I. Background

Section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits FDA to debar an individual if it finds that the individual has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and if FDA finds that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

On April 2, 2007, Dr. Choi pleaded guilty to one count of receipt in interstate commerce of a misbranded drug and delivery thereof in violation of sections 301(c), 303(c), and 502(f) of the FD&C Act (21 U.S.C. 331(c), 333(a)(1), and 352(f)). On August 11, 2008, the U.S. District Court for the Central District of California entered judgment against Dr. Choi for the misdemeanor offense of receipt in interstate commerce of a misbranded drug and delivery thereof.

FDA's finding that debarment is appropriate is based on the misdemeanor conviction referenced herein. The factual basis for the conviction is as follows: Dr. Choi was a licensed physician in the State of California. Prior to November 13, 2003, Dr. Choi injected patients with Botox®, an FDA-approved Botulinum Toxin Type A drug product manufactured by Allergan, Inc. In 2003, Dr. Choi began ordering an unapproved drug purported to be Botulinum Toxin Type A (TRI–Toxin) manufactured by Toxin Research International, Inc. (TRI), located in Tucson, Arizona, instead of the approved Botox®. From on or about November 13, 2003, and continuing until about August 3, 2004, Dr. Choi placed 14 orders for a total of 28 vials of TRI–Toxin, which he had shipped to his office in the Central District of California. The TRI–Toxin did not come with labeling or directions on how to dilute the product for injection. The TRI–Toxin label stated ''for research purposes only'' and ''not for human use,'' as did the TRI–Toxin invoices. Dr. Choi admitted to injecting the TRI–Toxin into his employees and patients. Between on or about November 13, 2003, and continuing until on or about August 3, 2004, Dr. Choi received and delivered the TRI–Toxin when he administered it to other persons, all in violation of sections 301(c), 303(c), and 502(f) of the FD&C Act.

As a result of his conviction, on April 22, 2011, FDA sent Dr. Choi a notice by certified mail proposing to debar him for 4 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA subsequently confirmed on May 9, 2011, that Dr. Choi personally received the notice. The proposal was based on a finding, under section 306(b)(2)(B)(i)(I) of the FD&C Act that Dr. Choi was convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and that the conduct that served as a basis for the conviction undermines the process for the regulation of drugs. The proposal also offered Dr. Choi 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. Dr. Choi failed to respond within the timeframe prescribed by regulation and has therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(b)(2)(B)(i)(I) of the FD&C Act under authority delegated to him (Staff Manual Guide 1410.35), finds that Andrew K. Choi has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of a drug product under the FD&C Act, and that the type of conduct that served as a basis for the conviction undermines the process for the regulation of drugs.

As a result of the foregoing finding, Dr. Choi is debarred for 4 years 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 306(c)(1)(B), (c)(2)(A)(iii), and 201(dd) of the FD&C Act (21 U.S.C. 335a(c)(1)(B), (c)(2)(A)(iii), and 321(dd))). 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 Dr. Choi, in any capacity during Dr. Choi's 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. Choi 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). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Choi during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Choi for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) should be identified with Docket No. FDA–2011–N–0126 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(j).

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

Dated: July 27, 2011.

Armando Zamora,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2011–19976 Filed 8–5–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0557]

Advancing Regulatory Science for Highly Multiplexed Microbiology/ Medical Countermeasure Devices; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing the following public meeting: ''Advancing Regulatory Science for Highly Multiplexed Microbiology/Medical Countermeasure Devices.'' The purpose of the public meeting is to discuss performance evaluation of highly multiplexed microbiology/medical countermeasure (MCM) devices, their clinical application and public health/clinical needs, and quality criteria for establishing the accuracy of reference databases. These considerations are essential to establish the safety and effectiveness of highly multiplexed devices when used for the clinical diagnosis of infectious diseases from a human specimen.

Date and Time: The public meeting will be held on October 13, 2011, from 8 a.m. to 6 p.m.

Location: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31,

rm. 1503 (the Great Room), Silver Spring, MD 20993–0002. For parking and security information, please visit the following Web site: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.* The public meeting will also be available to be viewed online via webcast.

Contact Person: Raquel Peat, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5561, Silver Spring, MD 20993–0002, 301–796–6218, e-mail: *raquel.peat@fda.hhs.gov.*

Registration and Requests for Oral Presentations: If you wish to attend or view the webcast of the public meeting, you must register online at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list).

Provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Registration requests should be received by September 13, 2011.

If you wish to make an oral presentation during the open comment session at the meeting, you must indicate this at the time of registration. FDA has included general discussion topics for comment in section III of this document, Topics for Input. You should also identify which discussion topic you wish to address in your presentation. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. If the number of registrants requesting to speak is greater than what can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open comment session.

Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once their registration has been accepted. Onsite registration on the day of the public meeting will be provided on a space-available basis beginning at 7 a.m. Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4321, Silver Spring, MD 20993–0002, 301–796–5661, e-mail: *susan.monahan@fda.hhs.gov* at least 7 days in advance of the meeting.

