
Behavioral Intention	37.7	32.4	37.2	$X^2(2)=$ 1.37	0.25

*Intention to talk to doctor and look for more information about Zintria



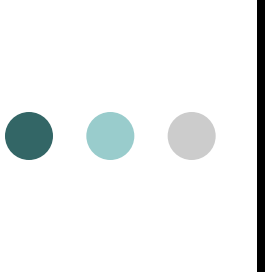
Estimated Marginal Means (*SE*) of Dependent Variables, by Tone Condition

	Static Logo	Mildly Positive	Strongly Positive	Test Stat	p
N	458	453	456		
Risk Comprehension (0 to 11)	7.34 (0.20)	7.55 (0.20)	7.21 (0.21)	F(2,1351)= 2.04	0.13
Benefit Comprehension (0 to 9)	6.49 (0.18)	6.59 (0.18)	6.51 (0.18)	F(2,1351)= 0.37	0.69



Estimated Marginal Means (*SE*) of Dependent Variables, by Tone Condition

	Static Logo	Mildly Positive	Strongly Positive	Test Stat	p
N	458	453	456		
Attitude toward Drug (0 to 5)	2.99 (0.08)	2.95 (0.08)	3.00 (0.08)	F(2,1351)= 0.67	0.51
Product-Related Affect (0 to 5)	3.26 (0.09)	3.19 (0.09)	3.34 (0.10)	F(2,1285)= 3.12	0.04



Estimated Marginal Means (*SE*) of Dependent Variables, by Tone Condition

	Static Logo	Mildly Positive	Strongly Positive	Test Stat	p
N	458	453	456		
Attitude toward Drug (0 to 5)	2.99 (0.08)	2.95 (0.08)	3.00 (0.08)	F(2,1351)= 0.67	0.51
Product-Related Affect (0 to 5)	3.26 (0.09)	3.19 (0.09)	3.34 (0.10)	F(2,1285)= 3.12	0.04

Percent of Participants who Expressed Some Behavioral Intention, by Tone Condition

	No Super	Small Super	Large Super	Test Stat	p
N	462	451	454		
Behavioral Intention	37.7	32.4	37.2	$X^2(2)=$ 3.06	0.22

*Intention to talk to doctor and look for more information about Zintria



Distraction Study

Design 1 Specific Questions

- Q1: Do *supers* that reinforce the audio risks facilitate risk comprehension?
 - Yes, supported
- Q2: Do visuals that vary in degree of positive tone influence how viewers feel about the product?
 - Yes, supported



Distraction Study

Design 1 Specific Questions

- Q3: Do visuals that vary in degree of positive tone influence understanding of risk?
 - No, not supported
- Q4: Does the presence of risk-reinforcing *supers* alter the affects of tonally positive visuals?
 - No, not supported



Distraction Study

Design 2 Specific Questions

Related to informational visuals:

- Q5: Do visuals that are inconsistent with the major statement interfere with risk comprehension?
- Q6: Do visuals that are consistent with the major statement facilitate risk comprehension?



Estimated Marginal Means (*SE*) of Dependent Variables, by Visual Condition

	Static Logo	Very Consist	Somewhat Consist	Somewhat Inconsist	Very Inconsist	Test Stat	p
N	154	159	152	151	151		
Risk Comp (0 to 11)	7.47 (0.32)	7.52 (0.31)	7.26 (0.32)	7.17 (0.31)	6.84 (0.32)	F(4,755) = 0.52	0.72
Benefit Comp (0 to 9)	6.48 (0.29)	6.36 (0.28)	6.60 (0.28)	6.74 (0.28)	7.25 (0.29)	F(4,755) = 3.77	.005



Estimated Marginal Means (*SE*) of Dependent Variables, by Visual Condition

	Static Logo	Very Consist	Somewhat Consist	Somewhat Inconsist	Very Inconsist	Test Stat	p
N	154	159	152	151	151		
Risk Comp (0 to 11)	7.47 (0.32)	7.52 (0.31)	7.26 (0.32)	7.17 (0.31)	6.84 (0.32)	F(4,755) = 0.52	0.72
Benefit Comp (0 to 9)	6.48 (0.29)	6.36 (0.28)	6.60 (0.28)	6.74 (0.28)	7.25 (0.29)	F(4,755) = 3.77	.005



