TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR part | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| 58.35(b)(7); Quality assurance unit | 300 | 60.25 | 18,075 | 1 | 18,075 |
| 58.185; Reporting of nonclinical laboratory study results | 300 | 60.25 | 18,075 | 27.65 | 499,774 |
| Total | | | | | 517,849 |

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| 21 CFR part | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| 58.29(b); Personnel | 300 | 20 | 6,000 | .21 (13 minutes) | 1,260 |
| 58.35(b)(1)–(6), and (c); Quality assurance unit | 300 | 270.76 | 81,228 | 3.36 | 272,926 |
| 58.63(b) and (c); Maintenance and calibration of equipment | 300 | 60 | 18,000 | .09 (5 minutes) | 1,620 |
| 58.81(a)–(c); SOPs | 300 | 301.80 | 90,540 | .14 (8 minutes) | 12,676 |
| 58.90(c) and (g); Animal care | 300 | 62.70 | 18,810 | .13 (8 minutes) | 2,445 |
| 58.105(a) and (b); Test and control article characterization | 300 | 5 | 1,500 | 11.8 | 17,700 |
| 58.107(d); Test and control article handling | 300 | 1 | 300 | 4.25 | 1,275 |
| 58.113(a); Mixtures of articles with carriers | 300 | 15.33 | 4,599 | 6.8 | 31,273 |
| 58.120; Protocol | 300 | 15.38 | 4,614 | 32.7 | 150,878 |
| 58.195; Retention of records | 300 | 251.50 | 75,450 | 3.9 | 294,255 |
| Total | | | | | 786,308 |

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: July 20, 2020.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2020–16095 Filed 7–23–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. FDA–2015–D–3327 and FDA–2018–D–0719]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on E6(R2) Good Clinical Practice; International Council for Harmonisation; Integrated Addendum to International Council for Harmonisation E6(R1)

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by August 24, 2020.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0843. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Guidance for Industry on E6(R2) Good Clinical Practice; International Council for Harmonisation; Integrated Addendum to ICH E6(R1)

*OMB Control Number 0910–0843—Extension*

This information collection request supports recommendations found in the Agency guidance entitled ''E6(R2) Good Clinical Practice; Integrated Addendum to ICH E6(R1)'' (ICH E6(R2)). The guidance was originally prepared under the auspices of the International Council for Harmonisation (ICH) (formerly the International Conference on Harmonisation); it amends the ICH guidance for industry entitled ''E6 Good Clinical Practice: Consolidated Guidance'' (issued in April 1996). The guidance is intended to facilitate implementation of improved and more efficient approaches to clinical trial design, including conduct, oversight, recording, and reporting. This is intended to increase clinical trial quality and efficiency while continuing

to ensure human subject protection and reliability of trial results. Included in the guidance are additions identified as ''ADDENDUM'' and marked with vertical lines on both sides of the text.

Standards regarding electronic records and essential documents intended to increase clinical trial quality and efficiency have also been updated. The guidance is available from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e6r2-good-clinical-practice-integrated-addendum-ich-e6r1*.

In the **Federal Register** of September 5, 2019 (84 FR 46742), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HUMAN DRUGS [1]

| Guidance for industry on E6(R2) good clinical practice; International Council for Harmonisation; integrated addendum to ICH E6(R1) | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| Section 5. Quality Management (including sections 5.0.1 to 5.0.7)—Developing a Quality Management System .... | 1,457 | 1 | 1,457 | 60 | 87,420 |

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS [1]

| Guidance for industry on E6(R2) good clinical practice; International Council for Harmonisation; integrated addendum to ICH E6(R1) | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Section 5.0.7. Risk Reporting—Describing the Quality Management Approach Implemented in a Clinical Trial and Summarizing Important Deviations From the Predefined Quality Tolerance Limits and Remedial Actions Taken in the Clinical Study Report ..... | 1,457 | 4.6 | 6,702 | 3 | 20,106 |

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

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS [1]

| Guidance for industry on E6(R2) good clinical practice; International Council for Harmonisation; integrated addendum to ICH E6(R1) | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| Section 5. Quality Management (including sections 5.0.1 to 5.0.7)—Developing a Quality Management System .... | 423 | 1 | 423 | 60 | 25,380 |

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

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS [1]

| Guidance for industry on E6(R2) good clinical practice; International Council for Harmonisation; integrated addendum to ICH E6(R1) | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Section 5.0.7. Risk Reporting—Describing the Quality Management Approach Implemented in a Clinical Trial and Summarizing Important Deviations From the Predefined Quality Tolerance Limits and Remedial Actions Taken in the Clinical Study Report ..... | 423 | 1.56 | 660 | 3 | 1,980 |

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

In table 1, we estimate 1,457 sponsors of clinical trials of human drugs will develop approximately 1,457 quality management systems per year (as described in ICH E6(R2) in section 5.0, including sections 5.0.1 to 5.0.7). We assume it will take respondents 60 hours to develop and implement each quality management system, totaling 87,420 hours annually. The estimated number of sponsors who will develop a quality management system as described in ICH E6(R2) is based on the number of annual investigational new drug applications (INDs) and new drug applications (NDAs) submitted to FDA's Center for Drug Evaluation and Research. The estimated number of hours we assume it takes to develop a quality management system is based on informal interactions with industry about activities that support drug development plans.

