DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-983/S-016

Elan Pharmaceutical Research Corporation
Attention: Roger Wayne Wiley, R.Ph.
Director, North America Regulatory Affairs
1300 Gould Drive
Gainesville, GA 30504

Dear Mr. Riley:

Please refer to your supplemental new drug application dated November 1, 2001, received November 2, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prostep® (11 mg/day and 22 mg/day nicotine transdermal patch).

This "Changes Being Effected" supplemental new drug application provides for labeling changes requested in our letters addressed to supplemental application S-012, dated May 24, 2001, and August 17, 2001.

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 final printed labeling (immediate pouch and carton labels and patient information leaflet submitted November 1, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

We have the following recommendations for your consideration. These recommendations should be incorporated at the next printing or within 180 days, whichever comes first, and should be submitted in a "Changes Being Effected" supplemental application to this NDA.

1. Revise the "Drug Facts" carton labeling as follows.

    a. On the 11 mg and 22 mg refill cartons, change the heading from "***Uses***" to "***Use***" and revise this section in all labeling to read, "**Use** reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking".

    b. Under the subheading ***Warnings***, **Ask a doctor or pharmacist before use if you are**:

        (i) Add as the first bullet, "using a non-nicotine stop smoking drug".

        (ii) Delete the bulleted phrase, "under 18 years of age".

c. Under the heading ***Directions***:

(i) Add, in bold type, as the first bullet, "if you are under 18 years of age, ask a doctor before use".

(ii) In the bulleted statement beginning "the used patch should be removed", move the sentence reading, "do not wear more than one patch at a time", to a new line as a separate bulleted statement.

(iii) Add additional bulleted statements as follows.

- do not wear more than one patch at a time.
- do not cut patch in half or into smaller pieces.
- remove backing from patch and immediately press onto skin. Hold for 10 seconds.

d. Revise the order under the heading ***Directions*** to read as follows:

- **if you are under 18 years of age, ask a doctor before use**
- read the enclosed Information and Instructions Leaflet before using this product
- stop smoking completely before starting to use this product
- if you smoke **15 or less cigarettes per day, use one 11 mg patch each day** for 6 weeks
- if you smoke **16 or more cigarettes per day, use one 22 mg patch each day** for 6 weeks
- apply one new patch every 24 hours on skin that is dry, clean and hairless for six weeks
- remove backing from patch and immediately press onto skin. Hold for 10 seconds.
- wash hands after applying or removing a patch. Dispose of patch in the enclosed Disposal Unit. See enclosed instructions for safety and handling.
- the used patch should be removed and a new one applied to a different skin site at the same time each day
- do not wear more than one patch at a time
- do not cut patch in half or into smaller pieces
- do not leave patch on for more than 24 hours because it may irritate your skin and loses strength after 24 hours
- stop using Nicotine Transdermal System at the end of 6 weeks. If you still feel the need to use Nicotine Transdermal System talk to you doctor

e. In connection with item 1.d. above, you may wish to replace the name "Nicotine Transdermal System," wherever it occurs, with the words "the patch" to save space.

f. The information under the heading ***Questions*** should be enclosed in the "***Drug Facts***" box, in accordance with 21 CFR 201.66(d)(8).

2. The Information and Instructions Leaflet should be consistent with the above Drug Facts labeling revisions.

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

Please submit one market package of the drug product when it is available.

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 Elaine Abraham, Regulatory Health Project Manager, at (301) 827-2293.

Sincerely,

{See appended electronic signature page}

Linda M. Katz, M.D., M.P.H.
Deputy 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/

Linda Katz

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