Estimated Marginal Means (*SE*) of Dependent Variables, by Visual Condition

	Static Logo	Very Consist	Somewhat Consist	Somewhat Inconsist	Very Inconsist	Test Stat	p
N	154	159	152	151	151		
Attitude toward drug (0 to 5)	2.93 (0.71)	2.85 (0.13)	2.89 (0.13)	2.96 (0.13)	2.88 (0.13)	F(4,755) = 0.51	0.73
Product Related Affect (0 to 5)	3.32 (0.16)	3.27 (0.16)	3.29 (0.16)	3.47 (0.16)	3.34 (0.16)	F(4,714) = 1.07	0.37

Percent of Participants who Expressed Some Behavioral Intention, by Visual Condition

	Static Logo	Very Consist	Somewhat Consist	Somewhat Inconsist	Very Inconsist	Test Stat	p
N	154	159	152	151	151		
Behavioral Intention	42.9	44.7	40.8	39.7	46.4	$X^2(4)=$ 1.83	0.77

*Intention to talk to doctor and look for more information about Zintria



Distraction Study

Design 2 Specific Questions

- Q5: Do visuals that are inconsistent with the major statement interfere with risk comprehension?
 - No, not supported (but trended in this direction)



Distraction Study

Design 2 Specific Questions

- Q6: Do visuals that are consistent with the major statement facilitate risk comprehension?
 - No, not supported (but trended in this direction)



Distraction Study Limitations

- Mock ads not as originally conceptualized
- Manipulations were subtle



Distraction Study Implications

- Findings regarding *supers* are clear
 - *supers* facilitate comprehension
- Findings about visuals are much less clear
 - Tone influenced product-related affect but not understanding of risk
 - Visual consistency influenced benefit comprehension but not understanding of risk



Distraction Study

Next Steps

- Directions for future research
 - Correct mock ad issues
 - Utilize stronger manipulations



Upcoming Data

- Quantitative study
- Toll-Free Statement study
 - Both nearing completion
 - Results expected within the next 6 months



Contact Information

email:

amie.odonoghue@fda.hhs.gov

DDMAC research page:

[http://www.fda.gov/AboutFDA/CentersOffices/
CDER/ucm090276.htm](http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090276.htm)



*Direct-to-Consumer
Promotion:
DDMAC Update*

Michael Sauers

Group Leader, DTC1

FDA/CDER/DDMAC

DTC National Conference

April 8, 2011



Direct-to-Consumer Promotion

- Annual Update on DDMAC Organizational Structure
- Submission Totals
- Bad Ad Program
- DTC Enforcement
- Advisory Process Basics

