CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: NDA 19-983/S-012

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Approval Package for:

Application Number: NDA 19-983/S-012

Trade Name: PROSTEP 11mg/day and 22mg/day patches

Generic Name:(nicotine transdermal system)

Sponsor: Elan Pharmaceutical Research Corporation

Approval Date:December 23, 1998

Indication: Provides for the Over-the-Counter (OTC) marketing of Nicotine Transdermal System 22 mg/day and 11 mg/day patches to adults (those who are at least 18 years of age) for use as an aid to stop smoking cigarettes.

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Application Number:NDA 19-983/S-012

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 19-983/S-012

Elan Pharmaceutical Research Corporation
1300 Gould Drive
Gainesville, Georgia 30504

DEC 23 1998

Attention: Sharon Hamm, Pharm.D., R. Ph.
Senior Vice President, R & D Technical Operation

Dear Dr. Hamm:

Please refer to your supplemental New Drug Application dated September 23, 1998, received September 24, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ProStep (nicotine transdermal system) 11 mg/day and 22 mg/day patches.

We acknowledge receipt of your submissions dated October 30, 1998, December 10, 1998, December 21, 1998, and December 22, 1998.

This supplemental New Drug Application provides for the Over-the-Counter (OTC) marketing of Nicotine Transdermal System 22 mg/day and 11 mg/day patches to adults (those who are at least 18 years of age) for use as an aid to stop smoking cigarettes. This age restriction is essential to the agency's finding that this product is safe and effective for OTC use.

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 enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the consumer information and instruction leaflet, immediate container and carton labels) and incorporate the instructions in the addendum to this letter. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 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. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-983/S-012." Approval of this submission by FDA is not required before the labeling is used.

We acknowledge your letter dated December 22, 1998 to fulfil the following Phase IV Commitments:

We refer to our telecommunications dated December 18, 21 and 22, 1998, and your letter dated December 21, 1998, regarding nomenclature issues. We concur with your use of the established name, Nicotine Transdermal System, instead of the brand name, ProStep. However, due to the unique marketing aspects of the OTC nicotine replacement patches, any changes to the nomenclature should be submitted in accordance with 21 CFR 314.70(b).

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. Should an IND not be required to meet your Phase IV commitments, please submit protocols, data, and final reports to this NDA as correspondence. For administrative purposes, all submissions, including labeling supplements, relating to these Phase IV commitments must be clearly designated "Phase IV Commitments."

In addition, please submit four copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Anesthetic, Critical Care, and Addiction Drug Products, one to the Division of Over-the-Counter Drug Products, and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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

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.

In line with Center for Drug Evaluation and Research policy, oversight of this application is being transferred to the Division of Over-the-Counter Drug Products. If you have any questions, contact Sakineh Walther, Project Manager, at (301) 827-2222.

Sincerely,

/S/

Debra Bowen, M.D.
Acting Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

/S/ MD

Cynthia G. McCormick, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products, HFD-170
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure