TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1.280 through 1.281	[3] 3540	13,000	231	3,003,000	0.384 (23 minutes).	1,153,152
Subtotal						3,658,236
Cancellations:						
Through ABI/ACE.						
1.282	N/A	25,000	1	25,000	0.25 (15 minutes).	6,250
Through PNSI.						
1.282 and 1.283(a)(5)	3540	50,000	1	50,000	0.25 (15 minutes).	12,500
Subtotal						18,750
Requests for Review and Post-hold Submissions:						
1.283(d) and 1.285(j)	N/A	1	1	1	8	8
1.285(i)	N/A	500	1	500	1	500
Subtotal:						508
Total				18,079,001		3,677,494

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] To avoid double counting, an estimated 396,416 burden hours already accounted for in the importer's entry notice information collection approved under OMB control number 0910–0046 are not included in the total.
[3] The term "Form FDA 3540" refers to the electronic submission system known as PNSI, which is available at *https://www.access.fda.gov.*

Table 1 reflects the annual estimated reporting burden associated with the information collection. During the next 3 years, we estimate each respondent will need approximately 10 minutes per submission for a total of 15,000,500 annual submissions and 2,505,083.5 rounded up to 2,505,084 annual hours of burden. Similarly, we estimate 13,000 users submitting an average of 231 notices annually, requiring approximately 23 minutes per submission. Cumulatively, this totals 3,003,000 annual responses and 1,153,152 annual hours of burden.

Regarding cancellations of prior notices, we estimate 25,000 respondents averaging 1 cancellation annually and requiring 15 minutes to do so. Cumulatively, this totals 25,000 annual submissions and 6,250 annual hours of burden. Similarly, we estimate 50,000 registered users submitting an average of 1 cancellation annually and requiring 15 minutes to do so. Cumulatively, this totals 50,000 annual responses and 12,500 annual hours of burden.

We estimate that we will receive one submission annually under § 1.283(d) or § 1.285(j) over the next 3 years. It takes approximately 8 hours to prepare a submission, which results in 8 hours of burden.

Finally, for an average of 500 post-hold submissions annually, we estimate it will take respondents 1 hour to prepare the written notification described in § 1.285(i)(2)(i), for a total of 500 annual burden hours.

Based on our experience and the average number of prior notice submissions, cancellations, and requests for review received in the past 3 years, we are adjusting our burden estimate for this information collection by increasing the number of responses and total burden. The number of responses has increased by 3,146,589 responses (from 14,932,412 to 18,079,001). The total burden has increased by 769,918 hours (from 2,907,576 to 3,677,494). We attribute the adjustment to an increase in the number of responses.

Dated: July 31, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16568 Filed 8–2–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2175]

Raidel Figueroa: 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 (the FD&C Act) permanently debarring Raidel Figueroa 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. Figueroa was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Figueroa was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why he should not be debarred within the timeframe prescribed by regulation. Mr. Figueroa has not responded to the notice. Mr. Figueroa's failure to respond and request a hearing within the prescribed timeframe constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective August 3, 2023.

ADDRESSES: Any application by Mr. Figueroa for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact

information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov.*

• If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2022–N–2175. Received applications will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, at 240–402–8743, or *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application 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 August 31, 2022, Mr. Figueroa was convicted in the U.S. District Court for the Southern District of Florida, Fort Lauderdale Division, when the court entered a judgment of conviction, after his plea of guilty, to one count of conspiracy to defraud the United States in violation of 18 U.S.C. 371, one count of falsification of records in a Federal investigation in violation of 18 U.S.C. 1519, one count of obstruction of proceedings before an Agency of the United States in violation of 18 U.S.C. 1505, and one count of distribution of adulterated drugs in interstate commerce in violation of 21 U.S.C. 331(a) (section 301(a) of the FD&C Act), all felony offenses under Federal law.

The factual basis for this conviction is as follows: Mr. Figueroa was the Chief Executive Officer and co-owner of Pharmatech, LLC, a drug and dietary supplement manufacturer that operated in Broward County, FL. From at least 2016 through at least March 2017, Pharmatech manufactured and distributed Diocto Liquid, a drug used to treat constipation in adults and children. In July 2016, FDA initiated an inspection at Pharmatech as part of an investigation into an outbreak of *Burkholderia cepacia* (*B. cepacia*) infections. *B. cepacia* is the name for a group or ''complex'' of bacteria typically found in soil and water. These bacteria pose little medical risk to healthy people, but people who have certain health problems like weakened immune systems or chronic lung diseases may be more susceptible to *B. cepacia* infections. The effects of *B. cepacia* can include serious respiratory infections and other types of infections. Contaminated medicines can transmit *B. cepacia,* and the bacteria are often resistant to common antibiotics. At the close of FDA's inspection in August of 2016, FDA notified Mr. Figueroa that a water sample taken from Pharmatech's water system had tested positive for the presence of *B. cepacia.* In his written response to FDA's inspectional observations, Mr. Figueroa advised FDA that Pharmatech was re-engineering its purified water system to prevent contamination of the water used for both production and cleaning purposes. Following the July–August 2016 FDA inspections, Mr. Figueroa also temporarily stopped manufacturing liquid products.