The Division of Drug Marketing, Advertising, and Communications

Director's Office

Director, Thomas Abrams

Deputy Director, vacancy

Associate Director, Mark Askine

Associate Director of Operations, Marci Kiester

Management Advisor, Catherine Gray

Management Advisor, Robert Dean

Special Assistant, Jean-Ah Kang

Program Specialist, Becki Vogt

Regulatory Counsel Team Leader, Sangeeta Vaswani

Regulatory Counsel, Marissa Chaet Brykman

Regulatory Counsel, Julie Burger Chronis

Regulatory Counsel, Bryant Godfrey

Regulatory Counsel, Ernest Voyard

Evidence Review & Division Support, Elaine Cunningham

Regulatory Project Manager, Olga Salis

Regulatory Project Manager, Michael Wade

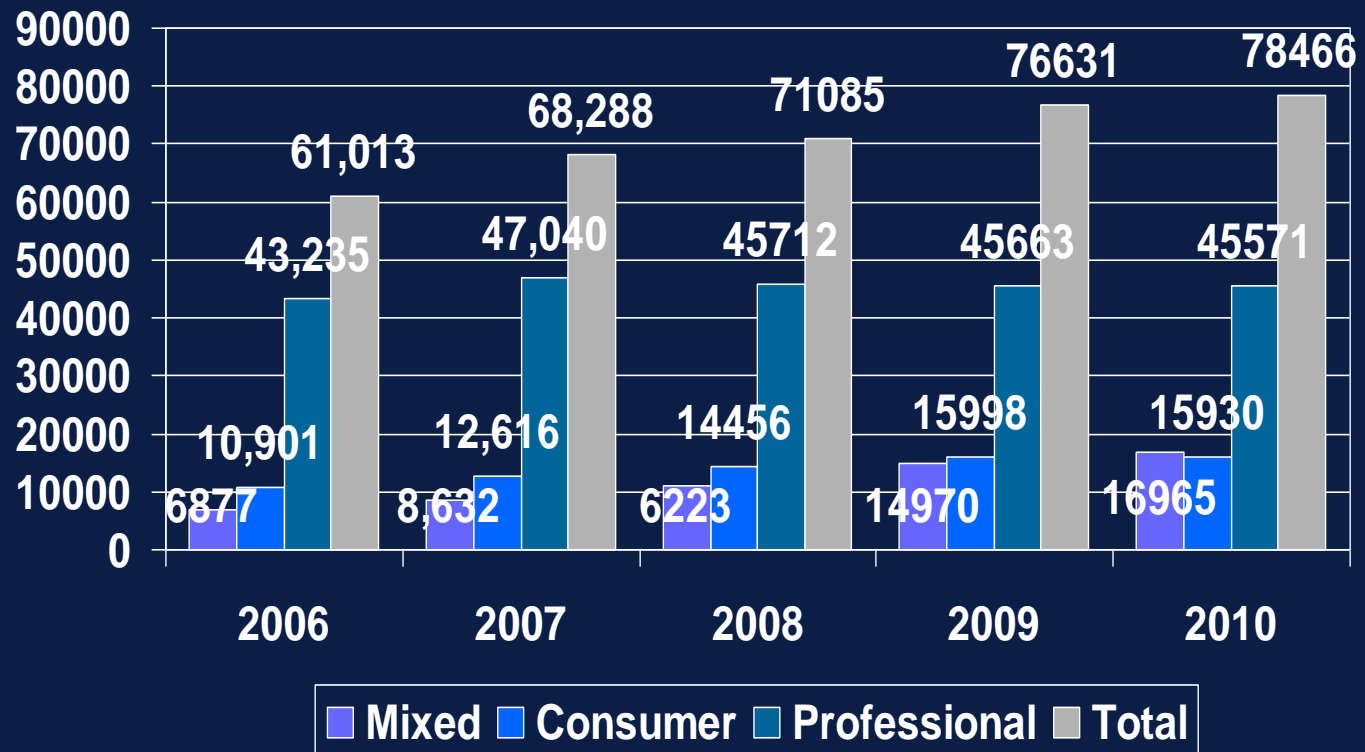
Training & Support, Barbara Chong

TIA, Janet Daly

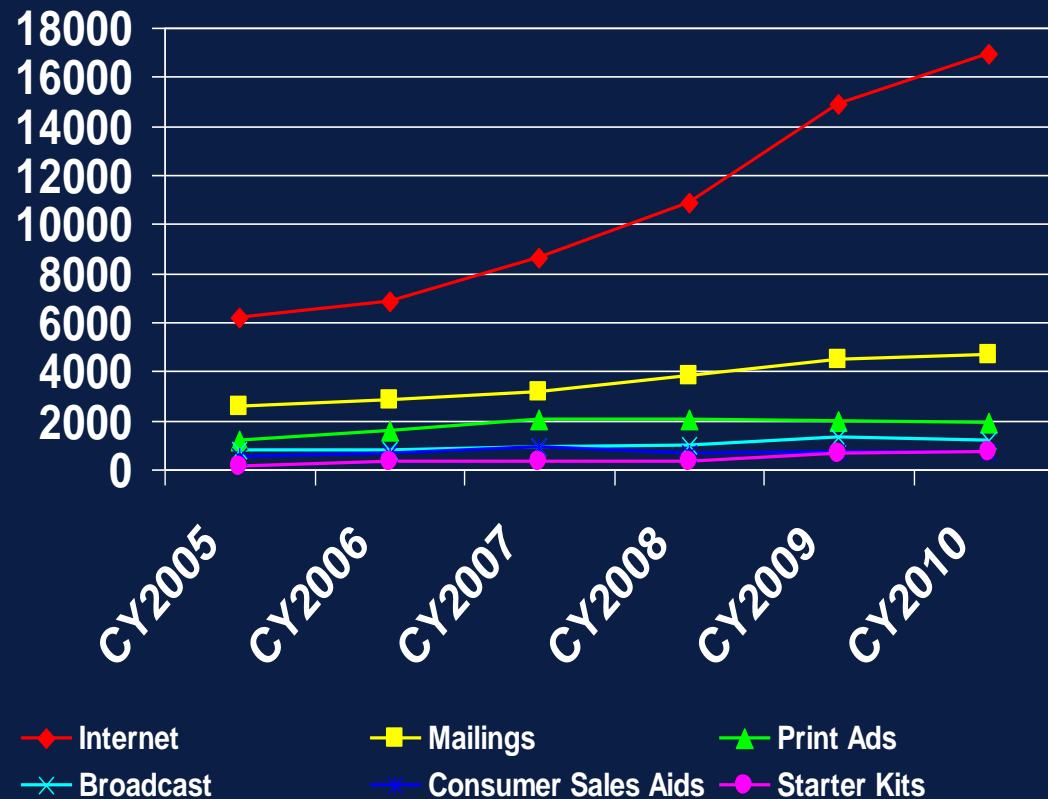
TIA, Sharon Smith

Professional Review Group I Leader Andrew Haffer	Professional Review Group II Leader Karen Rulli	Professional Review Group III Leader Lisa Hubbard	Professional Review Group IV Leader Sheila Ryan	Direct-To-Consumer Review Group I Leader Michael Sauers	Direct-To-Consumer Review Group II Leader (acting) Robyn Tyler	Direct-To-Consumer Review Group III Leader Shefali Doshi	Direct-To-Consumer Review Group IV Leader Amy Toscano
Neurology (Quynh-Van Tran)	Oncology Drugs: Solid tumors (Vacancy)	Pulmonary, Allergy, Rheumatology (Roberta Szydlo)	Cardiovascular and Renal (Emily Baker)	Reproductive (Carrie Newcomer)	Neurology (Sharon Watson, Vacancy)	Anesthetics, Analgesics, Rheumatology, (Twyla Thompson)	Cardiovascular and Renal (Zarna Patel)
Oncology Biologics (Carole Broadnax)	Oncology Drugs: Hematologic Cancers (Adam George, Nisha Patel)	Analgesics, Anesthetics (Mathilda Fienkeng)	Anti-Infectives, Ophthalmology, Special Pathogens, Transplant (Christine Corser)	Psychiatry (Susannah Hubert)	Pulmonary, Allergy (Mathew Falter)	Gastroenterology (Vacancy)	Oncology Drugs (Vacancy)