Streaming Webcast of the Public Meeting: There will be a registration process for the webcast, and it will be on a first-come, first-served basis (maximum capacity: 900). If you have never attended a Connect Pro meeting before, test your connection at: *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit: *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.**)

Comments: In advance of the meeting, FDA will place its proposed evaluation approach to assess the performance of highly multiplexed microbiology/MCM devices on file in the public docket (docket number found in brackets in the heading of this document) and will post it at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* The deadline for submitting comments to be presented at this public meeting is September 13, 2011 (see section III of this document.)

Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments on any discussion topic(s) to the open docket. The deadline for submitting comments to the docket is September 13, 2011. Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, if responding to specific topics as outlined in section III of this document, please identify the topic you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Background

Highly multiplexed devices for the diagnosis of infectious diseases, including those caused by MCM-related pathogens, are a new generation of diagnostic products designed to simultaneously identify and differentiate a large number of pathogens from a single clinical specimen. This involves the testing of multiple targets through a common process of sample preparation, amplification and/or detection, and result interpretation. The identification of the organism is often based on sequence information compared to reference databases created either by the device manufacturer or otherwise publicly available.

These diagnostic devices present several advantages, such as identifying potential disease etiology in situations where many different pathogens share a common clinical manifestation and the simultaneous detection of co-infections. However, establishing and validating the performance of these devices to make informed clinical and public health decisions poses significant scientific challenges. This public meeting is to discuss the performance evaluation of highly multiplexed microbiology/MCM device, their clinical application and public health/clinical needs and quality criteria for establishing the accuracy of reference databases. These considerations are essential to establish the safety and effectiveness of highly multiplexed devices when used for the clinical diagnosis of infectious diseases from a human specimen.

FDA is holding this public meeting to obtain input from academia, government, industry, clinical laboratories, and other stakeholders on the performance evaluation approach to be proposed by FDA, which includes validation methods, reference panels, and bioinformatic concepts needed to address the clinical and analytical performance requirements for highly multiplexed microbiology/MCM devices. The ultimate goal is to advance regulatory science for highly multiplexed devices used in pathogen detection in order to ensure their safety and effectiveness and thereby provide potential clinical and public health benefits.

II. Meeting Overview

The public meeting will consist of presentations providing background on current and anticipated uses for highly multiplexed microbiology devices that may contain MCM analytes, the performance evaluation approach

proposed by FDA, and information on reference databases; an open public comment session; and an open discussion on selected topics raised by the presentations (see section III of this document.) During the discussions, the participants will not be asked to develop consensus opinions but rather to provide their individual perspectives.

Additional information, including a meeting agenda, will be available on the Internet, immediately after publication of this document in the **Federal Register**. The evaluation approach proposed by FDA is expected to be available at a later date. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at *http://www.regulations.gov.* This information will also be available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list).

III. Topics for Input

FDA will seek input on its proposed performance evaluation approach, which will include the following topics:

1. *Clinical Application of Highly Multiplexed Microbiology Devices:* Their clinical application and public health/clinical needs; inclusion of MCM-related pathogens that are expected to be rarely present in the tested specimens; the composition of clinically relevant panels of pathogens; the interpretation of the test results taking into consideration the possible detection of microorganisms that are not clinically relevant, and what is known and unknown about co-infections.

2. *Device Evaluation:* How to evaluate the analytical and clinical performance of highly multiplexed microbiology devices; approaches to device validation when positive specimens are not easily available, which is the case for many MCM pathogens; sufficiency, feasibility, and practicality of the proposed FDA evaluation approach to establish device performance.

3. *Reference Databases:* Quality criteria for establishing the accuracy of reference databases; methods for curating, maintaining, and updating these databases; what is the current practice for creating and maintaining reference databases.

IV. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., rm. 1050, Rockville, MD 20857.

Dated: August 2, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–19996 Filed 8–5–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection 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 on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Health Service Corps Site Application (OMB No. 0915–0230)—Revision

The National Health Service Corps (NHSC) of the Bureau of Clinician Recruitment and Service (BCRS), Health Resources and Services Administration, is committed to improving the health of the Nation's underserved by uniting communities in need with caring health professionals, and by supporting their efforts to build better systems of care. The NHSC Site Application, which renames and revises the previous Recruitment and Retention Assistance Application, requests information on the clinical service site, sponsoring agency, recruitment contact, staffing levels, service users, charges for services, employment policies, and fiscal management capabilities. Assistance in completing the application may be obtained through the appropriate State Primary Care Offices, State Primary Care Associations and the NHSC. The information on the application is used for determining the eligibility of sites for assignment of NHSC-obligated health professionals and to verify the need for NHSC clinicians. Approval as an NHSC service site is good for 3 years; sites wishing to remain eligible for assignment of NHSC providers must submit a new Site Application every 3 years.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
NHSC Site Application	3000	1	3000	0.5	1500