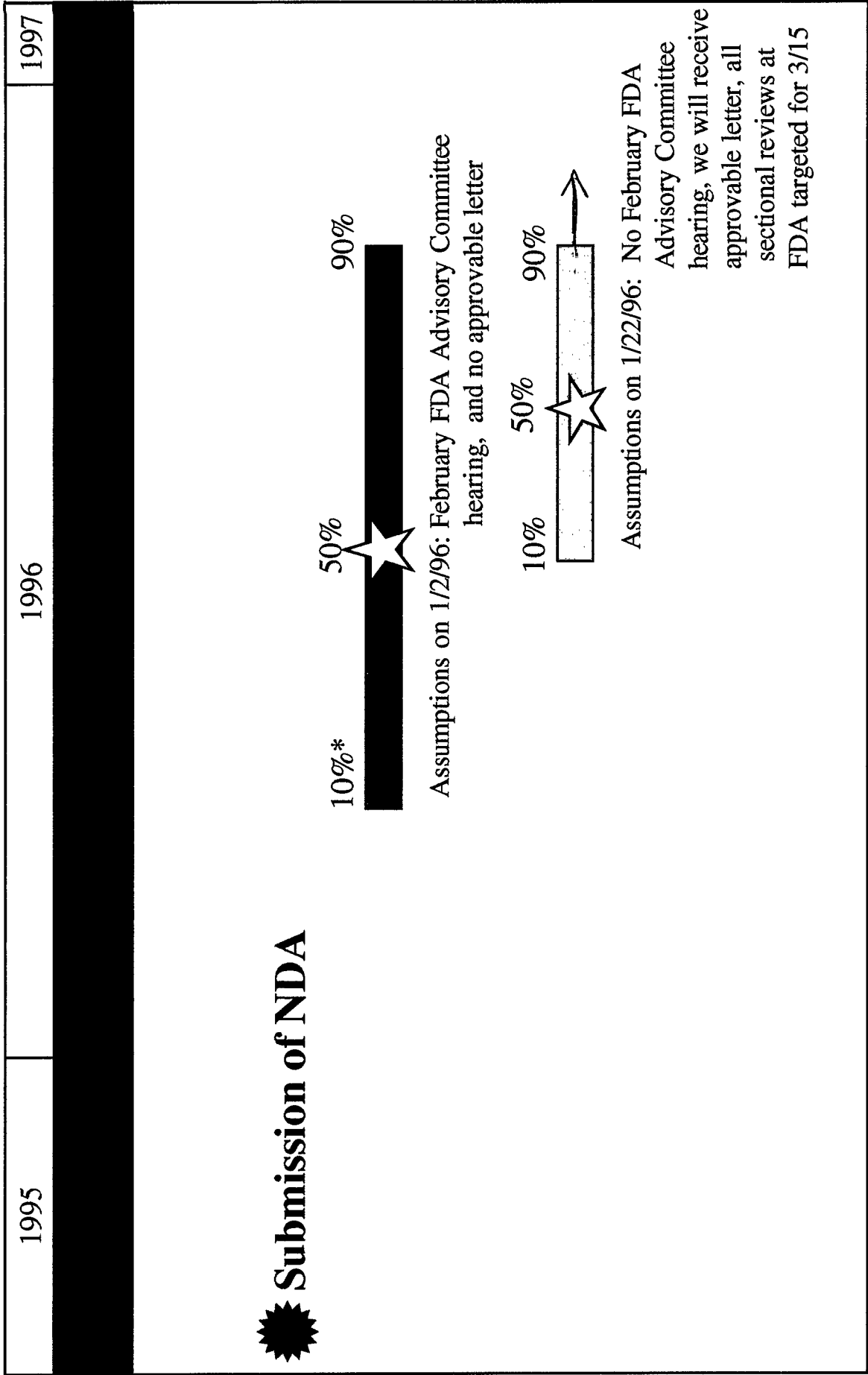


Probabilized Timeline for FDA Approval of Zyprex™



* Probability of approval by this date

01/23/96

BSM/sjc

Date: 2/1/96 5:00:06 PM
From: BAN MARGARET R
Subject: DANIELS' STAFF - MONDAY, FEBRUARY 5, CONF. ROOM 73/6/B - 1:00 P.M.