Reproductive, Urology (Janice Maniwang)	Hematology, Medical Imaging (James Dvorsky)	Metabolism and Endocrinology (Samuel Skariah)	Antivirals (Jessica Fox)	Urology (Osteo, Other), Antivirals, Special Pathogens, Transplant (Michelle Safarik)	Urology (Beth Carr)	Oncology Biologics (Vacancy)	Hematology, Medical Imaging, Anti-Infectives, Ophthalmology (Adora Ndu)
Psychiatry (Jessica Cleck Derenick)		Gastroenterology (Kathleen Klemm)	Dermatology, Dental (Lynn Panholzer)	Dermatology, Dental (Sheetal Patel)	Research Team (Kathryn Aikin, Amie O'Donoghue, Helen Sullivan)	Metabolism and Endocrinology (Kendra Jones)	(Vacancy)

of Final Promotional Pieces Submitted (2253s) 2006 - 2010



Direct-to-Consumer Drug Advertising Trends





The Bad Ad Program

- The Bad Ad Program is an FDA-sponsored outreach program designed to educate HCPs about the role they can play in helping FDA ensure that prescription drug advertising and promotion is truthful and not misleading.
- When HCPs recognize misleading drug promotion, they can help put a stop to it by reporting it to FDA:
 - Call
 - **877-RX-DDMAC (877-793-3622)**
 - Email
 - **BadAd@fda.gov**



The Bad Ad Program

- While the program is targeted at HCPs, that does not limit the type of misleading promotional materials HCPs can report to us
- HCPs and other healthcare professionals can recognize misleading DTC promotion and report it to the Bad Ad program
- Approximately 28% of the Bad Ad complaints received by DDMAC (and falling under our purview) have been regarding potentially misleading DTC advertising and promotion



Recent DTC Enforcement

- Premarin
- Vivitrol
- Ovide
- Derma-Smoothe/FS (Body Oil)



Premarin Untitled Letter

- In August of 2010, DDMAC issued an Untitled Letter to Wyeth for misleading patient testimonials that were embedded in the Premarin website. The violations were:
 - Overstatement of Efficacy
 - Minimization of Risk



Premarin Untitled Letter

Indications:

- Treatment of moderate to severe vasomotor symptoms due to menopause.
- Treatment of moderate to severe symptoms of vulvar and vaginal atrophy due to menopause. When prescribing solely for the treatment of symptoms of vulvar and vaginal atrophy, topical vaginal products should be considered.

