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: