2010R00611/JTE

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA	:	**Hon.**
	:	
	:	**Criminal No. 11-**
v.	:	
	:	
	:	**21 U.S.C. §§ 331(t),**
NITA PATEL	:	**333(b)(1)(d) & 353(e)(2)(A)**

I N F O R M A T I O N

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

1. At all times relevant to this Information:

a. The United States Food and Drug Administration ("FDA") was the agency of the United States responsible for, among other things, enforcing the provisions of the Federal Food, Drug, and Cosmetic Act ("the FDCA"), Title 21, United States Code, Section 301 *et seq*.

b. The FDA's responsibilities included regulating the wholesale distribution of prescription drugs.

c. The FDCA defined a "drug" as including (i) articles recognized as drugs in the official United States Pharmacopoeia and certain other enumerated recognized publications; (ii) articles intended for the use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans; (iii) articles (other than food) intended to affect the structure or any function of the human body; and (iv)

articles intended for use as components of drugs. Title 21, United States Code, Section 321(g)(1).

d. Under the FDCA, a "drug" was deemed to be a "prescription drug" if, because of its toxicity and other potential harmful effects, it was not safe for use except under the supervision of a practitioner licensed by law to administer the drug. Title 21, United States Code, Section 353(b)(1)(A). A "drug" was also deemed to be a "prescription drug" if a new drug application approved by the FDA limited the drug to use under the professional supervision of a practitioner licensed by law to administer the drug. Title 21, United States Code, Section 353(b)(1)(B).

e. The FDCA required that persons engaged in the wholesale distribution of prescription drugs in interstate commerce in a State be licensed by the State in accordance with guidelines established by the FDA. Title 21, United States Code, Section 353(e)(2)(A). The "wholesale distribution" of drugs was defined as "distribution of [prescription] drugs to someone other than the consumer or patient." Title 21, United States Code, Section 353(e)(3)(B).

f. In order for an individual or corporation to sell, purchase, trade, or offer to sell, purchase, or trade prescription drugs and be in compliance with the FDCA, that individual or corporation was required to hold a valid "Prescription Drug Wholesaler" license in a State where that

individual or corporation operates a facility from which that individual or corporation makes shipments of prescription drugs.

g. Sildenafil citrate was the active ingredient in the FDA-approved erectile dysfunction ("ED") drug marketed as Viagra. Vardenafil Hcl was the active ingredient in the FDA-approved ED drug marketed as Levitra. Tadalafil was the active ingredient in the FDA-approved ED drug marketed as Cialis. Each of these drugs was a "prescription drug" within the meaning of the FDCA. No generic versions of the patented drugs Viagra, Levitra, and Cialis were approved by the FDA for sale and distribution in the United States.

h. The defendant, **NITA PATEL**, did not possess a valid license to distribute wholesale quantities of prescription drugs in the State of New Jersey.

2. On or about February 4, 2010, in Bergen County, in the District of New Jersey, and elsewhere, defendant

NITA PATEL

did knowingly engage in the wholesale distribution of prescription drugs in interstate commerce, namely, by causing the wholesale distribution of unauthorized generic versions of the prescription drugs Viagra, Levitra, and Cialis, which were manufactured outside the state of New Jersey, at a time when the defendant was not licensed as a "Prescription Drug Wholesaler" in New Jersey or any other State, in violation of Title 21, United States Code, Sections 331(t), 333(b)(1)(D), and 353(e)(2)(A).

Paul J. Fishman

PAUL J. FISHMAN
UNITED STATES ATTORNEY

CASE NUMBER:_____

United States District Court
District of New Jersey

UNITED STATES OF AMERICA

v.

NITA PATEL

INFORMATION FOR

21 U.S.C. §§ 331(t), 333(b)(1)(D) & 353(e)(2)(A)

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