Correction

In the **Federal Register** of June 22, 2015, in FR Vol. 80, No. 119, on page 35649, in the third column, on lines 13–14, correct the **ADDRESSES** caption to read:

ADDRESSES: CECANF will convene its meeting at the Madison Marriott West, 1313 John Q. Hammons Drive, Middleton, Wisconsin. This site is accessible to individuals with disabilities. The meeting also will be made available via teleconference and/or webinar.

Dated: June 30, 2015.

Amy Templeman,

Acting Executive Director.

[FR Doc. 2015–16698 Filed 7–7–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''*Assessing the Impact of the National Implementation of TeamSTEPPS Master Training Program.*'' In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on April 10th, 2015 and allowed 60 days for public comment. No substantive comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by August 7, 2015.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by email at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer). Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Assessing the Impact of the National Implementation of TeamSTEPPS Master Training Program

AHRQ, in collaboration with the Department of Defense's (DoD) Tricare Management Activity (TMA), developed TeamSTEPPS® (''Team Strategies and Tools to Enhance Performance and Patient Safety'') to provide an evidence-based suite of tools and strategies for teaching teamwork-based patient safety to health care professionals. In 2007, AHRQ and DoD coordinated the national implementation of the TeamSTEPPS Program. The main objective of this program is to improve patient safety by training a select group of stakeholders such as Quality Improvement Organization (QIO) personnel, High Reliability Organization (HRO) staff, and health care system staff in various teamwork, communication, and patient safety concepts, tools, and techniques. Ultimately, TeamSTEPPS will help to build a national and state-level infrastructure for supporting teamwork-based patient safety efforts in health care organizations.

The National Implementation of TeamSTEPPS Master Training Program includes the training of ''Master Trainers'' in various health care systems capable of stimulating the utilization and adoption of TeamSTEPPS in their health care delivery systems, providing technical assistance and consultation on implementing TeamSTEPPS, and developing various channels of learning (*e.g.,* user networks, various educational venues) for continuing support and improvement of teamwork in health care. AHRQ has already trained a corps of over 5,000 participants to serve as the Master Trainer infrastructure supporting national adoption of TeamSTEPPS. An anticipated 2,400 participants, who are undergoing training now, will be studied in this assessment. After training, these participants will become Master Trainers in TeamSTEPPS and will have the opportunity to observe the program's tools and strategies in action. In addition to developing a corps of Master Trainers, AHRQ has also developed a series of support mechanisms for this effort including a data collection Web tool, a TeamSTEPPS call support center, and a monthly consortium to address any challenges encountered implementing TeamSTEPPS.

Participants applied to the program as teams representing their organizations and were accepted as training participants after having completed an organizational readiness assessment. Due to the differences among the types of organizations participating in the program, participants will apply the tools and concepts differently within and/or beyond their home organizations. For example:

- Health care system staff (or implementers) from hospitals, home health agencies, nursing homes, large physician practices, and other direct care organizations are more likely than other participants to implement the TeamSTEPPS materials on a daily basis and will be more likely to affect specific work processes being conducted within an organization. As a result, health care system participants are likely to have a focused and specific impact that is limited to their organization.
- QIO\HRO\Hospital Association\State Health Department participants (or facilitators) will be more likely to have both an in-depth and broad impact if they use the TeamSTEPPS materials to assist a particular organization in its patient safety activities, as well as to provide general patient safety guidance to a large number of organizations.

To clarify the differences among the participants, a logic model has been developed that highlights the roles of the different types of participants, the types of activities in which they are likely to engage after training, and the potential outcomes that may stem from these activities. The logic model served as a guide for developing questions for a web-based questionnaire and qualitative interviews to ensure that participant and leadership feedback is captured as thoroughly and accurately as possible.

AHRQ is conducting an ongoing evaluation of the National Implementation of TeamSTEPPS Master Training Program. The goals of this evaluation are to examine the extent to which training participants have been able to:

(1) Implement the TeamSTEPPS products, concepts, tools, and techniques in their home organizations and,

(2) spread that training, knowledge, and skills to their organizations, local areas, regions, and states.

The National Implementation of TeamSTEPPS program is led by AHRQ through its contractor, the Health Research and Educational Trust (HRET). This study is being conducted by HRET's subcontractor, IMPAQ International. The work is being

conducted pursuant to AHRQ's statutory authority to conduct and support research, evaluations, and training on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

To achieve the goals of this assessment the following two data collections will be implemented:

(1) Training participant questionnaires to examine post-training activities and teamwork outcomes as a result of training from multiple perspectives. The questionnaire is directed to all Master Training participants, and will cover post-training activities, implementation experiences, facilitators and barriers to implementation encountered, and perceived outcomes as a result of these activities. Advance notice, invitations to participate, reminder emails, and thank you letters to respondents are included in the participant questionnaire.

(2) Semi-structured interviews will be conducted with members from organizations who participated in the TeamSTEPPS Master Training Program. Information gathered from these interviews will be analyzed and used to draft a ''lessons learned'' document that will capture additional detail on the issues related to participants' and organizations' abilities to implement and disseminate TeamSTEPPS post-training. The organizations will vary in terms of type of organization (*e.g.,* QIO or hospital associations versus health care systems) and region (*i.e.,* Northeast, Midwest, Southwest, Southeast, Mid-Atlantic, West Coast). In addition, we will strive to ensure that the distribution of organizations mirrors the distribution of organizations in the Master Training population. For example, if the distribution of organizations is such that only one out of every five organizations is a QIO, we will ensure that a maximum of two organizations in the site visit sample are QIOs. The interviews will more accurately reveal the degree of training spread for the organizations included. Interviewees will be drawn from qualified individuals serving in one of two roles (*i.e.,* implementers or facilitators). The interview protocol will be adapted for each role based on the respondent group and to some degree, for each individual, based on their training and patient safety experience. There is also an informed consent form that each participant will be required to sign prior to beginning the interview.

