DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 07-409 (S-040), NDA 07-961 (S-026), NDA 08-370 (S-031)

Axcan Scandiapharm Inc.
c/o CANREG INC
Attention: Irma Monaco
450 North Lakeshore Dr.
Mundelein, IL 60060

Dear Ms. Monaco:

Please refer to your supplemental new drug applications dated July 31, 2006, received August 2, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Bentyl (dicyclomine hydrochloride), Capsules and Tablets, Syrup, and Injection.

These "Changes Being Effected" supplemental new drug applications provide for the addition of a geriatric use subsection of the PRECAUTIONS section of the package insert labeling as required under 21CFR 201.57(f)(10)(ii)(A) (i.e. where insufficient data exist to determine whether the responses of geriatric patients to a drug are different from responses of younger patients).

We also acknowledge your submissions dated August 16, 2006, and October 11, 2006, which contained the Package Insert in the Structured Product Labeling (SPL) format.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

Please make the following change at your next printing:

> Clinical Pharmacology Section: in the second paragraph, fourth sentence "concentration" should be changed to "concentrations."

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and at the next printing include the minor editorial revisions listed above. Marketing the product(s) with FPL that is not identical to the approved labeling text may render the products misbranded and unapproved new drugs.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approve**d NDA 07-409, NDA 07-961, and NDA 08-370." Approval of these submissions by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA

(21CFR 314.80 and 314.81).

If you have any questions, call Thomas Moreno, Regulatory Project Manager, at (301) 796-2247.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
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/

Joyce Korvick
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