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Application Number:NDA 20281/S14

APPROVAL LETTER

DF

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-281/S-014/S-015

AUG 21 1998

The R.W. Johnson Pharmaceutical Research Institute
Attention: Natasha Rogozenski
Manager, Regulatory Affairs
920 Route 202 South, P.O. Box 300
Raritan, New Jersey 08869

Dear Ms. Rogozenski:

Please refer to your supplemental new drug applications dated August 21, 1997, received August 22, 1997, and dated April 9, 1998, received April 10, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ultram (tramadol hydrochloride tablets).

These supplemental new drug applications (S-014) provide for the addition of the following text in the DOSAGE AND ADMINISTRATION section of the labeling:

These supplemental new drug applications (S-015) also provide for minor administrative changes and the following change in the ADVERSE EVENTS section of the labeling:

We have completed the review of these supplemental applications 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 proposed labeling dated April 9, 1998, with the following addition to the DOSAGE AND ADMINISTRATION section:

Accordingly, these supplemental applications are approved effective on the date of this letter.

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 20-281/S-014/S-015." 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 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

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, contact D'Annie Gunter, Project Manager, at (301) 827-2090.

Sincerely,

/S/ 8-21-98

John E. Hyde, Ph.D, M.D.
Acting Deputy Director
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research