Clinical Studies:

- Patients taking Premarin experienced a reduction of 9 - 11.5 hot flashes per day at the end of the 12 week study.
- The mean # of hot flashes for Premarin patients at the end of the study was between 0.75 - 2.5 hot flushes per day.



Premarin Untitled Letter

Overstatement of Efficacy:

- *“I said, ‘How would being on Premarin affect me?’ She [Mary’s physician] said, ‘**You’re not going to go through menopause. You won’t have hot flashes. You won’t have any type of discomfort. And it would actually circumvent being on menopause at all.**’ And I said, ‘Great.’”*
- *“After surgery, for those 4 or 5 days that I was without any type of hormone therapy, I had some sensations that I’m really grateful I’m not going to go through. **After a few days when the hormone therapy started to get into my system, it was gone.**”*



Premarin Untitled Letter

Overstatement of Efficacy:

- *“It for me was an issue between my husband and myself . . . the vaginal dryness was very uncomfortable for me. . . . I went to my doctor. She put me on Premarin. She put me on the lowest dose. **I noticed the changes immediately. I didn’t experience any more dryness, any vaginal dryness. That was just gone.**”*



Premarin Untitled Letter

Overstatement of Efficacy:

- *“My life after Premarin became absolutely different. . . . I got up feeling like the day is better.”* (Connie)
- *“I started feeling very much alive again.”*
(text next to video of Rochelle’s testimonial)
- *“PREMARIN brought my life back into a normal balance and I thought it made it more bearable.”* (text next to video of Jeanne’s testimonial)



Premarin Untitled Letter

Minimization of Risk:

- These patient testimonials presented audio efficacy claims for the drug, but no risk information
 - Risk information was presented below the testimonial in text-format; however, this was unlikely to draw the viewers attention and not comparably prominent to the claims of efficacy (audio).



Vivitrol Untitled Letter

- In November of 2010, DDMAC issued an Untitled Letter to Alkermes for a misleading Patient Welcome Kit which included patient testimonials and a patient brochure. The violations were:
 - Overstatement of Efficacy
 - Minimization of Risk
 - Inadequate Communication of Indication
 - Failure to Provide Adequate Directions for Use



Vivitrol Untitled Letter

Indication:

- Treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with VIVITROL.
 - Patients should not be actively drinking at the time of initial VIVITROL administration.
 - Treatment with VIVITROL should be part of a comprehensive management program that includes psychosocial support.

Risks:

- Boxed Warning on Hepatotoxicity; as well as other Contraindications, Warnings, and Precautions



Vivitrol Untitled Letter

Overstatement of Efficacy:

- *“It [Vivitrol] sounded like something that I wanted to try....I’m really much more present, I’m much more positive. I’m a much better dad.”*
- *“... It really did help my relationships to go on Vivitrol.”*
- *“Julie at the clinic, she suggested Vivitrol. . . . Since I’ve been on the shot. . . . I feel better about myself now that I’m sober. I’ve got a little bit more respect from the kids and that I feel like a mother now. Physically I’m in better shape than I was. . . . Couldn’t even crawl out of bed and now I’m back to work. . . . My life has changed so much in the past year. I’ve gotten remarried.”*



Vivitrol Untitled Letter

Overstatement of Efficacy:

- Jason S: “Received VIVITROL therapy for **12 months**”
- Tina S: “Received VIVITROL therapy for **18 months**”
- Chris J: “Received VIVITROL therapy for **12 months**”
- However, Vivitrol clinical trials evaluated the drug in a 24-week study of alcohol dependent outpatients (6 months)
 - FDA is not aware of substantial evidence demonstrating effectiveness of Vivitrol beyond 24 weeks.



