
From: Nathalie Leitch
Sent: Thursday, May 13, 2010 1:15 PM
To: Terrence Fullem
Subject: FW: Kadian re-launch budget
Attachments: Kadian Relaunch selected.doc; Kadian Direct Mail.doc

Hi – Z&J provided some additional info re a direct mail program in the attached. I think this is a better option for us than a media campaign. I like the combined mail/sales rep program concept.

Nathalie Leitch
Director, Specialty Rx Products



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From: Tom Johnson [<mailto:tj@adwise.com>]
Sent: Tuesday, May 11, 2010 4:19 PM
To: Nathalie Leitch
Cc: Angela Johnson
Subject: Kadian re-launch budget

Hello Nathalie,

Attached is the revised re-launch budget as per our discussion last week. Also attached is a more detailed description of the direct mail program.

We have received the competitive marketing materials. We will send you two binders containing the materials for your reference. A quick review of them shows that Opana ER is much more aggressive than Embeda.

I look forward to receiving the confidentiality agreement and the production approval PO so we can get started. Thanks again for thinking of Z&J. Hopefully this is the beginning of a very long, mutually beneficial relationship.

Tom Johnson
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CLIENT: Actavis

DATE: May 11, 2010

CONTACT: Nathalie Leitch

Project Outline:

Kadian (morphine sulfate extended-release) Capsules, CII Re-Launch

Situation: Actavis received a fax letter from FDA in February, 2010 regarding Kadian (morphine sulfate extended-release) Capsules, CII. As a result, all Kadian promotional literature has been pulled from circulation and a letter explaining the FDA objections has been mailed to physicians nationally.

Actavis has decided to re-launch Kadian with purposely conservative marketing materials. Black box rules will be strictly followed and fair balance will be used throughout the materials. Claims will be limited to those included in Kadian prescribing information.

Re-Launch Components:

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|--|-------------------------------|
| Competitor Marketing Materials Acquisition | Detail Aid |
| Conversion Guide | Patient Rebate Carrier |
| Dosing Guide | Physician Direct Mail Program |
| Patient Consultation Booklet | |

Competitor Marketing Materials Acquisition

Competitive marketing materials have been ordered.

Total Cost: \$8,610

Detail Aid

A new detail aid will be developed. The existing detail aid was pulled from circulation after receipt of the FDA letter. It did not present black box warnings appropriately, It did not present Important Safety Information appropriately and it used questionable studies according to FDA.

The design of the new detail aid will begin with a full review and discussion of the existing claims as compared to materials used by competitive products. The new detail aid should be designed to compete. If competitors rely on substantial claims, it may be important to meet with FDA to review Kadian's desired claims as compared to competitive claims.

A selection of new layouts will be submitted. The choice will range from similar to existing Kadian literature, to a completely new design. The selected design will be used for all future literature design.

Estimated Budget

New Image Creative Design	\$6,500
Layout, Design Comp	2,400
Mechanical Production	3,200
Photography (stock or existing for retouch)	2,800
Copywriting	1,800
Traffic	680
Art Sub-Total	\$ 10,880

Printing will be quoted after design work is approved.

Conversion Guide

The existing conversion guide is a valuable tool for reps and physicians. However, it does not meet black box and fair balance requirements. We recommend a quick re-design of the conversion guide to remove unnecessary statements and add the proper warnings. Before undergoing this redesign we would want confirmation that the actual conversion recommendations meet FDA guidelines for accuracy.

Art re-design Budget (assuming the original art is available)	\$ 7,400
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This piece also needs to reach the field quickly. A redo of the existing piece can be completed quickly. Over time, we recommend expanding to individual product conversion pages for use in targeting high prescribers of certain products who also occasionally prescribe Kadian. Highly targeted mailing lists will be purchased to accomplish this.

Patient Rebate Carrier

FDA rejected the reprint carrier. A new simple carrier should be designed. The new carrier should focus only on redemption of the rebate card, Patients get the card after they are prescribed Kadian. There is no need to report on pain and pain relief choices. This project will be delayed until existing card inventory is reduced.

Art Budget	\$1,200
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Dosing Guide

A basic dosing guide should be available to physicians. The guide will include dosing as described in the PI and the appropriate black box and Important Safety Information.

Art Budget: 4,200

Physician Direct Mail Program

A direct mail program is recommended. Direct mail is a strong tool to supplement the sales force efforts and the other marketing efforts. Direct mail works as a consistent reminder of Kadian's benefits to patients between sales force visits and to physicians the sales force may not reach. We recommend a six wave campaign to the target physician audience. Each wave will be designed to achieve maximum top-of-mind awareness. Dimensional mailers will be included as well as mailers designed to distribute the dosing card, conversion guide and other valued tools.

