



JUN 29 2000

TRANSMITTED BY FACSIMILE

Richard K. Bourne, Ph.D.
Vice President, Regulatory Affairs
Block Drug Company, Inc.
257 Cornelison Avenue
Jersey City, NJ 07302-3198

RE: NDA 50-751
Atridox (doxycycline hyclate, 10%)
MACMIS ID # 9083

Dear Dr. Bourne:

This letter refers to Block Drug Company, Inc.'s (Block) submission, dated April 17, 2000, of promotional materials under cover of Form FDA 2253 for Atridox. The submission included a professional sales aid titled, "There is a simple, fast, and effective treatment for every patient you see with 5 and 6mm pockets" identified as ATX1542. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed the sales aid and has concluded that it is false or misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

Lack of Fair Balance

Your professional brochure, identified as ATX1542, is misleading because it fails to present any risk information about Atridox. You have made numerous claims regarding safety and efficacy for the product, but have not provided information regarding the warnings, precautions, and adverse reactions associated with the use of the drug. For example, the approved product labeling for Atridox includes a prominent warning concerning possible permanent discoloration of the teeth in certain patients taking drugs of this type.

Requested Action

In order to address these objections, we request that you immediately cease the dissemination of this violative sales aid and all similar promotional materials that lack fair balance.

Richard K. Bourne, Ph.D.
Block Drug Company, Inc.
NDA 50-751

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You should respond in writing to us regarding this issue by July 13, 2000. Your response should include Block's intent to comply with the above request, the date that it ceased disseminating the sales aid and any other violative promotional materials lacking fair balance, and a list of the discontinued materials.

If you have any questions, please contact me by telephone at (301) 827-2831, facsimile (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-42; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. DDMAC reminds Block that only written communications are considered official.

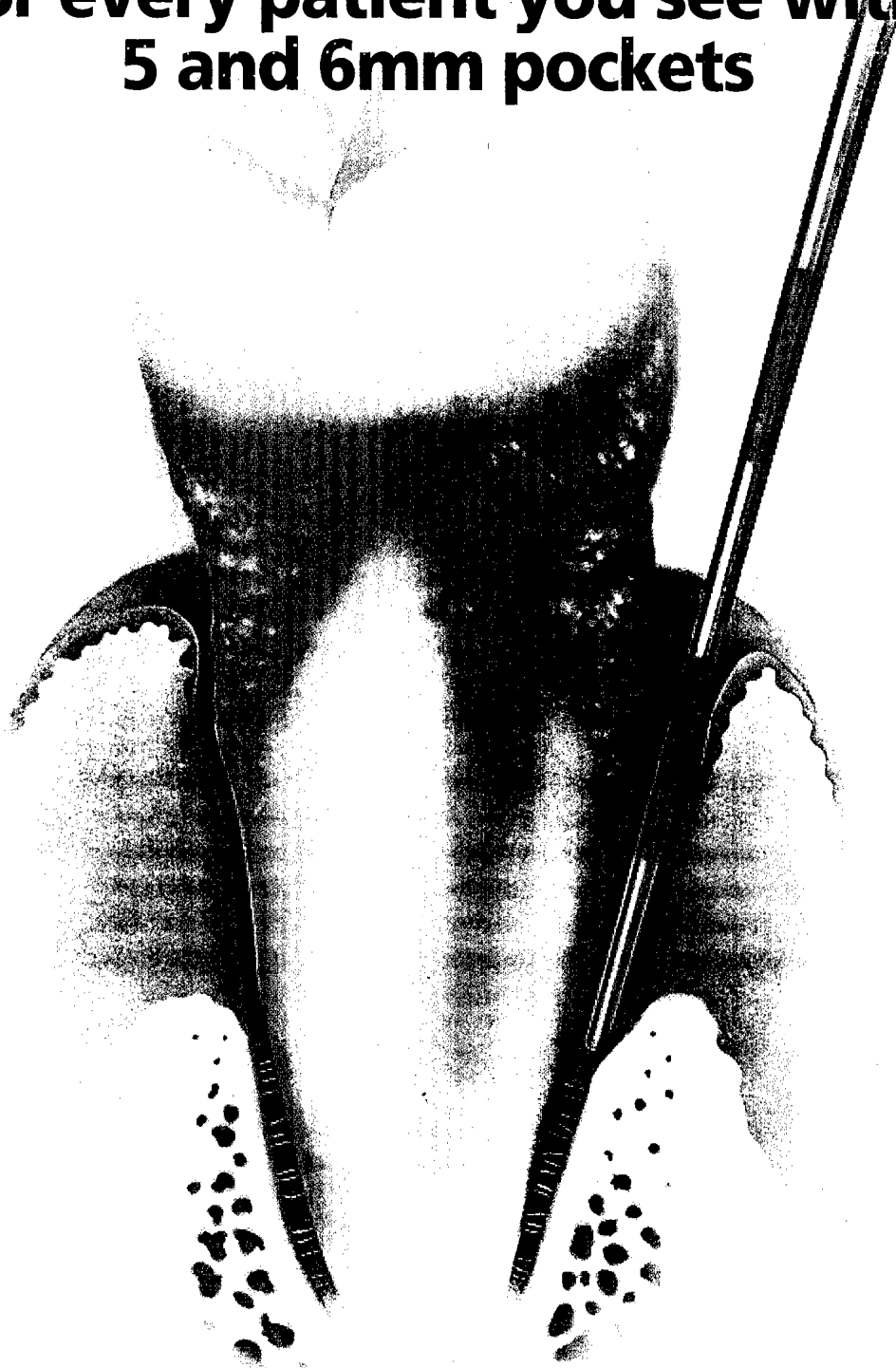
In all future correspondence regarding this matter, please refer to MACMIS # 9083 and NDA 50-751.

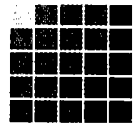
Sincerely,

/S/

Warren F. Rumble
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications

**There is a simple, fast, and
effective treatment
for every patient you see with
5 and 6mm pockets**





ATRIDOX[®]

(doxycycline hyclate) 10%

Antimicrobial gel



DESCRIPTION:

- 10% doxycycline hyclate
- Broad spectrum semi-synthetic tetracycline
- "Flowable" polymer gel
- Applied subgingivally to periodontal pocket
- Solidifies to wax-like substance upon contact with crevicular fluid
- Controlled release of doxycycline for 7 days

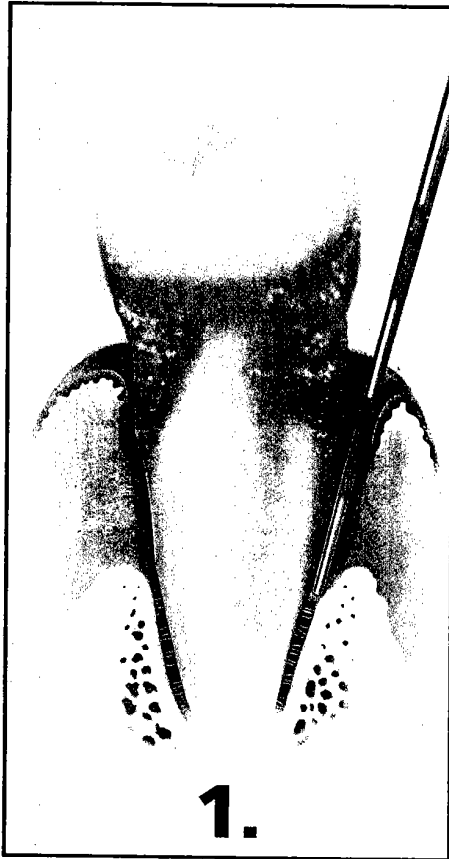
SIGNIFICANT CLINICAL PERFORMANCE

- Two well-controlled, parallel-design, 9-month studies involving 19 medical centers and 831 patients
- Significantly increased clinical attachment levels
- Significantly reduced pocket depths
- Significantly reduced bleeding on probing