In table 2, we estimate 1,457 sponsors of clinical trials of human drugs will describe the quality management approach implemented in a clinical trial and summarize important deviations from the predefined quality tolerance limits and remedial actions taken in the clinical study report (as described in section 5.0.7 of ICH E6(R2)). We further estimate that sponsors will submit approximately 4.6 responses per respondent and that it will take sponsors 3 hours to complete this reporting task, totaling 20,106 reporting hours annually. These estimates are based on our past experiences with INDs and NDAs.

In table 3, we estimate 423 sponsors of clinical trials of biological products will develop 423 quality management systems per year (as described in ICH

E6(R2) in section 5.0, including sections 5.0.1 to 5.0.7). We assume it will take respondents 60 hours to develop and implement each quality management system, totaling 25,380 hours annually. The estimated number of sponsors who will develop a quality management system as described in ICH E6(R2) is based on the number of annual INDs and biologics license applications (BLAs) submitted to FDA's Center for Biologics Evaluation and Research. The estimated number of hours we assume it takes to develop a quality management system is based on informal interactions with industry about activities that support drug development plans.

In table 4, we estimate 423 sponsors of clinical trials of biological products will describe the quality management approach implemented in a clinical trial and summarize important deviations from the predefined quality tolerance limits and remedial actions taken in a clinical study report (as described in section 5.0.7 of ICH E6(R2)). We further estimate that sponsors will submit approximately 660 responses per respondent and that it will take sponsors 3 hours to complete this reporting task, totaling 1,980 reporting hours annually. As described previously, these estimates are based on past experiences with INDs and BLAs submitted to FDA.

Although our estimated burden for the information collection reflects an overall decrease of 433 hours, we have increased the estimate by 861 records. We are making this adjustment based on an increase in the number of submissions we received over the last few years. We have also finalized the guidance since last OMB review, consistent with our good guidance practices regulation, which provide for public comment at any time, announcing its availability in the **Federal Register** of March 1, 2018 (83 FR 8882).

Dated: July 20, 2020.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2020–16036 Filed 7–23–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–N–4829]**

### Jin Su Park: Final 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 (FD&C Act) debarring Jin Su Park for a period of 10 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Park was convicted of one felony count under Federal law for Importing Merchandise Contrary to Law, Causing an Act to be Done and of one felony count of introducing Misbranded Drugs into Interstate Commerce, causing an Act to be Done. The factual basis supporting both of Mr. Park's convictions, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Park was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of January 19, 2019 (30 days after receipt of the notice), Mr. Park had not responded. Mr. Park's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

**DATES:** This order is applicable July 24, 2020.

**ADDRESSES:** Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Jaime Espinosa, Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240 402–8743, or at *debarments@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if the FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On March 25, 2019, Mr. Park was convicted, as defined in section 306(l)(1)(B) of the FD&C Act, in the United States District Court for the Central District of California, when the court accepted his plea of guilty and entered judgment against him for the felony offenses of Importing Merchandise Contrary to Law, Causing an Act to be Done in violation of 18 U.S.C. 545, 2(b) and of Introducing Misbranded Drugs into Interstate Commerce, causing an Act to be Done in violation of 21 U.S.C. 331(a), 352, and 333(a)(2) (sections 301(a), 502, and 303(a)(2) of the FD&C Act).

The FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for these convictions is as follows: As contained in the Plea Agreement, filed on February 7, 2019, Mr. Park did, no later than 2015, begin providing minor assistance to his long-time friend ''J.L.'' who owned and operated several companies that manufactured and distributed misbranded male sexual enhancement pills across the United States. In February 2017, J.L.'s operation was shut down after the FDA and Department of Homeland Security executed a search warrant at J.L.'s pill business as part of an investigation into J.L.'s smuggling of Tadalafil into the United States from China. Mr. Park knew that J.L. had been unlawfully selling misbranded pills containing Tadalafil and other active pharmaceutical ingredients smuggled from China. Mr. Park took approximately 14,000 male sexual enhancement pills, all containing undisclosed Tadalafil, from J.L.'s business, and stored them at Mr. Park's home. Mr. Park then set up a new company, RNG Global Management and Trading Group, Inc. (RNG). Mr. Park repackaged the 14,000 pills with new labeling that failed to disclose the presence of Tadalafil and he commenced selling the misbranded pills to various customers throughout the United States.

Furthermore, in April 2018, Mr. Park ordered, and subsequently paid for, five kilograms of Dapoxetine and five kilograms of Rhodiola rosea from suppliers in China. Mr. Park had the Chinese supplier ship five kilograms of Dapoxetine to him, through a Korean intermediary, in a parcel mislabeled as containing, ''Glass Colour Sample (Zinc Sulfide)'' to a commercial mailbox Mr. Park controlled in Michigan. Mr. Park subsequently had the same Chinese supplier ship to his Michigan mailbox the five kilograms of Rhodiola rosea, through the same Korean intermediary, in a parcel mislabeled as containing, ''Glass Colour (Zinc Sulfide) Sample.'' Mr. Park intended to use both the Dapoxetine and Rhodiola rosea in the male sexual enhancement pills he would sell.

As a result of this conviction, FDA sent Mr. Park by certified mail on December 16, 2019, a notice proposing