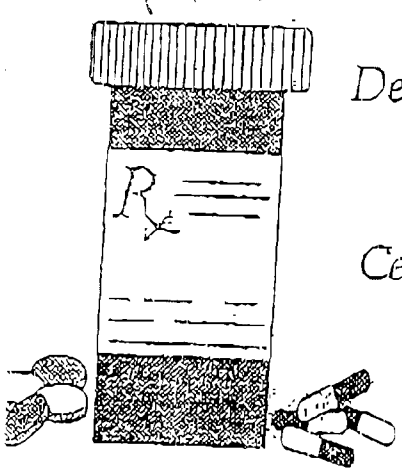
Attn. Dr Chen

FAX COVER SHEET



Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Rockville, Maryland

Date: 12/8/06

To: Lanie

Phone: 760-431-8284 Fax: 760-431-7507

From: Simon Eng

Phone: (301) 827-5848 FAX: (301) 594-0180

Number of pages: 3
(Including Cover Sheet)

Comments: Congrats! 77.918 Meloxicam has been approved!

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-918

DEC 7 2006

Carlsbad Technology Inc.
Attention: Lanie Harrington, RAC
Supervisor, Regulatory
5923 Balfour Court
Carlsbad, CA 92008

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated October 13, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Meloxicam Tablets, 7.5 mg and 15 mg.

Reference is also made to your amendments dated March 8, July 14, July 17, August 1, August 10, August 11, September 22 and October 13, 2006.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved. The Division of Bioequivalence has determined your Meloxicam Tablets, 7.5 mg and 15 mg to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Mobic Tablets, 7.5 mg and 15 mg, respectively, of Boehringer Ingelheim Pharmaceuticals, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research