DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-324/SCS-001

AstraZeneca LP
Attention: Barbara Blandin
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

Dear Ms. Blandin:

Please refer to your supplemental new drug application dated February 8, 2002 received February 11, 2002 submitted under section 505(b) pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for ENTOCORT™ C (budesonide) 3 mg Capsules.

We acknowledge receipt of your submission dated February 15, 2002.

This "Changes Being Effected in 30 days" supplemental new drug application provides for removal of the "CIR" imprint on the surface of the ENTOCORT™ EC Capsule.

We have completed the review of this supplemental application, as amended, 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 final printed labeling dated February 8, 2002. Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" 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 requirements for an approved NDA set forth under 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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