Z&J will prepare a brief slide presentation of the direct mail and sales support program for the Kadian sales meeting. This will invite sales force input.

There will be no charge for the slide development. See separate page for final direct mail/sales support estimate.

Patient Consultation Booklet

When physicians prescribe a new drug they speak with the patient about the purpose and proper usage of the drug. The Patient Consultation Booklet is a hand held kit that the physician will use to detail the drug to the patient. The kit includes flash cards with product facts and information in a concealed pocket for physician use, a dosing card, tear-off FAQ page for distribution to the patient and complete P.I. and safety information.

The booklet uses a high-end leather or leather-like folder to ensure physician re-use.

Art Budget 9,800

Total re-launch art budget: \$ 48,590

The estimate does not include printing, original photography or original illustrations.

CLIENT: Actavis

DATE: May 11, 2010



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CONTACT: Nathalie Leitch

PROJECT COST ESTIMATE:

Kadian Direct Mail Program

Situation: After discussion with Nathalie, Zuchelli & Johnson did a brief review of journal advertising versus direct mail costs. While it is always better to utilize direct mail and media simultaneously; when the budget will not allow, it is prudent to compare them.

We have concluded that an effective media campaign would require an annual budget between \$600,000 and \$1,000,000. We feel better results can be realized with a direct mail campaign (described below) and support media. The support media budget suggested is \$300,000. The direct mail budget and outline is detailed below.

Six Wave Direct Mail Component List

Up to 5,000 high-prescribing physicians will be targeted.
Waves will be mailed every fifteen days.

Wave One: Creative Visual Letter

In letter form with a creative, attention getting layout. It will be mailed in an oversize envelope with a teaser line. This format is used first because it represents a balance between a formal letter and a traditional direct mail piece. Some physicians are more attracted to letters, while others are more attracted to creative mailers. This format seeks to satisfy both types of physician.

Wave Two: Dimensional Mailer

A dimensional mailer can be a pop-up, a slide chart or other type of interactive mailer. They are designed to get attention. Also, if a nurse or receptionist opens the mail, dimensional mailers are designed to create conversation (“Hey, look at this”) to increase the chance that the physician will see it.

Wave Three: Dimensional Mailer

Will include an article reprint (if available.) This increases the chance that a letter opening receptionist will pass it along to the physician.

Wave Four: Dimensional Mailer

All mailings will include offers for items such as the dosing card and conversion guide. Returned cards will be tracked to measure interest, but all targeted physicians will receive the giveaways beginning with mailing number four.

Wave Five: Maintenance mailer with conversion guide

Wave Six: Recap mailer with giveaway offers.

Budget:

The budget is calculated as a turn-key project managed by Zuchelli & Johnson, including research, concept, creative, production, printing, mailing.

Targeted Physician Mail Campaign	\$180,000
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Note:

The budget is a “ceiling-estimate.” It will not exceed \$180,000 and every effort will be made to reduce costs wherever possible. Z&J is proud to state that we come in under the quoted budget on more than 90% of the projects we handle of this size.

Sales Force Support

The direct mail components can be wrapped around a sales force support program to maximize the awareness impact of the mailings and sales visits. The mailing list will be split between sales force target physicians and other physicians. The non-targeted physicians will receive direct mail as described above. The sales force targeted physicians will receive the following:

- The wave one letter mailing will be a custom letter from the representative. It will be mailed immediately after an office visit. This will mean the mailings to sales force targeted physicians will have a varied schedule.
- When BRC cards are received from these physicians, the giveaway (dosing card, etc) will be delivered by the representative. The carrier will be a non-dimensional version of the direct mailer. The dimensional mailers are designed to get attention when a sales representative is not present.
- A second custom rep letter will be mailed after the rep visit that results in delivery of the dosing card.
- The balance of the direct mail program will follow the schedule above.

Sales Force Component Budget (includes design and administration of program)
Estimated three months @ \$2,200 per month \$6,600
Postage and letter printing will be extra, based on volume.

Total Direct Mail Budget (three options)

Option A: Direct Mail with Media Support and Sales Force Support	\$486,500
Option B: Direct Mail with Sales Force Support	\$186,500
Option B: Direct Mail only	\$180,000

Postage and letter printing for the sales force component will be extra, based on volume