



FOOD AND DRUG ADMINISTRATION

Office of Criminal Investigations
555 12th Street, Suite 275
Oakland, California 94607

ACKNOWLEDGMENT

The undersigned interviewing Special Agent advised the interviewee, _____, that non-FDA approved drugs, which are virtually always also misbranded and/or adulterated under the Federal Food, Drug, and Cosmetic Act (FDCA), puts individuals' health at risk. The Special Agent further informed the interviewee that drugs that have not undergone scientific and regulatory review by FDA to ensure their safety and efficacy may have unknown ingredients, improper labeling, or may not have been manufactured, transported, or stored under proper conditions.

The undersigned Special Agent further advised the interviewee that receiving misbranded and/or adulterated drugs in interstate commerce, and delivering or offering to deliver those drugs violates the FDCA. *See* 21 U.S.C. § 331(c). This includes, but is not limited to, ordering and providing drugs manufactured for non-U.S. markets that have not been approved/cleared by the FDA for distribution in the United States.

The Special Agent also informed the interviewee that both past and future violations of the law are subject to enforcement actions, including criminal prosecution. The interviewee was advised that the minimum penalties for a criminal violation of the FDCA authorizes a sentence of up to one year in prison, a fine that could exceed \$100,000, or both, for each separate offense committed. *See* 21 U.S.C. § 333(a)(1) and 18 U.S.C. § 3571(b)(5), (c)(5), and (d). The Special Agent also advised that under the FDCA, a responsible corporate official can be held liable for a misdemeanor violation without proof that the corporate official acted with intent or even negligence, and even if such corporate official did not have any actual knowledge of, or participation in, the specific offense. *See U.S. v. Park*, 421 U.S. 658 (1975).

Interviewee's Printed Name

Special Agent Interviewer (Printed Name)

Interviewee's Signature

Special Agent (Printed Name)
Secondary Interviewer / Witness

Date