

Ethos Environmental, Inc.
Form 8-K
June 01, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934

May 27, 2011
Date of Report (Date of earliest event reported)

000-30237
Commission File Number

ETHOS ENVIRONMENTAL, INC.

(Exact name of registrant as specified in its charter)

Nevada
(State or other jurisdiction of incorporation
or organization)

88-0467241
(I.R.S. Employer Identification Number)

1 Technology, Suite C515

Irvine, CA 92618
(Address of Principal Executive Offices) (Zip Code)

(886) 925-9553
(Registrant's telephone number, including area code)

Edgar Filing: Ethos Environmental, Inc. - Form 8-K

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- . Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

 - . Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

 - . Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

 - . Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

Item 8.01 Other Events

On May 27, 2011, the Company received a warning letter from the US Food and Drug Administration, Department of Health and Human Service (the FDA) dated May 25, 2011 (the Warning Letter). The Warning Letter asserts that the FDA tested lots of the Company s dietary supplement, RegenErect , and concluded that it contained a pharmaceutical ingredient and is, therefore, subject to regulation as a new prescription drug, requiring FDA approval prior to introduction and delivery. The FDA also asserts that, because it is a new prescription drug, RegenErect is misbranded as a dietary supplement, and that the advertising and promotional claims of the Company exceed the claims permitted for dietary supplements. The Warning Letter requires the Company to respond within 15 days, disclosing the specific steps taken to correct the alleged violations.

The Company s formulation and ingredient list for RegenErect did not include the pharmaceutical discovered by the FDA. The raw ingredients for the lots tested by the FDA were supplied by a previous supplier that is no longer used by the Company. The Company stopped shipment and recalled the tainted lots and has since procured a new source of raw ingredients. The raw ingredients from our new supplier have been tested by an FDA-approved testing facility, and product shipment has resumed.

The Company takes this matter very seriously and intends to fully respond to the FDA. If unresolved, the claims in the Warning Letter would have a substantial impact on the Company s ability to market and sell RegenErect and would materially affect the business, operations and financial condition of the Company. However, the Company believes that it can adequately address all of the FDA s concerns without a material impact on the Company s business. Nonetheless, the Company cannot give any assurances that the FDA will be satisfied with the Company s response or its remedial plan, and cannot estimate the date on which these concerns will be resolved, if ever.

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ETHOS ENVIRONMENTAL, INC.

May 31, 2011

Matthew Nicosia
Name: Matthew Nicosia
Title: Chief Executive Officer