VAX-D

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VAX -D® THERAPEUTIC TABLE
K951622

RESPONSE TO DEFICIENCY LETTER (SEPTEMBER 14, 1995)

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VAT-TECH INC.
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September 28, 1995

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Addressee:	Document Control Center
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Product:	VAX-B Tuberculin Tablet
Sponsor:	VAX-TECH INC.
Establishment Registration Number:	9041377
Sponsor Identification:	Allen L. Dyer, Ph.D., M.D. President VAX-Tech, Inc. [redacted] Palm Harbor, Florida 34684

Dear Sir/Madam:

On September 25, 1995, Allen Dyer, the FDA reviewer for the June 27, 1995 510(k) [redacted] telephoned up by a letter dated September 22, 1995 from Marjorie Shulman. The questions and responses are as follows:

[redacted]

[redacted]
Telephone [redacted] • Fax [redacted]

1. **Please provide information about the fire retardant properties of the cushion.**

TAB 1 contains the specifications for the VAX-D™ Therapy Table and cushions, including those for fire retardancy.

3. **Clarify which claims Vat-Tech intends to make in this submission and supply supporting clinical data.**

In the April 20, 1995 letter from Paul R. Beninger, M.D., only one claim was questioned. The letter states that "claims for decompression of the intervertebral disc, as measured by the lowering of intradiscal pressure, represents a new intended use." We stated our disagreement with this conclusion in the June 27, 1995 cover letter for our 510(k) submission since reference to "decompression" explains the mechanism of action for the intended use of "helping to relieve low back pain". In addition, our original cleared submission for this device (K894435) uses the term "Distract intervertebral spaces", a term which has the identical meaning to "Decompress intervertebral discs" or "Vertebral Axial Decompression". See the comparison table in TAB 3 of this submission. (For convenience, in the text we refer to the device cleared in K894435 as the "VAX-T" even though its name was changed to the "VAX-D" soon after clearance.)

Vat-Tech has, in order to expedite clearance of this submission, supplied clinical data in the K951622 submission which is ample to support use of these terms. Please see the study, *Effects of Vertebral axial decompression on intradiscal pressure* by Gustav Ramos, M.D. and William Martin, M.D., Journal of Neurosurgery 81: 350 -353, 1994. A reprint of this paper is included on page 53 (TAB 6U) of the June 27, 1995 510(k) submission (K951622). Copies of the brochures included with K894435 are also included in TAB 4 of the present submission, for your convenience. Copies of the proposed patient and practitioner brochures for K951622 appear on pages 89 - 102 (TAB 9) of the June 27, 1995 submission.

While there are changes in the wording of some terms used in the 1989 brochures for the VAX-T compared with the proposed brochure and Manual for the 1995 submission, the changes are not fundamental (TAB 3). Alternative wording for the same intended use and indications for use are grouped together. The changes and additions are meant to clarify or modernize terminology consistent with current medical practice. For example, the term

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"peripheral radiation" has been used for K894435 and K961622. Since "sciatica" and "[illegible]" are generally accepted as manifestations of peripheral radiation, Vax-Tech would like the flexibility to use these terms as well. The term "peripheral radiation" is being replaced in medical practice with the more accurate term, radicular radiculopathy". We request clearance for use of this alternative term. The term "Disc [illegible]" has been replaced by "degenerative disc disease" to make the nomenclature consistent with the standard nomenclature adopted by the American Back Society. We have made this change reluctantly because of the controversy surrounding the use of the term "disease" for erosion of a disc when the actual process is considered by many experts not to be a disease process.

Claims

It may be of interest that the Technology Assessment Division of the Medical Technologies Group, Ltd. (MTG), an independent health care assessment group, recently reviewed the literature relating to spinal decompression and concluded that "Coupled with modern imaging technology that recorded modifications in the extent of herniated discs with VAX-D therapy, no other non-interventional means of treating low back pain, mechanical or otherwise, has shown such promise." A cost comparison of use of the VAX-D™ compared to surgical procedures, such as laminectomy, discectomy or percutaneous discectomy revealed dramatic savings to the health care system. (*MTG Newsletter* August 1995/ Vol.4 No. 8; *MTG Newsletter* September 1995/Vol.4 No. 9)

If there is any problem, please call our consultant as soon as possible:

Norman F. Estrin, Ph.D., RAC
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Potomac, MD 20854
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FAX: (301) 294-0126

Thank you for your assistance.

Sincerely,

Allan E. Dyer, Ph.D., M.D.
President

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