

## INTERNATIONAL TRADE COMMISSION

### Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Athletic Footwear, DN 3166*; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing under section 210.8(b) of the Commission's Rules of Practice and Procedure (19 CFR 210.8(b)).

**FOR FURTHER INFORMATION CONTACT:** Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205-2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at EDIS,<sup>1</sup> and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205-2000.

General information concerning the Commission may also be obtained by accessing its Internet server at United States International Trade Commission (USITC) at USITC.<sup>2</sup> The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at EDIS.<sup>3</sup> Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

**SUPPLEMENTARY INFORMATION:** The Commission has received a complaint and a submission pursuant to section 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Reebok International Ltd. and Reebok International Limited on August 10, 2016. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of

certain athletic footwear. The complaint names as respondents TRB Acquisitions LLC of New York, NY; RBX Active 01 LLC of New York, NY; RBX DIRECT LLC of New York, NY; RBX.COM LLC of New York, NY; and Elite Performance Footwear, LLC of New York, NY. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or section 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

- (i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;
- (ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;
- (iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;
- (iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and
- (v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document

electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number ("Docket No. 3166") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, Electronic Filing Procedures<sup>4</sup>). Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,<sup>5</sup> solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.<sup>6</sup>

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

<sup>4</sup> Handbook for Electronic Filing Procedures: [http://www.usitc.gov/secretary/fed\\_reg\\_notices/rules/handbook\\_on\\_electronic\\_filing.pdf](http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf).

<sup>5</sup> All contract personnel will sign appropriate nondisclosure agreements.

<sup>6</sup> Electronic Document Information System (EDIS): <http://edis.usitc.gov>.

<sup>1</sup> Electronic Document Information System (EDIS): <http://edis.usitc.gov>.

<sup>2</sup> United States International Trade Commission (USITC): <http://edis.usitc.gov>.

<sup>3</sup> Electronic Document Information System (EDIS): <http://edis.usitc.gov>.

By order of the Commission.

Issued: August 10, 2016.

**Lisa R. Barton,**

*Secretary to the Commission.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. 16-14]

#### Lawrence E. Stewart, M.D.; Decision and Order

On June 1, 2016, Administrative Law Judge (ALJ) Charles Wm. Dorman issued the attached Recommended Decision. Therein, the ALJ found that on multiple occasions, Respondent issued prescriptions outside of the usual course of professional practice and which lacked a legitimate medical purpose for schedule II controlled substances such as Norco 10/325mg (hydrocodone/acetaminophen) and Hycodan (hydrocodone/homatropine cough syrup),<sup>1</sup> the schedule III controlled substance phentermine, and the schedule IV controlled substance alprazolam, in violation of 21 CFR 1306.04(a). See R.D. at 34-60.<sup>2</sup>

More specifically, the evidence showed that Respondent prescribed the controlled substances to his girlfriend knowing that she was seeking the drugs to abuse them. The evidence also showed that while some of the prescriptions were issued in the name of Respondent's girlfriend, in multiple instances, Respondent issued prescriptions, including multiple prescriptions for Hycodan, listing his girlfriend's two children, who were then three and five years old respectively, as the patients, and that Respondent did so knowing that his girlfriend intended to use the cough syrup because she enjoyed drinking it. The evidence further showed that on multiple occasions, Respondent issued prescriptions for Norco<sup>3</sup> to undercover agents who posed as acquaintances of

his girlfriend, knowing that the drugs would then be provided to his girlfriend and that Respondent further instructed his girlfriend as to how her purported acquaintances should present as having headaches so that he could document a reason in their charts for having issued the prescriptions.

The ALJ also found that on multiple occasions, Respondent violated Rule 1.4 of the Mississippi State Board of Medical Licensure's Rules by failing to document in his girlfriend's chart the diagnosis or justification for issuing the prescription, as well as required information including the drug's name, the dose, strength and quantity. R.D. at 37-39 (citing Miss. Code R. § 30-17-2640:1.4; also citing *id.* § 30-17-2640:1.16; Miss. Code §§ 73-25-29(3) and (13)). The ALJ also made a similar finding with respect to four hydrocodone cough syrup prescriptions Respondent issued in the names of his girlfriend's children. R.D. at 46-47 (Rx's issued on 6/17/14, 7/23/14, 11/19/14); *id.* at 49 (Rx 11/3/14).