Vivitrol Untitled Letter

Inadequate Communication of Indication:

- *“Your doctor has prescribed VIVITROL to target the biologic urge to drink. To be effective, treatment with VIVITROL must be used along with other alcohol recovery measures, such as psychosocial counseling, mutual support, and faith-based groups.”*
- Fails to include important limitations to the indication that the drug is for patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment and that patients should not be actively drinking at the time of administration.
 - Also, above claim is presented on page 10 of 24 page brochure



Vivitrol Untitled Letter

Minimization of Risk:

- Patient testimonials presented audio efficacy claims for the drug, but no audio risk information
 - Risk information was presented after the testimonials towards the end of the video in a telescript format with rapidly scrolling text in small font; where it was unlikely to draw the viewers attention
- Also presented testimonial of a 30-yo patient “with alcohol dependence and a **history of liver problems.**”
 - Minimizes the Boxed Warning risk of Hepatotoxicity



Ovide Untitled Letter

- In March of 2011, DDMAC issued an Untitled Letter to Taro Pharmaceuticals for a children's storybook. The violation cited was:
 - Omission of Risk

There's a Louse in My House



TaroPharma™

OVIDE
(malathion)
LOTION, 0.5%

Prescribe with Confidence

There's a Louse in My House



TaroPharma™

OVIDE
(malathion)
LOTION, 0.5%

Prescribe with Confidence





Derma-Smoothie Warning Letter

- In December of 2010, DDMAC issued a Warning Letter to Hill Dermaceuticals for a violative website. This was the first enforcement resulting from a Bad Ad program complaint. The violations cited were:
 - Overstated efficacy
 - Omitted/Minimized risk
 - Presented Unsubstantiated Superiority claims
 - Broadened the indication



Derma-Smoothie Warning Letter

Indication:

- Topical treatment of moderate to severe atopic dermatitis in pediatric patients, 3 months and older for up to 3 weeks
 - Also states to apply the least amount of Derma-Smoothie to cover the affected areas, and not to apply to the diaper area, face, axillae, or groin unless directed

Warning:

- The systemic absorption of topical corticosteroids can produce reversible **hypothalamic-pituitary-adrenal (HPA) axis suppression** with the potential for glucocorticosteroid insufficiency...Children may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.

[skin problems we treat](#)

[products](#)

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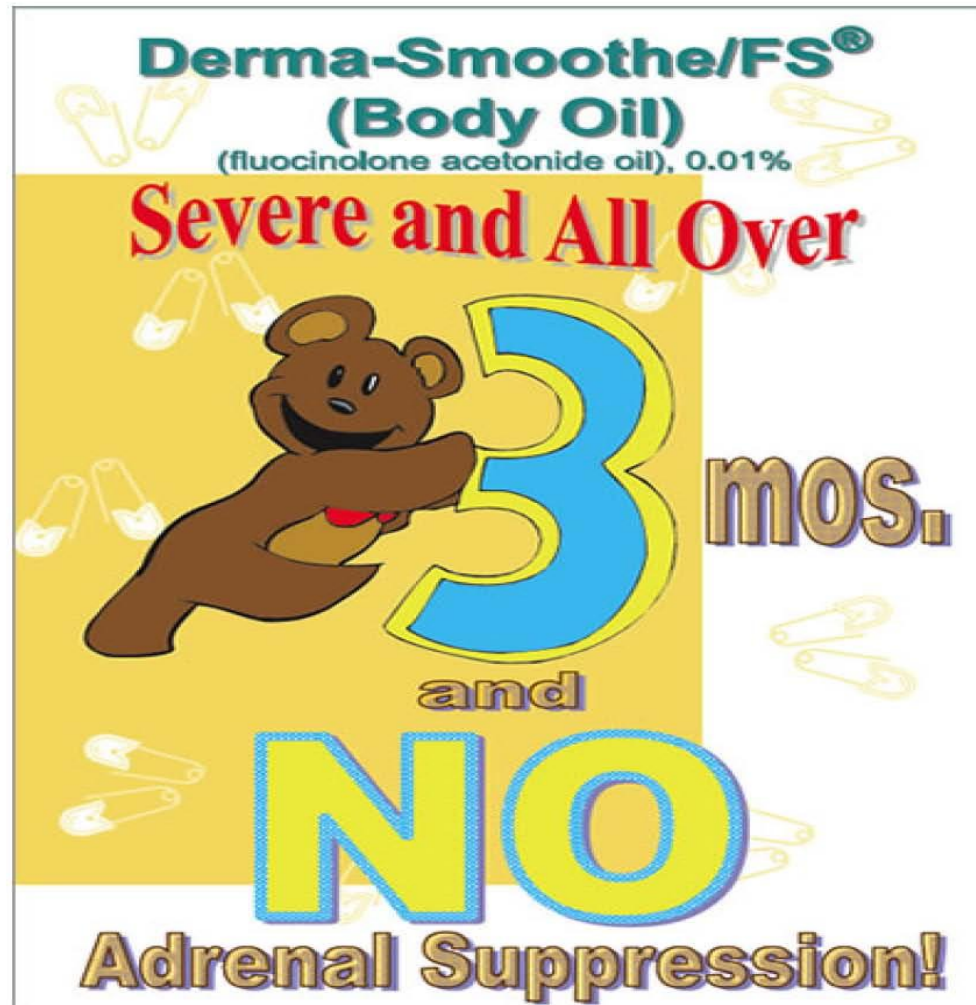