In March 2017, FDA initiated another inspection at Pharmatech. FDA investigators asked Mr. Figueroa to provide a product list of all products that Pharmatech had manufactured after it resumed manufacturing in November 2016. Mr. Figueroa knowingly excluded Diocto Liquid from Pharmatech's products list that he provided FDA investigators despite Pharmatech having shipped approximately 7,308 units of the drug earlier that month. When FDA investigators later discovered that the product list Mr. Figueroa provided them was incomplete, FDA investigators again requested he provide them with a complete list. Mr. Figueroa caused a second product list to be produced to FDA; he again falsely represented to FDA that it was a complete list when he knew it was false because it omitted Diocto Liquid.

In April 2017, Mr. Figueroa provided FDA a written memorandum regarding Pharmatech's water system. That memorandum falsely stated that all data for Phase 3 testing of Pharmatech's new water system had met ''acceptance criteria,'' although Mr. Figueroa was aware the water system had not met acceptance criteria because a water sample taken on February 15, 2017, tested presumptive positive for the presence of *B. cepacia.*

During this same March–May 2017 inspection, when FDA investigators requested that Mr. Figueroa identify any other business he owned, he failed to disclose that he owned and controlled Ofcus Pharma, which was a company established for the purpose of manufacturing oral solid drugs and dietary supplements. Mr. Figueroa later asked someone else to tell FDA investigators that they were the owner of Ofcus Pharma if that firm was ever inspected by FDA, and not to disclose that Mr. Figueroa was the owner of Ofcus Pharma.

In July 2017, the Centers for Disease Control and Prevention notified FDA of multiple cases of *B. cepacia* infections in pediatric patients at Stanford Children's Health Lucile Packard Children's Hospital in Palo Alto, CA and Johns Hopkins Children's Center in Baltimore, MD. FDA investigated and collected bottles of Diocto Liquid from these medical centers. The collected bottles were from the same lot that Pharmatech distributed in March 2017—the same lot that Pharmatech failed to disclose to FDA. Several of the bottles contained total aerobic microbial counts and total yeast and mold counts in excess of acceptable limits and some of the bottles also tested positive for the presence of *B. cepacia.*

In September 2017, FDA initiated an inspection of Ofcus Pharma. During that inspection the individual Mr. Figueroa asked to misrepresent to FDA that they owned Ofcus Pharma, did in fact make false statements to an FDA investigator when they told the investigator they had full ownership of Ofcus Pharma.

Based on this conviction, FDA sent Mr. Figueroa by certified mail on March 20, 2023, 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)(B) of the FD&C Act, that Mr. Figueroa was convicted, as set forth in section 306(l)(1) of the FD&C Act, of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Figueroa 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 file a timely request for a hearing would constitute an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Mr. Figueroa received the proposal on March 30, 2023. He did not request a hearing within the timeframe prescribed by regulation 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 Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Figueroa has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Figueroa is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(B) and (c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Mr. Figueroa 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. Figueroa 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 application from Mr. Figueroa during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of sections 306 and 307 of the FD&C Act, a ''drug product'' is defined as a ''drug subject to regulation under section 505, 512, or 802 of this Act [(21 U.S.C. 355, 360b, 382)] or under section 351 of the Public Health Service Act [(42 U.S.C. 262)]'' (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Dated: July 31, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16550 Filed 8–2–23; 8:45 am]

BILLING CODE 4161–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2850]

Prescription Drug User Fee Rates for Fiscal Year 2024; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Prescription Drug User Fee Rates for Fiscal Year 2024'' that appeared in the **Federal Register** of July 28, 2023. The document announced the rates for prescription drug user fees for fiscal year 2024. The document was published with an incorrect value in a table. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy, Legislation, and International Affairs, Food and Drug Administration, 301–796–9115, *Lisa.Granger@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 28, 2023 (88 FR 48881), in FR Doc. 2023–15911, the following correction is made:

On page 48883, in section II.C., table 4, ''CDER Actual FY 2022 Workload Volumes and Predicted FY 2024 Workload Volumes,'' in the third column (''FY 2024 predictions''), fourth row (''NDA/BLA Original''), ''1,136'' is corrected to read ''136.''

Dated: July 31, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16575 Filed 8–2–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Award; Early Childhood Developmental Health Systems Cooperative Agreement

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of a HRSA-initiated supplemental award.

SUMMARY: HRSA announces the award of a supplement for a total of approximately $1 million in fiscal year (FY) 2023 for the Early Childhood Developmental Health Systems (ECDHS) cooperative agreement. The supplement will provide approximately $600,000 to the current recipient during the period of September 30, 2023, to September 29, 2024, to continue to support the implementation, spread, and scale of early childhood development (ECD) expert integration, and associated early childhood systems development. This includes providing intensive, individualized technical assistance (TA) to four additional Transforming Pediatrics in Early Childhood (TPEC) Program state-level recipients. In addition, the supplement further includes approximately $400,000 to provide TA to HRSA-funded health centers who are expanding early childhood developmental services through ECD funding.

FOR FURTHER INFORMATION CONTACT: Natalie Surfus, MPH; Public Health Analyst, Division of Home Visiting and Early Childhood Systems, Maternal and Child Health Bureau. Telephone: (240) 381–8202; Email: *NSurfus@hrsa.gov.*

SUPPLEMENTARY INFORMATION: