U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Inspections, Compliance, Enforcement, and Criminal Investigations

Mundo Natural Inc 4/22/14

Department of Health and Human Services

Public Health Service
Food and Drug Administration
San Juan District
Compliance Branch
466 Fernandez Juncos
San Juan, Puerto Rico 00901-3223
Telephone: 781-729-8764
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14-SJN-WL-05

OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

April 22, 2014

Mr. Ricardo Panneflek
President and Treasurer
Mundo Natural Inc
881 Ave. Campo Rico
San Juan, PR 00924

Dear Mr. Panneflek:

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address www.mundonatural.tv in March of 2014 and has determined that you take orders there for the products "Neuro AD," "Stop Diabetes," "Stop High Blood Pressure," "Moringa 7" and "Purpurea Echinacea," which the website promotes for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims on your website establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act.

Examples of some of the website claims that provide evidence that your product(s) are intended for use a drugs include:

On your web page titled "Productos por Catalogo: Brain Health" (translation: products by catalog)

Neuro AD:

- *"Neuro AD…suplemento anti-depresivo que permite minimizar los síntomas de la depresión ya que regula el desequilibrio quimio-cerebral."*

English Translation: "Neuro AD…supplement anti-depressant that allows minimizing depression symptoms since it regulates the brain's chemical imbalance."

On your web page titled "Productos por Catalogo: Stop" (translation: products by catalog):

Stop Diabetes:

- *"Stop Diabetes es un suplemento…que ayudan a reducir los altos niveles de azúcar en la sangre."*

English Translation: "Stop Diabetes is a supplement…help to reduce high blood sugar levels."

Stop High Blood Pressure:

- *"Stop High Blood Pressure...regular la presión arterial."*

English Translation: "Stop High Blood Pressure…regulating blood pressure."

In addition, the names of these products (i.e., "Stop Diabetes" and "Stop High Blood Pressure ") are disease claims.

On your web page titled "Productos por Catalogo" (translation: products by catalog): under the heading "Compre por Ingredientes" (translation: buy per ingredient), under "Buscar Ingrediente" (translation: search ingredient):

Purpurea Echinacea:

- *"Echinacea Purpurea... fomentan la actividad del sistema inmunológico...anti-inflamatorio, antiviral y ayuda a combatir los resfriados, la influenza y las infecciones del sistema respiratorio.*

English Translation: "Purpurea Echinacea…promote the immunological system activity…anti-inflammatory, antiviral, and helps to fight colds, influenza, and respiratory system infections."

Moringa 7:

- *"Moringa 7, más que un suplemento nutricional...combatir el insomnio, Además, ayuda a combatir...dolor en las articulaciones, asma, diabetes úlceras estomacales, diarreas.."*

English Translation: "Moringa 7, more than a nutritional supplement…fight insomnia…it helps to fight…joint pain, asthma, diabetes, stomach ulcers, diarrhea…"

Your ""Neuro AD," "Stop Diabetes," "Stop High Blood Pressure," "Moringa 7" and "Echinacea Purpura" products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)];see also section 301(d) of the Act [21 U.S.C § 331(d)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Furthermore, your products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. Thus, these drugs are misbranded within the meaning of section 502(f)(1) of the Act, in that their labeling fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)]. The introduction of misbranded drugs into interstate commerce is a violation of § 301(a) of the Act [21 U.S.C. § 331(a)].

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including seizure and/or injunction.

Please notify this office in writing within 15 working days from your receipt of this letter as to the specific steps you have taken to correct the violations noted above. Your response should include any documentation that would assist in evaluating your corrections. If you cannot complete all corrections within 15 working days, please explain the reason for the delay and the date by which each such item will be corrected.

Please send your written response to the attention of Ms. Marilyn Santiago, Compliance Officer, Food and Drug Administration, San Juan District Office. If you have any questions regarding this letter, please

contact Marilyn Santiago at (787) 729-8707 or via email at Marilyn.Santiago@fda.hhs.gov.

Sincerely,
/s/
Maridalia Torres
District Director
San Juan District

Page Last Updated: 05/23/2014
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Links on this page: