Department of Health and Human Services, Administration for Children and Families (ACF), as follows: Chapter KT, as last amended, 65 FR 30413–14, May 11, 2000.

I. Under Chapter KT, Office of Legislative Affairs and Budget, delete KT.00 Mission in its entirety and replace with the following:

KT.00 MISSION. The Office of Legislative Affairs and Budget (OLAB) provides leadership in the development of legislation, budget, and policy, ensuring consistency in these areas among ACF program and staff offices, and with ACF and the Department's vision and goals. It advises the Assistant Secretary for Children and Families on all policy and programmatic matters that substantially impact the agency's legislative program, budget development, budget execution, and regulatory agenda. The Office serves as the primary contact for the Department, the Executive Branch, and the Congress on all legislative, budget development and execution, and regulatory activities. The Office serves as the ACF liaison to the Government Accountability Office and to the Office of Inspector General (OIG) for OIG engagements relating to the management of ACF programs.

II. Under Chapter KT, Office of Legislative Affairs and Budget, delete KT.20, Functions, Paragraph B, in its entirety and replace with the following:

B. The Division of Legislative and Regulatory Affairs serves as the focal point for congressional liaison in ACF; provides guidance to the Assistant Secretary for Children and Families and senior ACF staff on congressional activities and relations; manages the preparation of testimony and briefings for programmatic and budget-related hearings; negotiates clearance of testimony; monitors hearings and other congressional activities that affect ACF programs; and responds to congressional inquiries.

The Division manages the ACF legislative planning cycle and the development of Reports to Congress; reviews and analyzes a wide range of congressional policy documents including: legislative proposals, pending legislation, and bill reports; solicits and synthesizes internal ACF comments on such documents; negotiates legislative policy positions with the Department and the Executive Branch; and reviews other policy significant documents to ensure consistency with statutory and congressional intent and the agency legislative agenda.

The Division manages the ACF regulatory development process; negotiates regulatory policy positions with the Department and the Executive Branch; and provides guidance to ACF program and staff components on policy and programmatic matters related to the regulatory development process.

The Division manages all Government Accountability Office (GAO) engagements with ACF; coordinates entrance and exit conferences within ACF; ensures GAO requests for information are fulfilled; and coordinates ACF comments on GAO draft reports and Statements of Action on GAO's recommendations.

The Division facilitates OIG engagements relating to the management of ACF programs, to include, but not be limited to, audits to determine whether an ACF program office met its statutory requirements; audits to determine whether an ACF program office complied with internal policies and procedures; evaluations of an ACF program for efficiency and effectiveness; and evaluation of both ACF management and selected grantees' management of their grants.

III. Continuation of Policy. Except as inconsistent with this realignment, all statements of policy and interpretations with respect to organizational components affected by this notice within ACF, heretofore issued and in effect on this date of this realignment are continued in full force and effect.

IV. Delegation of Authority. All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this realignment.

V. Funds, Personnel, and Equipment. Transfer of organizations and functions affected by this realignment shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

This realignment will be effective upon date of signature.

Dated: June 12, 2015.

Mark H. Greenberg,

Acting Assistant Secretary for Children and Families.

[FR Doc. 2015–15237 Filed 6–19–15; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0097]

Mirwaiss Aminzada: 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 Mirwaiss Aminzada 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 Mr. Aminzada was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Mr. Aminzada was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Aminzada failed to request a hearing. Mr. Aminzada'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 June 10, 2014, the U.S. District Court for the Eastern District of Virginia entered judgment against Mr. Aminzada for one count of introducing misbranded drugs into interstate commerce with intent to defraud or mislead, in violation of sections 301(a) and 303(a)(2) of the FD&C Act (21 U.S.C. 331(a) and 333(a)(2)).

FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The

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.