factual basis for this conviction is as follows: Between around August 2009 and August 2013, Mr. Aminzada owned and operated several companies dedicated to international sales, including Royal Canadian Imports (headquartered in Canada), and Essa Gulf Trading (headquartered in Dubai, United Arab Emirates).

Between approximately August 2009 and August 2012, Mr. Aminzada sold misbranded chemotherapy drugs and injectable cosmetic drugs to Gallant Pharma International, Inc. (Gallant Pharma) for resale in the United States. Neither of Mr. Aminzada's companies were licensed as a prescription drug wholesaler anywhere in the United States. Mr. Aminzada admitted that the drugs he sold to Gallant Pharma for resale in the United States were prescription only, and that many of the drugs were misbranded in that the drugs did not bear adequate directions for use and were not subject to an exemption from that requirement, and were accompanied by non-FDA approved packaging and inserts, which were sometimes written in foreign languages. The drugs Mr. Aminzada sold to Gallant Pharma also lacked the FDA-required pedigree, which protects patients' health by tracking each sale, purchase, or trade of a drug from the time of manufacturing to delivery to the patient. Between August 2009 and August 2012, Mr. Aminzada received at least $586,798 in wire transfers from Gallant Pharma, representing revenues from sales of such drugs to Gallant Pharma. Mr. Aminzada admitted that his actions were in all respect knowing, voluntary, intentional, and did not occur by accident, mistake, or for another innocent reason.

As a result of his conviction, on March 9, 2015, FDA sent Mr. Aminzada a notice by certified mail proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on the finding, under section 306(a)(2)(B) of the FD&C Act, that Mr. Aminzada was convicted of a felony under Federal law for conduct related to the regulation of a drug product. FDA determined that Mr. Aminzada's felony conviction was related to the regulation of drug products because the conduct underlying his conviction undermined FDA's regulatory oversight over drug products marketed in the United States by intentionally introducing into interstate commerce drug products that did not bear adequate directions for use and were not subject to an exemption from that requirement, and which, among other things, were accompanied by non-FDA approved packaging and inserts. The proposal also offered Mr. Aminzada an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. The proposal was received on March 16, 2015. Mr. Aminzada failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and has waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Mirwaiss Aminzada has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Section 306(c)(2)(A)(ii) of the FD&C Act (21 U.S.C. 335a(c)(2)(A)(ii)) requires that Mr. Aminzada's debarment be permanent.

As a result of the foregoing findings, Mirwaiss Aminzada is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (see sections 201(dd), 306(c)(1)(B), and 306(c)(2)(A)(ii) of the FD&C Act, (21 U.S.C. 321(dd), 335a(c)(1)(B), and 335a(c)(2)(A)(ii)). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mirwaiss Aminzada, in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Aminzada provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mirwaiss Aminzada during his period of debarment (section 306(c)(1)(A) of the FD&C Act (21 U.S.C. 335a(c)(1)(A))).

Any application by Mr. Aminzada for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) should be identified with Docket No. FDA–2015–N–0097 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 16, 2015.

Douglass Stearn,

Director, Division of Compliance Policy, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2015–15162 Filed 6–19–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2101]

Anoushirvan Sarraf: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Anoushirvan Sarraf from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Dr. Sarraf was convicted of seven felonies under Federal law for conduct relating to the regulation of a drug product. Dr. Sarraf was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Sarraf failed to request a hearing. Dr. Sarraf's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective June 22, 2015.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade (ELEM–4144) Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Drive, Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act.

On July 23, 2014, the U.S. District Court for the Eastern District of Virginia entered judgment against Dr. Sarraf after a jury found him guilty of one count of conspiracy, in violation of 18 U.S.C. 371, three counts of importation contrary to law, in violation of 18 U.S.C. 545 and 18 U.S.C. 2, two counts of receipt and delivery of misbranded drugs, in violation of 21 U.S.C. 331(c), 333(a)(2), and 18 U.S.C. 2, and one count of unlicensed wholesale distribution of prescription drugs, in violation of 21 U.S.C. 331(t), 333(b)(1)(D), 353(e)(2)(A), 353(e)(3)(B), and 18 U.S.C. 2.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for these convictions is as follows: Dr. Sarraf was a physician and owner of Aphrodite in McLean, Virginia, in the Eastern District of Virginia. Dr. Sarraf provided his medical license to Gallant Pharma International Inc. (Gallant Pharma), for use by international co-conspirators, received importations in his and Aphrodite's name on behalf of Gallant Pharma, and purchased misbranded and non-FDA approved drugs and devices from Gallant Pharma. In exchange for use of his medical license, mailing name, and address, Dr. Sarraf received discounted pricing from Gallant Pharma.

Beginning in or around June 2009, and continuing until at least August 2013, in the Eastern District of Virginia and elsewhere, Dr. Sarraf knowingly and intentionally conspired and agreed to commit offenses against the United States by: Fraudulently and knowingly importing misbranded drugs; knowingly engaging in the wholesale distribution of prescription drugs in Virginia without being licensed to do so; receiving in interstate commerce, delivering and proffering delivery for pay, misbranded drugs; defrauding the United States and its Agencies by impeding, impairing, and defeating the lawful functions of FDA to protect the health and safety of the public.

Dr. Sarraf provided Gallant Pharma with his medical license to enable Gallant Pharma to order non-FDA-approved chemotherapy and cosmetic drugs from around the world, and allowed those drugs to be shipped into the United States to Aphrodite. When the drugs arrived, he would alert individuals at Gallant Pharma to retrieve the illegal drugs. He additionally would take some of the misbranded and non-FDA-approved drugs from the packages intended for Gallant Pharma for use on his patients at Aphrodite.

Between August 2009 and August 2012, Dr. Sarraf received and handed off at least 40 shipments containing illegally imported drugs and devices. Between August 2009 and August 2012, Dr. Sarraf purchased approximately $250,000 in misbranded and non-FDA-approved drugs and devices from Gallant Pharma.

As a result of his convictions, on March 9, 2015, FDA sent Dr. Sarraf a notice by certified mail proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on the finding, under section 306(a)(2)(B) of the FD&C Act, that Dr. Sarraf was convicted of felonies under Federal law for conduct related to the regulation of a drug product. FDA determined that Dr. Sarraf's felony convictions were related to the regulation of drug products because the conduct underlying his convictions undermined FDA's regulatory oversight over drug products marketed in the United States, by intentionally introducing into interstate commerce drug misbranded products. The proposal also offered Dr. Sarraf an opportunity to request a hearing, provided him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. The proposal was received on March 12, 2015. Dr. Sarraf failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and has waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Anoushirvan Sarraf has been convicted of seven felonies under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing findings, Anoushirvan Sarraf is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (see section 201(dd), 306(c)(1)(B), and 306(c)(2)(A)(ii) of the FD&C Act, (21 U.S.C. 321(dd), 335a(c)(1)(B), and 335a(c)(2)(A)(ii)). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Anoushirvan Sarraf, in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Sarraf provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the Act (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Anoushirvan Sarraf during his period of debarment (section 306(c)(1)(A) of the FD&C Act (21 U.S.C. 335a(c)(1)(A))).

Any application by Dr. Sarraf for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) should be identified with Docket No. FDA–2014–N–2101 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 16, 2015.

Douglass Stearn,

Director, Division of Compliance Policy, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2015–15163 Filed 6–19–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Delegation of Authority

Notice is hereby given that I have delegated to the Administrator of the Health Resources and Services Administration, or his or her successor,