CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-589

PHARMACOLOGY REVIEW(S)

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10/3/03

PHARMACOLOGIST REVIEW OF NDA 21589 (BACLOFEN ORALLY DISINTEGRATING TABLETS)

ORIGINAL SUMMARY

Baclofen is currently marketed in other formulations. According to the reviewing chemist there are no unusual excipients or impurities needing qualification in the present product.

The animal studies on baclofen are rather old. The current labeling for baclofen products describes no genotoxicity studies and only one carcinogenicity study (in rats). Since the present product is for the same indication as the marketed products and likely will not expand overall use of baclofen, this is not an urgent concern. However, since the carcinogenic potential of baclofen has not been fully evaluated, it is recommended that, as a start, a genotoxicity battery be performed, which may be submitted post-marketing. (The same recommendation was made to the sponsor of pre-IND 63,915 for baclofen ER tablets).

RECOMMENDATIONS:

This NDA is approvable. A complete genotoxicity battery (per ICH guidelines) should be performed as a Phase IV commitment.

Barry N. Rosloff, Ph.D.

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