DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-324/ SCM-004

AstraZeneca LP
Attention: Barbara J. Blandin
Director, Regulatory Affairs
725 Chesterbrook Blvd.
Mailstop E-3C
Wayne, PA 19087-5677

Dear Ms. Blandin:

Please refer to your supplemental new drug application dated September 12, 2002 received September 13, 2003 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Entocort™ EC (budesonide) 3 mg Capsules.

We also acknowledge receipt of your October 10, 2002 submission containing final printed labeling (FPL).

This "Changes Being Effected in Thirty Days" supplemental new drug application provides for

1) The addition of a new site as an alternate packaging facility for the drug product

2) The addition of alternate container closure systems for trade product and physician samples to support the packaging at the proposed alternate site

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling must be identical to the physician sample label FPL and label FPL submitted October 10, 2002.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format* – NDAs (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-324/S-004." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Betsy Scroggs, Pharm. D., Consumer Safety Officer, at (301) 827-1250.

Sincerely,

{See appended electronic signature page}
Liang Zhou, Ph.D.
Chemistry Team Leader for the
Division of Gastrointestinal and Coagulation Drug Products
(HFD-180)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Liang Zhou

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