Health Canada Santé Canada

NATURAL AND NON-PRESCRIPTION HEALTH PRODUCTS DIRECTORATE

Company Code: 37769
File Number: 216491
Submission Number: 216491

August 2, 2016

Mr. Vassili Goussakov
Mineral Medix Corp.
58 Albright Crescent
Richmond Hill, Ontario
Canada, L4E 4Z4

Dear Mr. Vassili Goussakov:

Re: Product Licence Issuance - NPN 80071580
Non-Traditional - ZEOLITE DX (Powder)

The Natural and Non-prescription Health Products Directorate (NNHPD) has concluded that the application is in compliance pursuant to section 7 of the *Natural Health Products Regulations* (NHPR). Please find enclosed a copy of the Product Licence hereby authorizing the sale of the product described therein.

Any labels used in the marketing of this product must reflect the information outlined on the product licence and must comply with the labelling requirements as per Part 5 of the NHPR. Please note that you are responsible for ensuring that advertising claims on the label do not contravene Section 9 of the Food and Drugs Act. Additional information on acceptable advertising claims can be obtained from the "Consumer Advertising Guidelines for Marketed Health Products (for Non-prescription Drugs including Natural Health Products)" at http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/guide-ldir_consom_consum_e.html#a.1. Section 87 (Labelling and Packaging), specifies that you are responsible for ensuring the label text information is translated into French.

No person shall sell a natural health product unless it is manufactured, packaged, labelled, imported, distributed or stored in accordance with Part 3 - Good Manufacturing Practices of the NHPR or in accordance with equivalent requirements if the natural health product is imported. Section 44 of the NHPR outlines that each product available for sale in Canada must comply with the specifications submitted to Health Canada.

The submission of a signed Product Licence Application (PLA) form is regarded as an attestation acknowledging the licence holder's responsibility to meet the requirements set out in the NHPR and associated guidance documents relating to quality and Good Manufacturing Practices.

Product licence applications and post licensing changes based partially or completely on NNHPD monograph(s) are required to submit a Monograph Attestation Form. The submission of a signed Monograph Attestation form confirms that all conditions of the attestation are met, including the acceptance of any liabilities that may arise out of selling a product outside of the conditions of the attestation for which a product licence was issued based on this attestation.

As per the NHPR, you are responsible for providing the NNHPD with the Canadian site information prior to commencing the importation and/or sale of the natural health product. All information required is outlined in Part 1, Section 22 (1 & 2). If this information has not already been provided to NNHPD, please submit this information as a notification, as per section 12 (2) (b) of the NHPR.

Changes made in respect of a licensed product require the submission of an amendment, notification or a new product licence application as per sections 11, 12 and 13 of the NHPR.

If you notice any discrepancies concerning the information on the licence in comparison to the last submitted PLA form, please submit a notice entitled "Request for Correction to the Product Licence" indicating the corrections to be made, within 60 days after the day on which the product licence is issued, to NNHPD_DPSNSO@hc-sc.gc.ca. The File Number (provided at the top right corner of the title page) and Product Number must be quoted on all future correspondence regarding this product.

Yours truly,

Submission Management Division
Bureau of Product Review and Assessment
Natural and Non-prescription Health Products Directorate

encl.: Product Licence
c.c.: Victor Gorev