DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 24 1997

TRANSMITTED VIA FACSIMILE

Steven M. Viti, Ph.D.
Associate Director, Regulatory Affairs
Baker Norton Pharmaceuticals
4400 Biscayne Blvd.
Miami, Florida 33137

RE: NDA# 20-193
Elmiron (pentosan polysulfate sodium)
MACMIS ID #5189

Dear Dr. Viti:

Reference is made to Baker Norton's November 4, 1996, Form FDA 2253 submission consisting of promotional launch materials for Elmiron (pentosan polysulfate sodium). The Division of Drug Marketing, Advertising and Communications has reviewed these materials and has identified the following violations of the Federal Food, Drug, and Cosmetic Act and applicable regulations:

Journal Advertisement

DDMAC finds the journal ad (P001551) to be misleading because it promotes Elmiron for unapproved uses. Specifically, prescribers are instructed to "Consider Elmiron....when patients present with:

- pain, pressure or tenderness in the bladder, pelvis, or perineum
- frequent voiding
- urgency
- negative urine culture"

However, the approved labeling states, "Elmiron is indicated for the relief of bladder pain or discomfort associated with interstitial cystitis" (IC). While the symptoms above may lead to the suspicion of IC, they may also be indicative of a number of other conditions where Elmiron therapy is clearly not indicated, such as BPH. Further, Baker Norton is referred to DDMAC's correspondence dated September 26, 1996, in which we suggested that Baker Norton add information to the journal advertisement presenting a progression of actions that may lead to the decision to prescribe Elmiron (suspect, confirm, consider, prescribe).

Fair Balance

The brochure entitled "Questions and Answers about Interstitial Cystitis" (P001546), as well as the audio tape (P001556), lack fair balance because they fail to present information on side effects and other risk information.

Press kit

The fact sheet included in the press kit contains the statement "Clinical study data indicates that at least 38 percent of IC patients given Elmiron will respond to treatment." The qualifier "at least", as used in the fact sheet, Q&A sheet and the "Playing through the pain" piece, is misleading because it suggests that 38% is the low end of an efficacy range, thereby suggesting greater efficacy than was demonstrated in the clinical trial. The approved labeling states "...38% of patients who received Elmiron...showed greater than 50% improvement in bladder pain".

In order to address these objections, DDMAC recommends that Baker Norton immediately take the following actions:

1. Immediately discontinue the use of these, and all other promotional materials for Elmiron that contain the same or similar violations.

2. Provide to DDMAC, in writing, Baker Norton's intent to comply with #1 above. Baker Norton's response should be received by March 6, 1997.

3. This response should include a list of all violative promotional materials and Baker Norton's method for discontinuing their use.

If Baker Norton has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Baker Norton that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #5189 in addition to the NDA number.

Sincerely,

Mark W. Askine, R.Ph.
Regulatory Review officer
Division of Drug Marketing,
Advertising and Communications

File Name: elmirnov.let

Drafted: Askine	Date: 2/6/97
Comment: Fleischer	Date: 2/7/97
Comment: Palmer	Date: 2/7/97
Revised: Askine	Date: 2/19/97
Concur: Palmer	Date: 2/22/97

CC:
HFD-40/NDA 20-193
HFD-40/Chron/Askine/Palmer
HFD-580/Shames/Jolson
HFD-580/NDA 20-193

MACMIS ID #5189

MACMIS Type Code: LETT
MACMIS Action Code:VIOL

2253 ID#:45957 Material ID#(s): P001551, P001546, P001556,

Due Date: March 6, 1997
Close Out: NO

FOI Status: Releasable