Effective. Safe. Affordable.
Hill Dermaceuticals changes lives

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Pediatric Atopic Dermatitis

- Diseases We Treat
[Main](#)
- Scalp Psoriasis
- Eczema/Atopic Dermatitis
- Pediatric Atopic Dermatitis
- Itchy Ears
- Non-Prescription Products For:
 - Excessive Sweating
 - Oily Skin, Oily Hair
 - Dry Itchy Skin



Derma-Smoothe/FS[®]
(Body Oil)
(fluocinolone acetonide oil), 0.01%

Severe and All Over

3 mos.
and
NO
Adrenal Suppression!



[ONLINE STORE >>](#)

[Non-Prescription Products](#)



Derma-Smoothe/FS[®] (Body Oil)

(fluocinolone acetonide oil), 0.01%

The only product for patients 3 months and older that can be used when their eczema is severe and all over!

Go Beyond the Itch!!

- ✓ The refined peanut oil vehicle repairs the skin barrier function by driving moisture into the skin, which is the key to treating the disease.
- ✓ The only corticosteroid that does not cause adrenal suppression, even when used over 90% of the body!
- ✓ Patient cost is only \$45.00 for a full course of treatment!



Update on Internet/Social Media Promotion

- DDMAC has identified the following issues for guidance and policy development:
 - Responding to unsolicited requests
 - Fulfilling regulatory requirements when using tools associated with space limitations
 - Fulfilling post-marketing submission requirements
 - On-line communications for which manufacturers, packers, or distributors are accountable
 - Use of links on the Internet
 - Correcting misinformation



Advisory Review Goals

- Core Launch Materials – 45 calendar days, excluding review division consults.
- TV ads – 45 calendar days for new product, new indication, first time on TV, important safety update



What are Core Launch Materials?

- Professional

- 1 physician directed labeling piece (no more than 12 pages)
- 1 physician directed journal ad (no more than 4 pages)



What are Core Launch Materials?

- Consumer

- 1 comprehensive labeling piece such as a patient brochure (no more than 12 pages)
- 1 consumer directed journal ad (no more than 4 pages)



What are Core Launch Materials?

- Websites

- No more than 12 pages for Consumers
- No more than 12 pages for Professionals
- Should be similar to core sales aid or patient brochure



Current Review Priorities

- Reviewing voluntary submissions of TV ads as quickly as resources permit
- Current priorities
 - Egregious Violative Promotion (once identified)
 - Labeling reviews and risk information updates
 - First TV ad for a product/indication and subpart H launches – initial core pieces
 - Non-subpart H launches – initial core pieces
 - Other TV ads and other Subpart H launches and non launches
 - Other launch advisories
 - Other advisories



Tips for How to Submit to DDMAC

- Address:
 - Food and Drug Administration
 - Center for Drug Evaluation and Research
 - Division of Drug Marketing, Advertising and Communications**
 - 5901-B Ammendale Road
 - Beltsville, MD 20705
- Include a “DDMAC” sticker or other prominent directional notation on the exterior of the package and on the cover letter itself
- Be sure your submission is “complete”
- Currently not accepting electronic submission of any promotional materials over the ESG



Tips for How to Submit to DDMAC

- Consult DDMAC's website prior to submitting materials
(<http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>)
- For time sensitive materials, please confirm receipt of the submission to DDMAC with a phone call to the project manager or appropriate reviewer (301-796-1200)