information, a listing of all drug or device products manufactured, prepared, propagated, compounded, or processed by him or her for commercial distribution. In part 607 (21 CFR part 607), FDA has issued regulations implementing these requirements for manufacturers of human blood and blood products.

Section 607.20(a), in brief, requires owners or operators of certain establishments that engage in the manufacture of blood products to register and to submit a list of every blood product in commercial distribution. Section 607.21, in brief, requires the owners or operators of establishments entering into the manufacturing of blood products to register within 5 days after beginning such operation and to submit a list of every blood product in commercial distribution at the time. If the owner or operator of the establishment has not previously entered into such operation for which a license is required, registration must follow within 5 days after the submission of a biologics license application. In addition, owners or operators of all establishments so engaged must register annually between November 15 and December 31 and must update their blood product listing information every June and December. Section 607.22 requires the use of Form FDA 2830 (Blood Establishment Registration and Product Listing) for initial registration, subsequent annual registration, and for blood product listing information. Section 607.25 sets forth the information required for establishment registration and blood product listing. Section 607.26, in brief, requires certain changes to be submitted on Form FDA 2830 as an amendment to establishment registration within 5 days of such changes. Section 607.30(a), in brief, sets forth the information required from owners or operators of establishments when updating their blood product listing information every June and December, or at the discretion of the registrant at the time the change occurs. Section 607.31 requires that additional blood product listing information be provided upon FDA request. Section 607.40, in brief, requires certain foreign blood product establishments to comply with the establishment registration and blood product listing information requirements discussed above and to provide the name and address of the establishment and the name of the individual responsible for submitting establishment registration and blood product listing information as well as the name, address, and phone number of its U.S. agent.

Among other uses, this information assists FDA in its inspections of facilities, and its collection is essential to the overall regulatory scheme designed to ensure the safety of the nation's blood supply. Form FDA 2830 is used to collect this information.

Respondents to this collection of information are human blood and plasma donor centers, blood banks, certain transfusion services, other blood product manufacturers, and independent laboratories that engage in quality control and testing for registered blood product establishments.

FDA estimates the burden of this collection of information based upon information obtained from FDA's Center for Biologics Evaluation and Research's database and FDA experience with the blood establishment registration and product listing requirements.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Form FDA 2830	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
607.20(a), 607.21, 607.22, 607.25, and 607.40.	Initial Registration	49	1	49	1	49
607.21, 607.22, 607.25, 607.26, 607.31, and 607.40.	Re-registration	2,589	1	2,589	0.5	1,294
607.21, 607.25, 607.30(a), 607.31, and 607.40.	Product Listing Update	180	1	180	0.25	45
Total	.....	.....	.....	.....	.....	1,388

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 26, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–19955 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–0126]

Andrew K. Choi: 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) debarring Andrew K. Choi, M.D. for 4 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on findings that Dr. Choi was 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 underlying the conviction undermines the process for the regulation of drugs. Dr. Choi was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Choi failed to respond. Dr. Choi's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective August 8, 2011.

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, Division of Compliance Policy (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

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,