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VIA UPS NEXT DAY AIR

Dr. Robert Moore
Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740

**Re: Fulfillment of Reporting Obligation
Under 21 U.S.C. § 343 (r) and 21 C.F.R. § 101.93**

Dear Dr. Moore:

Whole World Botanicals, Inc.,¹ by counsel and in accordance with 21 U.S.C. § 343(r) and 21 C.F.R. § 101.93, hereby submits an original and two copies of its notification within thirty days of first marketing its products with the statements presented below. Whole World Botanicals retains scientific documentation supporting the statements.

1. Supplement Brand Name

Royal Maca

Ingredients

Lepidium peruvianum (meyenni)

Text of Statements of Nutritional Support

Promotes perimenopausal and menopausal health and supports hormonal balance.

Scientific research has demonstrated significant relief from hot flashes and mood swings associated with menopause.

Maca promotes healthy libido and erectile function in men.

Recent scientific research suggests maca supports erectile function and libido in mammals.

In accordance with 21 U.S.C. § 343(r)(6) and 21 C.F.R. § 101.93 (c), each of the above statements will be followed by an asterisk that will be cross-referenced to another asterisk on the

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very same panel or page next to which the following statement will appear in a box in bold face type: **“These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.”**

Respectfully submitted,

A handwritten signature in cursive script that reads "Viana Muller".

Viana Muller, PhD.
President