The final product for this evaluation will be a report that documents the background, methodology, results (including any patterns or themes emerging from the data), limitations of the study, and recommendations for future training programs and tool development. The results of this evaluation will help AHRQ understand the extent to which participants and participating organizations have been able to employ various TeamSTEPPS tools and concepts and the barriers and facilitators they encountered. This information will help guide AHRQ in developing and refining other patient safety tools and future training programs for patient safety.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondent's time to participate in the study. Semi-structured interviews will be conducted with a maximum of nine individuals from each of nine participating organizations and will last about one hour each. The training participant questionnaire will be completed by approximately 10 individuals from each of about 240 organizations and is estimated to require 20 minutes to complete. The total annualized burden is estimated to be 881 hours.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to participate in the study. The total cost burden is estimated to be $39,240.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Semi-structured interview	9	9	60/60	81
Training participant questionnaire	240	10	20/60	800
Total	249	NA	NA	881

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Semi-structured interview	9	81	$45.31	$3,670
Training participant questionnaire	240	800	45.31	36,248
Total	249	881	NA	39,918

* Based upon the mean of the average wages for all health professionals (29–0000) for the training participant questionnaire and for executives, administrators, and managers for the organizational leader questionnaire presented in the National Compensation Survey: Occupational Wages in the United States, May 2014, U.S. Department of Labor, Bureau of Labor Statistics. *http://www.bls.gov/oes/current/oes_nat.htm.*

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the

collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Sharon B. Arnold,

Deputy Director.

[FR Doc. 2015–16646 Filed 7–7–15; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2103]

Talib Khan: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Talib Khan 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. Khan was convicted of two felonies under Federal law for conduct relating to the regulation of a drug product. Mr. Khan was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Khan failed to respond. Mr. Khan's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective July 8, 2015.

ADDRESSES: Submit applications for special 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), Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., 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 March 11, 2014, the U.S. District Court for the Eastern District of Virginia entered judgment against Mr. Khan for one count of conspiracy in violation of 18 U.S.C. 371, and one count of introducing misbranded drugs into interstate commerce, in violation of 21 U.S.C. 331(a) and 333(a)(2) 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 this conviction is as follows: Mr. Khan was a cofounder and co-owner of Gallant Pharma International Inc. (Gallant Pharma), between August 2009 and August 2013. Gallant was a company dedicated to the illegal importation and sale of misbranded and non-FDA approved chemotherapy drugs and injectable cosmetic drugs and devices in the United States.

As cofounder and co-owner of Gallant Pharma, Mr. Khan was primarily responsible for the international aspect of the conspiracy, including: (1) Determining which drugs and devices to sell in the United States; (2) establishing relationships with international suppliers; (3) directing those suppliers to send drugs and devices to transshippers in Canada and the United Kingdom; (4) arranging for transshipment from Canada and the United Kingdom to the United States; (5) interviewing, hiring, and training sales representatives in the United States; (6) and paying suppliers, sales representatives, and office employees out of foreign bank accounts. Gallant Pharma was not licensed as a prescription drug wholesaler by the Commonwealth of Virginia. Some of the drugs and devices that Mr. Khan acquired were not approved by the FDA for use on patients in the United States. Mr. Khan admitted that the drugs sold by Gallant Pharma were prescription only and were misbranded in that, among other things, they did not bear adequate directions for use and were not subject to an exemption from that requirement, and they were accompanied by non-FDA approved packaging and inserts. The drugs Mr. Kahn's company sold also lacked the FDA-required pedigree, which protects patient health by tracking each sale, purchase, or trade of a drug from the time of manufacturing to delivery to the patient, and some drug packaging and inserts were written solely in languages other than English.

Immediately after establishing Gallant Pharma's presence in the Eastern District of Virginia, on or about September 25, 2009, Mr. Khan received a cease and desist letter from a law firm on behalf of Medicis, the exclusive authorized marketer of Restylane and Perlane in the United States and Canada. The letter informed Mr. Khan's company that its marketing of these drugs violated the FD&C Act and could subject Gallant Pharma to substantial criminal and civil penalties. The letter included Gallant Pharma's marketing materials, which falsely claimed that Gallant Pharma had been ''strictly working with the current FDA rules and regulations for almost 10 years.''

Mr. Khan purchased drugs and devices from suppliers in, among other places, Turkey, Switzerland, the United Kingdom, and the United Arab Emirates. In or around March 2011, after a coconspirator's medical license had expired, Mr. Khan altered the expiration date on the medical license to make it appear that the license was still valid.

On at least 18 occasions, Mr. Khan personally completed false customs declarations and thereby illegally imported misbranded drugs and devices from Canada to the Eastern District of Virginia. Mr. Khan also personally accepted and processed orders for Gallant Pharma customers.

Between August 2009 and August 2013, Gallant Pharma received illegal proceeds of at least $12,400,000 from the sale of misbranded and non-FDA approved drugs and devices in the United States. Mr. Khan admitted that he was an organizer or leader of this criminal activity and he additionally admitted that his actions were in all respects knowing, voluntary, and intentional, and did not occur by accident, mistake, or for another innocent reason.

As a result of his conviction, on March 19, 2015, FDA sent Mr. Khan 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. Khan was convicted of felonies under Federal law for conduct related to the regulation of a drug product. The proposal also offered Mr. Khan 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