

the questionnaire programming works as expected. For the main study, we will then recruit 350 consumers who self-identify as having been diagnosed with diabetes and 350 primary care physicians who treat diabetes. Each

participant will see one of five versions of a consumer web page for a fictitious prescription diabetes treatment, as reflected in table 1. They will answer a questionnaire designed to take no more than 20 minutes regarding their

perception of the product's benefits, risks, and effect on adherence.

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN^{1 2}

Activity	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response	Total hours
Screener Consumers	680	1	680	.08 (5 minutes)	54.4
Screener Primary Care Physicians	680	1	680	.08 (5 minutes)	54.4
Pretest Consumers	50	1	50	.33 (20 minutes) ..	16.5
Pretest Primary Care Physicians	50	1	50	.33 (20 minutes) ..	16.5
Main Study Consumers	350	1	350	.33 (20 minutes) ..	115.5
Main Study Primary Care Physicians	350	1	350	.33 (20 minutes) ..	115.5
Total					372.8

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

² Burden estimates of less than 1 hour are expressed as a fraction of an hour in decimal format.

References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

*1. World Health Organization, “Adherence to Long-Term Therapies: Evidence for Action,” p. 3, 2003, available at <https://apps.who.int/iris/handle/10665/42682>, accessed May 16, 2022.

2. Frias, J., N. Viridi, P. Raja, et al., “Effectiveness of Digital Medicines to Improve Clinical Outcomes in Patients with Uncontrolled Hypertension and Type 2 Diabetes: Prospective, Open-Label, Cluster-Randomized Pilot Clinical Trial,” *Journal of Medical Internet Research*, vol. 19, Issue 7, Article e246, 2017, doi:10.2196/jmir.7833.

3. Kleinsinger, F., “The Unmet Challenge of Medication Nonadherence,” *The Permanente Journal*, vol. 22, Issue 3, Article 18–033, 2018, doi:10.7812/TPP/18–033.

4. Karumbi, J. and P. Garner, “Directly Observed Therapy for Treating Tuberculosis,” *Cochrane Database of Systematic Reviews*, Issue 5, Article CD003343, 2015, doi:10.1002/14651858.CD003343.pub4.

5. Dayer, L., S. Heldenbrand, P.O. Gubbins, et al., “Smartphone Medication Adherence Apps: Potential Benefits to Patients and Providers,” *Journal of the American Pharmacy Association* (2003), vol. 53, Issue 2, pp. 172–181, 2013, doi:10.1331/JAPhA.2013.12202.

*6. FDA, “FDA Approves Pill with Sensor That Digitally Tracks If Patients Have Ingested Their Medication,” FDA News Release, November 13, 2017, available at <https://www.fda.gov/news-events/press-announcements/fda-approves-pill-sensor-digitally-tracks-if-patients-have-ingested-their-medication>, accessed May 16, 2022.

7. Browne, S.H., Y. Behzadi, and G. Littlewort, “Let Visuals Tell the Story: Medication Adherence in Patients with Type II Diabetes Captured by a Novel Ingestion Sensor Platform,” *JMIR mHealth uHealth*, vol. 3, Issue 4, Article e108, 2015, doi:10.2196/mhealth.4292.

8. Eisenberger, U., R.P. Wüthrich, A. Bock, et al., “Medication Adherence Assessment: High Accuracy of the New Ingestible Sensor System in Kidney Transplants,” *Transplantation*, vol. 96, Issue 3, pp. 245–250, 2013, doi:10.1097/TP.0b013e31829b7571.

9. Chai, P.R., S. Carreiro, B.J. Innes, et al., “Oxycodone Ingestion Patterns in Acute Fracture Pain with Digital Pills,” *Anesthesia and Analgesia*, vol. 125, Issue 6, pp. 2105–2112, 2017, doi:10.1213/ANE.0000000000002574.

*10. Amgen Inc., “Enbrel (etanercept): Highlights of Prescribing Information,” revised April 2021, available at https://www.pi.amgen.com/~media/amgen/repositories/pi-amgen-com/enbrel/enbrel_pi.pdf, accessed May 16, 2022.

