# Probabilized Timeline for FDA Approval of Zyprexa™

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## Submission of NDA

- **10%**
- **50%**
- **90%**

Assumptions on 1/2/96: February FDA Advisory Committee hearing, and no approvable letter

- **10%**
- **50%**
- **90%**

Assumptions on 1/22/96: No February FDA Advisory Committee hearing, we will receive approvable letter, all sectional reviews at FDA targeted for 3/15

* Probability of approval by this date

BSM/sjc

01/23/96
Need to integrate.

Much reason to be optimistic.

Maggie Ban

Can any component be viewed in isolation? What is cost of premature launch prep on COPs/other products? Nothing happens.

Ranges (home on the range)

Similar proj. in div. for other affiliate?

Are other affiliates receiving same level of attention from core team on regul. aspects (ie global launch team)?

PDUFA = 12 mo.

Fastest ever div. this div. = 20 mos (avg = 36 mos)

Recent productivity = 1/5 of q4 subm.

(to our advantage - under pressure to produce)

Frank met with Gary Beth

Trademark - GT/me & Temple
Projected U.S Zyprexa™ FDA Approval -- Cumulative Probability

NOTE: 1. High-lighted region as resolution on February Advisory Committee slot and question of "no-approvable" letter
2. July data could move forward in current estimate with continued proactive dialogue with FDA. 

January 22, 1996

BSM/sjc

Involve RNP

Rassess March

BSM/sjc

cost of sooner

BSM/sjc

Julu 50% launch qual. (sooner if 3 is FDA review final)

Conting plan dating

Actions

- Revisit timeline
- 8/12 m.o.
- I will share new info as before

New info = no Adv Comm?

Trademk (P.Temple)

Approv. letter

Assessing assump.

Trademark Values

P.R.R.

Approvable

% prob. triggering

Sales force

Mitch

non staff

30 min

Frank D

NIW

Call Alan Clarke

Gary T

Beth Morris 6-1109
Projected U.S Zyprexa™ FDA Approval -- Cumulative Probability

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January 22, 1996