

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 Stearns,

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

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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,

the following authorities vested in the Secretary:

- The authorities vested under Section 343 of the Illegal Immigration Reform and Immigrant Responsibility Act (IIRIRA) of 1996, [8 U.S.C. 1182(a)(5)], as amended, titled “Certification Requirements for Foreign Healthcare Workers.”

These authorities may be redelegated. Exercise of these authorities is concurrent and does not supplant existing delegations of authority from the Secretary. Exercise of these authorities shall be in accordance with established policies, procedures, guidelines, and regulations as prescribed by the Secretary.

This delegation is effective immediately upon date of signature.

Dated: June 16, 2015.

Sylvia M. Burwell,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS-OS-0990-0388-30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork

Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for renewal of the approved information collection assigned OMB control number 0990-0388, scheduled to expire on July 31, 2015. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before July 22, 2015.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690-6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the OMB control number 0990-0388 and document identifier HHS-OS-0990-0388 30D for reference.

Information Collection Request Title: *Let's Move! Cities, Towns, and Counties*

Abstract: The Office of the Assistant Secretary for Health (OASH) is requesting an approval on an extension by Office of Management and Budget (OMB) on a currently approved information collection; the OMB number is 0990-0388. The project on, *Let's Move! Cities, Towns and Counties (LMCTC)*, seeks to continue to conduct

a survey of local government organizations for the Initiative. *Let's Move* is a comprehensive initiative, launched by the First Lady, Michelle Obama, dedicated to solving the challenge of childhood obesity within a generation. The online survey is the mechanism by which *Let's Move! Cities, Towns and Counties* report progress on the initiative's goals and are recognized for that progress. LMCTC calls on local elected officials to adopt long-term, sustainable, and holistic approaches to addressing childhood obesity. Local elected officials who sign up for the initiative are willing to commit to five goals that are intended to create healthier, more livable communities.

Therefore, the online survey is essential to the successful operation of the initiative. Since July 2012 until January 31 2015, 463 sites had signed up for *Let's Move! Cities, Towns and Counties*. Sites who have completed the online survey report that they have implemented a total of 2170 promising practices intended to promote healthy eating and active living for community residents.

Likely Respondents: This activity is requesting comment on the burden for a survey for local government officials who have chosen to participate in *Let's Move! Cities, Towns and Counties*. The survey requests information about the activities the locality has undertaken against the initiative's goals. The responses to these questions are used to show progress, and to recognize municipal and county sites' success in participating in *Let's Move! Cities, Towns and Counties*.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Government Official (city, town, county)	500	1	30/60	250
Total

Terry S. Clark,

Asst Information Collection Clearance Officer.

[FR Doc. 2015-15225 Filed 6-19-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, 5 U.S.C., notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the SACHRP Web site at: <http://www.dhhs.gov/ohrp/sachrp/mtgings/index.html>.