With respect to the phentermine prescriptions Respondent issued to his girlfriend, the ALJ found that he "completely failed to comply" with the Board's Rule 1.5 because he did not prescribe "adjunctively with caloric restriction," "never conducted and recorded an initial comprehensive evaluation" including "a thorough patient history or physical examination," and never recorded required histories, nor her height, weight, BMI, body measurements, and vital signs. R.D. 43. The ALJ also found that Respondent did not conduct a re-evaluation of his girlfriend every 30 days as required by Rule 1.5. *Id.* Finally, noting that Rule 1.5 generally requires that the patient have a BMI greater than 30 in order to justify prescribing phentermine, the ALJ observed that Respondent's girlfriend testified that she had gone from 135 to 121 pounds and that she presented at the hearing "with a slender body type." *Id.* The ALJ thus explained that "[a]fter observing [her] appearance," he found "it difficult to comprehend . . . how Respondent could have possibly believed that [she] has a high enough BMI to justify" prescribing weight-loss medication. *Id.* The ALJ thus found that Respondent violated 21 CFR 1306.04(a), the Board's Rule 1.5, and Mississippi Code sections 73-25-29(3) and (13) when he prescribed phentermine to his girlfriend. *Id.* at 44.

Based on these findings, the ALJ concluded that Respondent had engaged in "an egregious level of intentional diversion" and that the Government had satisfied its *prima facie* burden of

showing that "Respondent's continued registration would be inconsistent with the public interest." R.D. at 61. Because "Respondent offered no evidence that he accepted responsibility for his misconduct or reformed his ways," the ALJ found that he "failed to rebut the Government's *prima facie* case." *Id.* The ALJ thus recommended that I revoke Respondent's registration and deny any application to renew or modify his registration. *Id.*

Respondent filed Exceptions to the ALJ's Recommended Decision. Thereafter, the ALJ forwarded the record to me for Final Agency Action.

Having considered the record in its entirety, including Respondent's Exceptions, I have decided to adopt the ALJ findings of fact, conclusions of law, and recommended Order. However, before I address Respondent's Exceptions, I deem it necessary to address the ALJ's ruling on the admissibility of the FDA package insert for Hycodan (GX 4).

On motion of Respondent's counsel, the ALJ ruled inadmissible Government Exhibit 4, which the Government represented was the FDA package insert for Hycodan.<sup>4</sup> Tr. 422, 427. The basis of Respondent's objection was that the exhibit contains "little more than generalizations and medical opinions" and that the ALJ's prehearing statement required the parties to disclose "the names and credentials and opinions of medical experts . . . who would be offering medical opinions in this case." *Id.* at 420. Respondent's counsel further argued that "[t]he government did not identify any expert capable of being cross-examined on any of these opinions" and that "[t]here is no reason to believe that [the Exhibit was] authored by a physician, much less do we know whether the author had credentials to offer these opinions." *Id.*

After the Government argued that the document was the FDA package insert, which is included "with every drug purchased or sold," *id.* at 422, Respondent argued that the copyright of the document was the manufacturer and that "we don't know who authored it, or what their credentials were, but it's a self-interested marketing pharmaceutical company" that is "trying to sell their [sic] medicine" and while the company has a "self-interest[] to comply with a federal regulation . . ." "[i]t doesn't mean that the content is government-sanctioned." *Id.* at 422-23. Respondent thus asserted that the

<sup>1</sup> Effective October 6, 2014, combination hydrocodone products including both Norco and Hycodan were transferred from schedule III to schedule II of the Controlled Substances Act. See *Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II*, 79 FR 49661. Thus, at the time Respondent issued some of the Norco and Hycodan prescriptions, the drug was a schedule III controlled substance. This, however, has no consequence for my decision.

<sup>2</sup> All citations to the Recommended Decision are to the slip opinion as issued by the ALJ.

<sup>3</sup> The evidence also showed that at one of the undercover agent's visits, Respondent also gave her a prescription for Hycodan cough syrup.

<sup>4</sup> There is no dispute that the Exhibit was what the Government represented it to be—a copy of the package insert. Nor is there any dispute as to how the document was obtained.