

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

16-620 / S-045

MEDICAL REVIEW

Medical Officer's Review of NDA 8-693/S-025,
NDA 9-175/S-019 and NDA 16-620/S-045

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FEB 16 1988

APPLICANT: Norwich Eaton Pharmaceuticals, Inc.

DATE OF SUBMISSIONS: 1/14/88

DATE OF REVIEW: 2/3/88

DRUG: Furadantin Tablets (nitrofurantoin)
Furadantin Oral Suspension (nitrofurantoin)
Macrochantin (nitrofurantoin macrocrystals)

ROUTE OF ADMINISTRATION: Oral

CATEGORY: Antibacterial agent

The applicant has filed revised package inserts to provide for modifications of the information dealing with pulmonary reactions associated with nitrofurantoin. In the "Warnings" section, the pulmonary reactions have been highlighted by boldface type, and the wording has been revised to emphasize the relationship of the chronic pulmonary reactions with prolonged therapy.

The "Adverse Reactions" section has been revised to lead off with pulmonary reactions, and the text dealing with the chronic reaction is in boldface type. Also, the wording has been revised to emphasize the relationship of the chronic pulmonary reactions with prolonged therapy.

The "Dosage and Administration" section text on long term therapy has also been highlighted in boldface type.

In addition to the labeling changes outlined above, the applicant submitted a copy of a "Dear Doctor" letter to be sent to physicians providing information on the nature of the pulmonary reactions associated with nitrofurantoin and alerting them of the changes in the package insert. This letter will be sent out to all urologists, OB-GYN's, family practitioners, internal medicine specialists, general practitioners, pediatricians, osteopathic physicians, general surgeons and pulmonary disease specialists.

Comments

The proposed labeling changes are acceptable; however, under "ADVERSE REACTIONS" the word "Respiratory" should also be highlighted by boldface type.

At the suggestion of Robert C. Nelson, Ph.D., Assistant Director, ODE II, CDER, the third paragraph on page 2 of the "Dear Doctor" letter should be changed to read:

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I have no objections to the editorial changes suggested by Dr. Nelson.

Conclusion

The applicant should be notified of the above comments.

Mercedes S. Albuerno, M.D.
Mercedes S. Albuerno, M.D.

cc:

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