TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN—(CBER) [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
320.31(d) Bioavailability and Bioequivalence Safety Reports	1	1	1	14	14
312.32(c)(1)(ii) and (c)(1)(iii) IND Safety Reports	137	4	548	12	6,576
312.32(c)(1)(iv) IND Safety Reports	5	1.4	7	12	84
Total (CBER)					6,674

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

Dated: March 14, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–06128 Filed 3–17–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3225]

Wesley A. McQuerry: 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 Wesley A. McQuerry 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. McQuerry was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product and otherwise relating to the regulation of a drug product under the FD&C Act. Mr. McQuerry was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. McQuerry failed to respond. Mr. McQuerry's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective March 18, 2016.

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)(A) of the FD&C Act (21 U.S.C. 335a(a)(2)(A)) 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 development or approval, including the process for development or approval, of any drug product. Section 306(a)(2)(B) of the FD&C Act requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the FD&C Act. On February 10, 2015, the U.S. District Court for the Northern District of Illinois entered judgment against Mr. McQuerry for one count of falsifying a material fact, in violation of 18 U.S.C. 1001(a)(1).

The factual basis for this conviction is as follows: Mr. McQuerry was the study coordinator for a drug clinical trial at an institution in the Northern District of Illinois. The clinical trial occurred under the authority of FDA, and clinical trial data was required to be submitted to FDA before the drug could be approved for sale in the United States.

As study coordinator, Mr. McQuerry's responsibilities for administering the clinical trial included, among other things, coordinating patient visits, maintaining patient files, ensuring that administrative procedures were followed regarding the collection of patient data, disbursing American Express gift checks to trial participants, and transmitting clinical trial data from the institution to the administrator, which was administering the clinical trial on behalf of the pharmaceutical company. Mr. McQuerry knew that the results of the clinical trial would be reported to FDA, and he knew it was unlawful to provide false information to the pharmaceutical company.

Beginning no later than January 2008, and continuing through at least October 2008, in the Northern District of Illinois, Mr. McQuerry knowingly and willfully falsified, concealed, and covered up by trick, scheme, and device material facts in a matter within the jurisdiction of FDA, namely that at least four patients and others were participating in the drug clinical trial, when in fact these patients did not participate in that clinical trial. Specifically, between January and October 2008, Mr. McQuerry created fifteen to twenty fictional patients, whom he claimed were participants in the clinical trial. Mr. McQuerry falsified signatures of those patients on consent forms and falsified doctors' signatures on medical evaluations for those patients. He provided his own blood, stool, and EKG results, which he claimed were provided by the fictional patients. He also transmitted false data and information to the administrator regarding these fictional patients and made and caused to be made false statements regarding their participation in the study and attendance at office visits, all of which he knew would be provided to the pharmaceutical company and to FDA.

Mr. McQuerry made false statements to the administrator about the whereabouts of the fictitious trial participants. In particular, on August 28, 2008, he provided false and fraudulent statements to the administrator regarding the attendance of two patients at study visits, knowing that the two patients were not in fact enrolled in the study and did not attend a single study visit.

As study coordinator, Mr. McQuerry was responsible for disbursing gift checks, which were provided by the pharmaceutical company to patients at various points during the patients' participation in the clinical trial. Mr. McQuerry falsely and fraudulently claimed to have disbursed gift checks when, in fact, no checks were disbursed

to patients. Instead, between approximately July 11, 2008 and September 3, 2008, Mr. McQuerry deposited over $2,300 of gift checks into his personal bank account. He additionally used the gift checks to make direct purchases at various retailers. Mr. McQuerry's fraud resulted in a loss of approximately $200,098 to the pharmaceutical company.

As a result of this conviction, FDA sent Mr. McQuerry by certified mail on October 30, 2015, a notice 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 a finding, under section 306(a)(2)(A) and (a)(2)(B) of the FD&C Act, that Mr. McQuerry was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product, and conduct otherwise relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. McQuerry 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. Mr. McQuerry did not request a hearing and has, therefore, waived his opportunity for a hearing and 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 sections 306(a)(2)(A) and (a)(2)(B) of the FD&C Act, under authority delegated to him (Staff Manual Guide 1410.35), finds that Wesley A. McQuerry has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product and conduct otherwise relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Wesley A. McQuerry 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 Wesley A. McQuerry, 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. McQuerry 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 from Wesley A. McQuerry during his period of debarment (section 306(c)(1)(B) of the FD&C Act.

Any application by Mr. McQuerry for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2015–N–3225 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: March 11, 2016.

Armando Zamora,

Deputy Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs.

[FR Doc. 2016–06104 Filed 3–17–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Advisory Committee on Research on Women's Health.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Advisory Committee on Research on Women's Health.

Date: April 19, 2016.

Time: 9:00 a.m. to 4:00 p.m.

Agenda: The Committee serves to advise and make recommendations to the Director, Office of Research on Women's Health (ORWH) on a broad range of topics. Information is also available on the Institute's/Center's home page: *http://orwh.od.nih.gov/about/acrwh/index.asp* where an agenda and any additional information for the meeting will be posted when available.

Place: National Institutes of Health, Building 31, Room 6C, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Terri L. Cornelison, MD, Ph.D., Associate Director for Clinical Research, Office of Research on Women's Health, Office of the Director, 6707 Democracy Blvd., Bethesda, MD 20817, 301–402–1770, *cornelit@od.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www4.ordh.od.nih.gov/*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: *March 14, 2016.*

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–06075 Filed 3–17–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.