

Germany
Fluox

Inside Comm
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Security Anal

CT02 0154 15:57GMT
IN02 0023 16:07GMT 01/29/85

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ZCZC DCC358 GE1011
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WEINSTEIN, AJ	(IND1)	*IND1* 31/2
ROBERTS, ER	(IND1)	*IND1* 74/12
CC: ARBAY, DA	(IND1)	*IND1* 74/5
BANDAK, S	(HOPA)	
HARPER, JA	(HOPA)	
NORTH, J	(HOPA)	
TAUREL, SA	(HOPA)	
THOMPSON, DW	(IND1)	***
WERNICKE, J	(IND1)	
ZERBE, RL	(IND1)	*IND1* 31/2

JANUARY 29, 1985

RE: FLUOXETINE REGISTRATION

WE INOFFICIALLY RECEIVED OUR CONFIRMATION THAT FLUOXETINE WAS DISCUSSED BY THE COMMISSION A AT THE BGA ON JANUARY 21ST. TWO MAJOR CONCERNS SEEM TO BE THE REASON THAT THE REGISTRATION WAS NOT ACCEPTED.

- EFFICACY QUESTIONED, THIS MAY BE DUE TO THE EXPERIENCES IN STUDY DESIGN AND CLASSIFICATIONS USED IN UNITED STATES VS. GERMANY.

- SUICIDAL RISK

IT SHOULD BE EMPHASIZED AT THIS TIME WE HAVE ONLY PRELIMINARY INFORMATION. WE EXPECT THE OFFICIAL LETTER WITHIN 4 WEEKS WHICH WILL PROVIDE US A CLEAR UNDERSTANDING OF ALL ISSUE AND HOW WE ARE TO REACT.

IN THE MEANTIME THE FOLLOWING ACTION PLANS HAVE BEEN INITIATED ON FLUOXETINE:

- MEETING SCHEDULED ON MONDAY AFTERNOON, FEBR. 4TH, AT 1 P.M. WITH OUR CLINICAL EXPERT TO DISCUSS THE POSSIBLE RAMIFICATIONS OF THE BGA'S POSITIONS TOWARDS THE PRODUCT.

- IMMEDIATE FOLLOW-UP ON ALL KEY OPINION LEADERS ON THE BGA

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COMMISSION FOR SELECTED VISITATION NEXT WEEK.

- CONTINUE TO FURTHER EXPEDITE OUR LOCAL GERMAN FLUOXETINE CLINICAL TRIALS.
- IDENTIFY THE POSSIBLE LEGAL ALTERNATIVES AND TIMING IMPLICATIONS THAT MAY BE ENCOUNTERED WITH THE BGA ON FLUOXETINE.
- DETERMINE THE BGA ACTIONS INITIATED TOWARDS DUPHAR DURING THEIR PRODUCT REVIEW SUBMISSION.

IT IS OUR INTENTION TO REVIEW ALL APPROPRIATE COMMUNICATION CHANNELS PRIOR TO THE OFFICIAL RESPONSE BY THE BGA. ALL PERTINENT INFORMATION WILL BE COMMUNICATED TO KEEP EVERYONE INFORMED ON THIS IMPORTANT ISSUE.

REGARDS,
WEHER, HJ (GE1)
CHANDLER, TA (GE1)
MAYR, G (GE1)

#01291416
NNNN