2022R00344/HMB

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA	:	Hon.
	:	
v.	:	Criminal No. 22-
	:	
	:	18 U.S.C. § 1001
ALAIN BOUAZIZ	:	18 U.S.C. § 2
	:	

INFORMATION

The defendant having waived in open court prosecution by indictment, the United States Attorney for the District of New Jersey charges:

(Making False Statements to the Food and Drug Administration)

1. Unless otherwise indicated, at all times relevant to this Information:

a. Defendant ALAIN BOUAZIZ was a French citizen and resident of the United Arab Emirates. BOUAZIZ represented himself to be the Chief Operating Officer (COO) of Hexim Pharmaceuticals (Hexim), a company headquartered in Secaucus, New Jersey. Hexim was known as Alkopharma USA, Inc. until its name was changed in or about June 2013.

b. The United States Food and Drug Administration (FDA) was an agency of the United States charged with, among other things, protecting the public health by ensuring the safety, efficacy, and security of drugs sold in the United States. As part of the FDA's duties, it reviewed New Drug Applications (NDAs), in which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the United States. The FDA published the Approved Drug Products

with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, which listed the owner of each NDA. Under 21 C.F.R. § 314.72, an NDA may be transferred to a new owner. Applicants submitted an FDA Form-356h, which was an application to market a new or abbreviated new drug or biologic for human use, to the FDA in order to, among other things, change the ownership of an NDA.

c. Sanorex (Mazindol) was a weight-loss pharmaceutical owned by a major international pharmaceutical company ("Pharmaceutical Company-1"). In or about 2008, Pharmaceutical Company-1 requested withdrawal of its Sanorex NDA from the FDA. Notice of this withdrawal application was published in the Federal Register in June 2009, meaning Sanorex could no longer be marketed in the United States.

d. In or about October 2009, Alkopharma purchased from Pharmaceutical Company-1 the rights to distribute a different pharmaceutical product in Europe. BOUAZIZ was listed in public records at the time as the president and CEO of Alkopharma. Neither Hexim nor BOUAZIZ obtained the rights to sell Sanorex in the United States or North America nor did they become the legal owner of the Sanorex NDA.

2. On or about February 13, 2018, BOUAZIZ caused a letter to be sent to the FDA that falsely stated that Hexim had purchased the North American rights to Sanorex and also requested a meeting with the FDA to discuss submission of a new marketing application for Sanorex. BOUAZIZ knew that these representations were false. Hexim had not purchased the rights to Sanorex from Pharmaceutical Company-

1. The FDA denied this initial meeting request for being substantially incomplete.

3. On or about April 30, 2018, BOUAZIZ caused another letter to be sent to the FDA, again requesting a meeting about Sanorex to seek to gain control of its NDA.

4. On or about May 1, 2018, BOUAZIZ, using his Hexim email address, sent an email to an FDA manager (the "May 1 Email"). In the signature block of the May 1 Email, BOUAZIZ described himself as Hexim's "C.O.O." and provided Hexim's physical address in Secaucus, New Jersey. The May 1 Email attached six fraudulent documents that purported to support BOUAZIZ's efforts to transfer ownership of Sanorex to Hexim. One of these fraudulent documents was a completed FDA Form-356h signed by BOUAZIZ on behalf of Hexim (the "Form-356h").

5. The Form-356h indicated that Hexim was applying to market Sanorex in the United States. The Form-356h further indicated that the reason for the submission was "CHANGE OD [SIC] OWNERSHIP OF SANOREX." The completed Form-356h that BOUAZIZ caused to be sent to the FDA bore an electronic signature, dated March 8, 2018, reflecting BOUAZIZ's email address. The Form-356h provided a warning that a willfully false statement was a criminal offense under 18 U.S.C. § 1001.

6. BOUAZIZ further sent a paper copy of the May 1 Email and its attachments to the FDA under the same cover letter described above. These paper documents were received by the FDA on or about May 11, 2018 and bore the address of Hexim's corporate headquarters in Secaucus, New Jersey.

7. From in or about February 2018 through in or about November 23, 2021, in Hudson County, in the District of New Jersey, and elsewhere, defendant

ALAIN BOUAZIZ

did willfully and knowingly make materially false, fictitious, and fraudulent statements and representations in a matter within the jurisdiction of the executive branch of the Government of the United States, by submitting and causing to be submitted to the United States Food and Drug Administration false statements and forged documents in an attempt to gain control of Sanorex, a weight-loss pharmaceutical owned by a Pharmaceutical Company-1, and by aiding and abetting the same.

In violation of Title 18, United States Code, Sections 1001(a)(2) and 2.

Philip R. Sellinger

PHILIP R. SELLINGER
United States Attorney