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Approvable Package
Lexapro (escitalopram oxalate) Tablets
NDA 21-440

UF DUE DATE Thursday August 29, 2001

SECTION

N: Approval Letter to Sponsor with Labeling
O: Supervisory Overview: Division Director's Memo
P: Group Leader's Memo

X Q: NDA Action Package Checklist
X R: Exclusivity Checklist
X S: Pediatric Checklist

T: Lexapro (escitalopram), NDA 21-323 AP Letter and labeling dated 8-14-02/
Labeling negotiation history (8/15/02 - 8/28-02)

U: Clinical Review
V: Statistical Review
W: DSI Reviews

APPEARS THIS WAY
ON ORIGINAL

d) Did the applicant request exclusivity?

YES / / NO / /

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

e) Has pediatric exclusivity been granted for this Active Moiety?

YES / / NO / /

Pediatric studies were conducted using the racemate formulation, Celexa (citalopram HBr) tablets, and submitted as pediatric efficacy supplements to NDA 20-822/SE5-016 (Celexa tablets) and 21-046/SE5-002 (Celexa solution). Pediatric exclusivity was granted for these applications on 7-12-02.

In a ruling by General Counsel, it was decided that pediatric exclusivity would extend to the enantiomer formulation, escitalopram, once approved if the racemate, citalopram, was granted pediatric exclusivity. The Agency has approved the parent NDA 21-323 in an approval letter dated 8-14-02, and the relapse prevention NDA (Type 6 NDA) was approved on 8-29-02. Pediatric exclusivity was granted for the racemate, citalopram, in an action dated 7-12-02.

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON Page 9.

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule previously been approved by FDA for the same use? (Rx to OTC) Switches should be answered No - Please indicate as such).

YES / / NO / /

If yes, NDA # 21-323 Drug Name Lexapro (escitalopram oxalate) Tablets

***At the time of submission of this clinical trial providing for a relapse prevention study in major depressive disorder (MDD), the Agency had, as yet, not taken a final action on the