

IN THE MATTER OF

*

BEFORE THE

MEDISCA INC.

*

MARYLAND BOARD

Permit Nos. D00970 & D02904

*

OF PHARMACY

* * * * *

PRE-CHARGE CONSENT ORDER

Background

On November 10, 2011, Medisca Inc., Permit Nos. D00970 and D02904, disclosed to the Maryland Board of Pharmacy (the "Board") that both Medisca and its owner had pled guilty to misdemeanor charges in federal court related to Medisca's distribution and advertising of a drug called Somatropin. Pursuant to the plea agreement, Medisca forfeited its profits from the sale of Somatropin and was fined \$10,000; the company's owner was also fined \$5,000. Subsequently, between May 15, 2012, and May 23, 2013, Medisca notified the Board of disciplinary actions taken in seven other states based on the federal convictions.

In lieu of instituting formal proceedings against Medisca, in accordance with the Maryland Pharmacy Act, Md. Code Ann., Health Occ. § 12-101 *et seq.*, the Board voted to propose a settlement without issuing charges. As a result, the Board and Medisca have agreed to resolve this matter by way of this Consent Order.

FINDINGS OF FACT

1. At all times relevant hereto, Medisca possessed a Maryland wholesale distributor permit, Permit No. D00970, and operated on the premises located at 661 Route 3, Unit C, Plattsburgh, New York. Medisca also possessed a second wholesale distributor permit, Permit No. D02904, and operated on the premises located at 3955 W. Mesa Vista

Avenue, Unit A-10, Las Vegas, Nevada. Both of Medisca's permits are active and are set to expire on May 31, 2015.

2. On November 10, 2011, Medisca informed the Board that both Medisca and its owner had pled guilty to a federal misdemeanor charge in the United States District Court for the Northern District of New York on October 14, 2011. Specifically, Medisca pled guilty to introducing a misbranded drug into interstate commerce, a violation of various federal laws, by the use of misleading and inappropriate advertising.
3. The plea agreement Medisca provided to the Board detailed that Medisca purchased Somatropin, a human growth hormone, from a manufacturer in China and then distributed the drug to pharmacies throughout the United States. Between approximately March 2005 and November 2007, Medisca promoted the sale of Somatropin with literature that stated Somatropin was "FDA approved" and/or from "an FDA-approved facility." Although the FDA had assigned a National Drug Code ("NDC") number to Somatropin, the drug was never approved for commercial distribution by the FDA.
4. Pursuant to the plea agreement, Medisca paid a \$10,000 fine and forfeited its profits from the sale of Somatropin, the company's owner also paid a \$5,000 fine. Medisca suspended all shipments of human growth hormone in 2007.
5. On May 15, 2012, Medisca notified the Board that it had entered into a disciplinary consent agreement with the Colorado Board of Pharmacy based on the federal guilty plea. In an order dated March 27, 2012, the Colorado Board placed Medisca on probation for three years, and Medisca agreed not to distribute any drug containing human growth hormone into Colorado during the probationary period.

6. On July 12, 2012, Medisca informed the Board that the Kansas State Board of Pharmacy had taken reciprocal disciplinary action against Medisca as a result of the Colorado Board's order. The Kansas Board's order, dated June 25, 2012, placed Medisca on probation to run concurrently with the probation in Colorado.
7. On November 1, 2012, Medisca notified the Board that it had entered into a consent order with the Rhode Island Board of Pharmacy based on the federal guilty plea. In three orders dated October 18, 2012, one for each license held in Rhode Island by Medisca, the Rhode Island Board placed each of Medisca's state licenses on probation for six months.
8. On December 13, 2012, Medisca notified the Board that it had agreed to a consent order with the State of Illinois Department of Financial and Profession Regulation, based on the federal guilty plea and the actions taken by Colorado and Kansas, that placed all three of its wholesale drug distributor licenses in Illinois on indefinite probation for a minimum of three years, effective November 26, 2012.
9. On May 17, 2013, Medisca filed applications to renew its permits with the Board. Medisca included with its renewal applications a document titled "Disciplinary Actions and Corrective Actions Taken," which disclosed the federal convictions, the actions taken by the boards in Colorado, Kansas, Rhode Island, and Illinois, and two additional actions taken by the boards of pharmacy in South Carolina and Iowa in response to the federal conviction and other state actions. On January 10, 2013, the South Carolina Board of Pharmacy placed Medisca on probation for three years; on January 16, 2013, the Iowa Board of Pharmacy also placed Medisca on probation for three years.
10. Under "Corrective Actions" on the document submitted with its renewal applications, Medisca notes that it trained all employees "not to respond to inquiries regarding the

approval or registration of products prior to speaking with the Regulatory Affairs Department” and informed all employees that “all documentation regarding the approval or registration of products must be written by the Regulatory Affairs Department, which in turn will be reviewed by counsel.”

