CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 74-986

ADMINISTRATIVE

E L E C T R O N I C M A I L M E S S A G E

Date: 03-Jul-1997 10:03am EDT
From: Anna Marie Weikel
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TO: Chan Park (PARKC)
TO: Upinder Atwal (ATWALU)

CC: Vilayat Sayeed (SAYEEDV)

Subject: re: Martec's Diclofenac Apps

Please note that ANDA was withdrawn per OGD request and the information was collapsed into ANDA 74-986.

Therefore, ANDA 74-986 is the only active application for both of the 50 mg and 75 mg strengths.

I apologize for the confusion...it has been very confusing for us in Reg Supp also.

If you have any questions, please call me.

Thanks,

Anna Marie

ANDA 74-986 APPROVAL SUMMARY

DRUG PRODUCT: Diclofenac Sodium Delayed-release Tablets USP

FIRM: Martec Scientific Incorporated

DOSAGE FORM: Tablets

STRENGTH: 50 mg and 75 mg

cGMP STATEMENT/EIR UPDATE STATUS: EER Acceptable Date 11/24/98

BIO STUDY: APPROVE, Bio Letter sent on 11/23/98

VALIDATION: N/A, DS and DP are compendial

STABILITY: Three months Stability data under CRT 25-30°C/60%±10% (RH), and Accelerated condition 40±2°C/75%±5% (RH) condition for both tablet strengths in the smallest and the largest marketing size container/closure systems, ie. 100's and 1000's, are provided.

LABELING: APPROVE, Labeling Review Dated 03/04/98

STERILIZATION VALIDATION: (IF APPLICABLE): N/A

SIZE OF BIO BATCH: The bio batch for 50 mg tablets, is lot #960103, size tablets, and for 75 mg tablets is lot #960105, size tablets. Bio batches are also the stability batches. The drug substance source is lot #9512701. 0 is adequate as of 02/04/99.

SIZE OF STABILITY BATCHES: Stability batches are the same as test batches, ie., lot #960103 (50 mg strength), size tablets and lot #960105 (75 mg strength), size tablets.

PROPOSED PRODUCTION BATCHES: The proposed production batch size for the 50 mg as well as the 75 mg strength is tablets. The manufacturing process for production batches remains the same as that for test batches.

CHEMIST: USAthal **DATE:** 2/8/99

SUPERVISOR: **DATE:**