DANIELS' STAFF - MONDAY, FEBRUARY 5, CONF. ROOM 73/6/B - 1:00 P.M.

1:00 - 1:30 Olanzapine launch plans - Tollefson/Morris
1:30 - 2:00 CDS Review - Jordan
2:00 - 3:15 PCS Strategy - Millon
3:15 - 3:30 Update - Daniels

Need to integrate

If you have any questions, please advise.

Maggie Ban

Lots of credit to team for quality/speed of subm. globally — *much reason to be optim.*

*Can any compd be viewed in isolation?
What is cost of premature launch prep
On COPs/other products? Nothing happens
Ranges 5 tradeoff!
(home on the range)*

*Alan asked: Similar proj & invldr for other affil?
Are other affil receiving same level of
attention from core team? re regul. aspects
(ie global launch team)*

*Calibration — PDUFA = 12 mo.
fastest ever via this division = 20 mo. (A) / avg = 36 mo.
recent productivity = 0/5 of 94 subm.
(to our advantage — under pressure to produce)*

*Frank I met — Temple review keyed to Adv Comm
Gary/Beth
Trademark — GT/me & Temple*

ZY 287

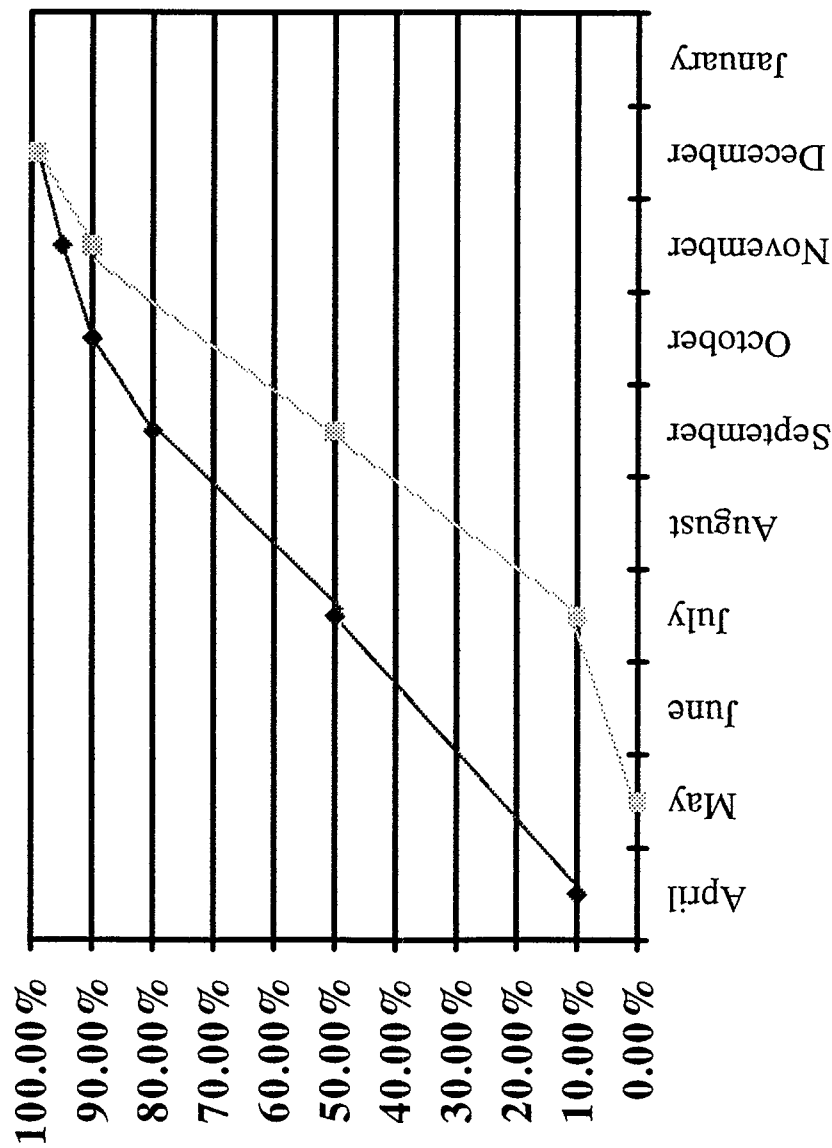
4

Projected U.S. Zyprextm FDA Approval --

Cumulative Probability

Gary T
 Beth Morris 6-1109
 Frank D
 Al W
 }
 call Alan Clark

◆ Previous Estimate
 ● Current Estimate
 5/97 - PRR



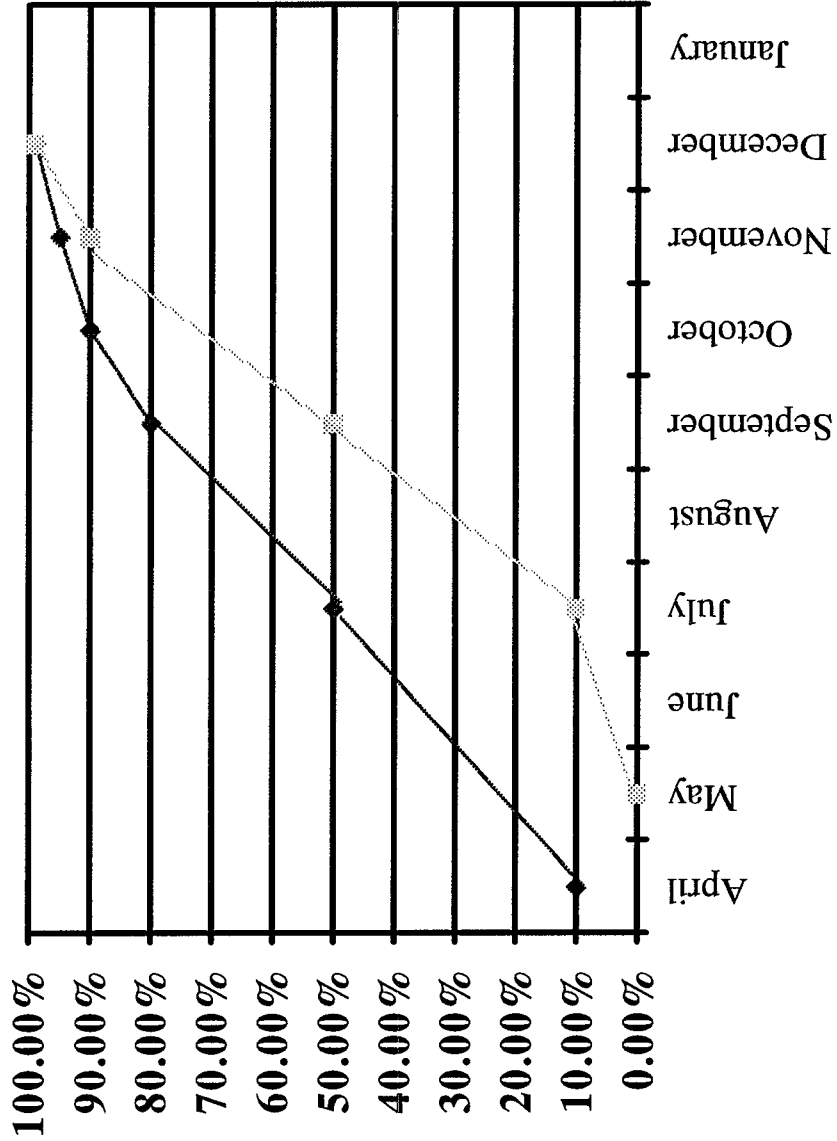
Approvable
 % prob. triggering
 - sales force
 - info
 Tradeoff values
 Assessing assumpt.
 New info - no Advs Comm?
 - approvab. later

Actions
 - Revisit timeline
 - 2-19 mo.
 - I will share new info as before
 condition on new data
 January 22, 1996
 Conting plan - dating

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 (X) Zyprex (PI Template)
 (sooner if 3/15 FDA review forward list)
 July - 50% launch grant
 Invite RNP
 BSM/sjc
 Reassess March
 Cost of sooner
 Gary Me - April 5
 Polig 13
 Another summary

Sub
Blomquist

Projected U.S. Zyprextm 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