11. On May 23, 2013, Medisca notified the Board that the Tennessee Board of Pharmacy had taken action against its three Tennessee licenses based on the federal conviction and the other state actions. In a final consent order dated May 15, 2013, the Tennessee Board placed Medisca’s licenses on indefinite probation for at least three years, and Medisca agreed to immediately cease distributing Somatropin into Tennessee.

CONCLUSION OF LAW

Based on the foregoing Findings of Fact, the Board concludes that Medisca is subject to disciplinary action in accordance with Md. Code Ann., Health Occ. §§ 12-601 and 12-6C-11(b) and COMAR 10.34.22.05.A(1) and (4).

ORDER

Based on an affirmative vote of a majority of the Board, it is this 13th day of September, 2013, hereby:

ORDERED that the wholesale distributor permits held by Medisca Inc., Permit Nos. D00970 and D02904, shall be placed on immediate PROBATION for at least THREE (3) YEARS, *munc pro tunc* to November 26, 2012, during which:

1. Medisca shall not distribute Somatropin into Maryland; and
2. Medisca shall inform the Board of any disciplinary actions taken against it by any other licensing authority within sixty (60) days of any final action; and be it further,

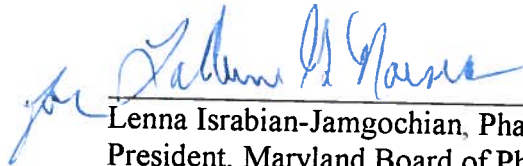
ORDERED that after three (3) years of probation, Medisca may petition the Board to terminate probation, provided it has been fully compliant with this Consent Order and does not have any charges filed against it; and be it further,

ORDERED that failure to comply with the terms and conditions of this Consent Order constitutes a violation of this Consent Order, and the Board, in its discretion, after notice and an opportunity for a show cause hearing before the Board, may impose any appropriate sanction under the Maryland Pharmacy act; and be it further

ORDERED that this is a formal order of the Maryland Board of Pharmacy and as such is a public document pursuant to Md. Code Ann., State Gov't § 10-617(h).

Date

9/13/13

A handwritten signature in blue ink, appearing to read "Lenna Israbian-Jamgochian", is written over a horizontal line. To the left of the signature, the word "for" is written in a cursive script.

Lenna Israbian-Jamgochian, Pharm.D.
President, Maryland Board of Pharmacy

CONSENT

1. By signing this Consent, Medisca submits to the foregoing Consent Order as a resolution of this matter in lieu of formal charges, which process would have afforded Medisca the right to a full evidentiary hearing. Medisca consents and submits to the foregoing Findings of Fact, Conclusions of Law, and Order as if made after a full evidentiary hearing in which Medisca would have the right to counsel, to confront witnesses, to give testimony, to call witnesses on its behalf, and to all other substantive and procedural protections provided by law.
2. By signing this Consent, Medisca waives any rights it may have had to contest the findings and determinations contained in this Consent Order.
3. Medisca acknowledges that this is a formal order of the Board and as such is a public document.
4. Medisca acknowledges the legal authority and the jurisdiction of the Board to enter into and enforce this Consent Order.
5. Medisca signs this Consent Order freely and voluntarily and after having had the opportunity to consult with counsel. Medisca fully understands the language, meaning, and effect of this Consent Order.

MEDISCA INC.
Permit Nos. D00970 & D02904

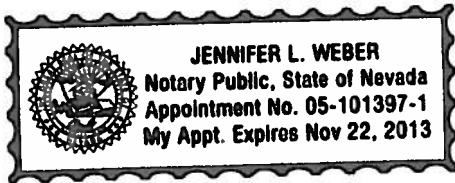
09/05/2013
Date



Antonio Dos Santos
President, Medisca Inc.

STATE OF Nevada
COUNTY/CITY OF Clark :

I hereby certify that on this 5th day of September, 2013, before me, a Notary Public of the State of Nevada and County/city aforesaid, personally appeared Antonio Dos Santos, on behalf of MEDISCA INC., and made an oath in due form that the foregoing Consent was his voluntary act and deed.



Jennifer L. Weber
Notary Public
My commission expires: 11-22-2013