DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-983/S-017

Elan Drug Delivery, Inc.
Attention: Roger Wayne Wiley, R.Ph.
Director, North America Regulatory Affairs
1300 Gould Drive
Gainesville, GA 30504

Dear Mr. Wiley:

Please refer to your supplemental new drug application dated April 5, 2002, received April 8, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prostep® (11mg/day and 22mg/day nicotine transdermal patch).

We acknowledge receipt of your submissions dated August 30 and September 26, 2002.

This Changes Being Effected supplemental new drug application provides for "Drug Facts" labeling changes as requested in FDA's letter of January 18, 2002.

We have completed the review of this supplemental application, as amended, and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (carton labels submitted September 26, 2002, and Information and Instruction Leaflet submitted April 5, 2002) and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated FPL for approved supplement NDA 19-983/S-017. 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 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 Laura Shay, Regulatory Project Manager, at (301) 827-2274.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
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/

Charles Ganley
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