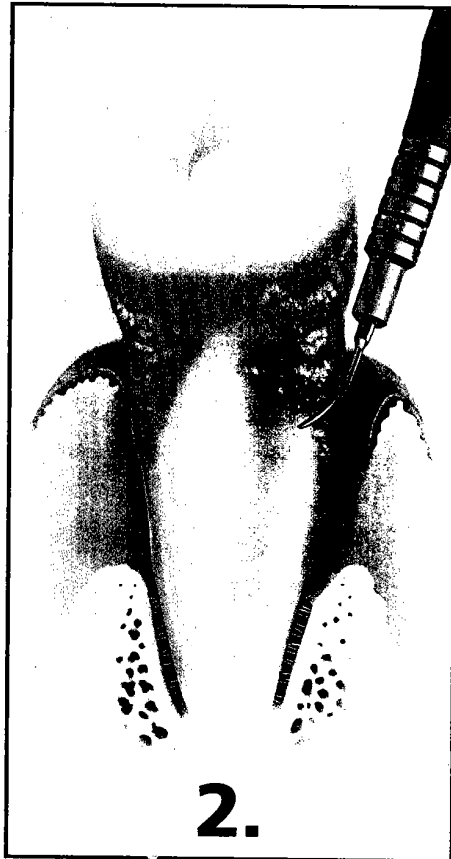
WHY CONSIDER USING ATRIDOX®?

- Non-invasive, comfortable
- Takes much less time to apply
- Can be applied by a hygienist
- Can enhance practice profitability
- Helps keep patients in your practice

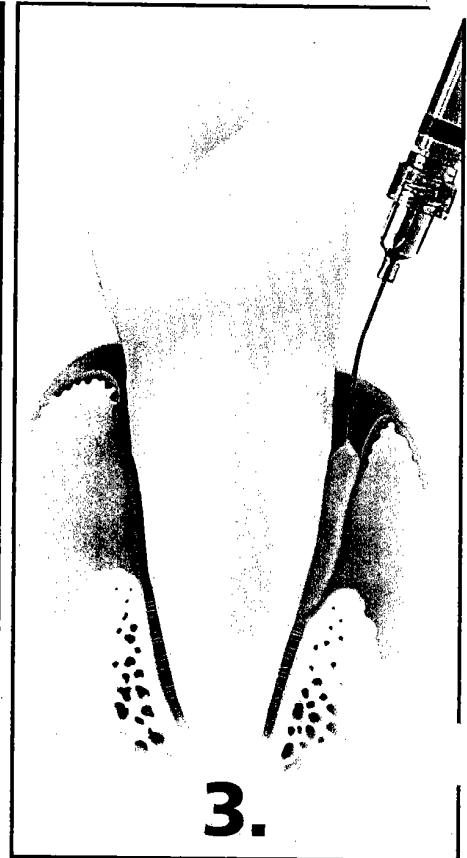
SIMPLE, FAST TREATMENT REGIMEN



**Probe and
diagnose**



**For pockets
5 and 6mm
perform routine
cleaning and
debridement**



Apply Atridox®

- A recent clinical study showed that 69% of 5 and 6mm sites will improve to 4mm or less with this regimen¹

RECOMMENDATION:

- Treat your next 18 hygiene patients who present with 5 and 6mm pockets with this treatment regimen
 - Routine subgingival debridement
 - Atridox®
- Charge appropriate fee for each Atridox® treatment
 - In presentations to patients, stress speed of treatment and comfort, versus mechanical therapy (or cost of referral)
- Re-evaluate patient upon next visit (≈4 months)
- If desired clinical improvements are not achieved, consider reapplication of Atridox® or alternative treatment options

In Chronic Adult Periodontitis

 **ATRIDOX®**
(doxycycline hyclate) 10%



NOT TO BE LEFT WITH DENTAL PROFESSIONAL

Atridox® is a registered trademark of Block Drug Corporation.

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BLOCK DRUG CORPORATION