*11. Reuter, E., “‘Smart Pill’ Startup EctRx Strikes Partnership with Pear Therapeutics,” *Med City News*, January 14, 2021, available at <https://medcitynews.com/2021/01/smart-pill-startup-ectrx-strikes-partnership-with-pear-therapeutics>, accessed May 16, 2022.

12. The Medical Futurist, “The Present and Future of Digital Pills,” July 21, 2020, available at <https://medicalfuturist.com/the-present-and-future-of-digital-pills>, accessed May 16, 2022.

13. George, C.E., “Should a Psychiatrist Prescribe a Nanodrug to Help Parents Monitor a Teen’s Adherence?,” *AMA Journal of Ethics*, vol. 21, issue 4, article e317–323, 2019, doi:10.1001/amajethics.2019.317.

*14. Yang, M., “A Psychiatrist’s Perspective on the Digital Pill,” *KevinMD.com*, December 2, 2017, available at <https://www.kevinmd.com/blog/2017/12/psychiatrists-perspective-digital-pill.html>, accessed May 16, 2022.

Dated: September 19, 2022.

Lauren K. Roth,
Associate Commissioner for Policy.

[FR Doc. 2022–20636 Filed 9–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1894]

Agency Information Collection Activities; Proposed Collection; Comment Request; Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation B12 Pediatric Device Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of

1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on “Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation (CERSI) B12 Pediatric Device Survey.”

DATES: Either electronic or written comments on the collection of information must be submitted by November 22, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 22, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on <https://www.regulations.gov>.

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

Written/Paper Submissions

Submit written/paper submissions as follows:

- **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 written/paper comments submitted to the Dockets Management

Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2022-N-1894 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation (CERSI) B12 Pediatric Device Survey.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments 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 comments. 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. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” 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 to read background documents or the electronic and written/paper comments received, 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, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: JennaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation (CERSI) B12 Pediatric Device Survey

OMB Control Number NEW

Despite numerous legislative, regulatory, and scientific efforts, there has been little change in the number of devices approved for use in pediatric patients. This has often led to devices being adapted for use in children without an appropriate level of evidence, exposing them to inconsistent benefit risk profiles. This health inequity highlights the need for devices that are designed, evaluated, and labelled for pediatric patients. To address these challenges, this collection is being done to survey industry and

other key stakeholders in the medical device ecosystem to identify the barriers that prevent product developers from entering the pediatric device market as well as the proper incentives that would motivate them to innovate and sustain within this market.

This survey is a followup to the public meeting that FDA held in August 2018, entitled, “Pediatric Medical Device Development.” As mandated by section 502(d) of the FDA Reauthorization Act of 2017 (Pub. L.

115–52) the meeting was convened to address several topics, including consideration of ways to: (1) increase FDA assistance to medical device manufacturers in developing devices for pediatric populations that are approved or cleared, and labeled, for their use and (2) identify current barriers to pediatric device development and incentives to address such barriers.

Feedback from this meeting clarified the need to better understand factors influencing suboptimal engagement and

participation by diverse innovators in the pediatric medical device space. Information garnered from this survey may help inform strategic plans to optimize existing programs for the needs of pediatric medical device innovators and develop new programs that will support sustained development in this space.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours ²
Phone Survey	17	1	17	0.5 (30 minutes)	9
Online Survey	56	1	56	1	56
Total					65

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

² Rounded to the nearest hour.

The targeted groups for this collection of information include representatives from the medical device industry, academia, recipients of funding under section 305 of the Pediatric Medical Device Safety and Improvement Act of 2007 (Pub. L. 110–85; 42 U.S.C. 282 note), and trade organizations, medical provider organizations, organizations and individuals involved with financing and reimbursement associated with medical devices, pediatric healthcare leaders, clinicians who regularly use medical devices in caring for children, and organizations and individuals representing patients and consumers.

Phone survey: Respondents participating in the phone survey will be executives from companies either producing products in pediatrics or from companies that produce products that could be used in pediatrics. Executives will be invited to engage in the 30-minute phone survey.

Online survey: The 1-hour online survey will be administered to leaders within pediatric companies and key decision makers in the pediatric medical device industry (e.g., venture capitalists, banking investors, leaders in children’s hospitals and research networks, and pediatric patient advocates).

Dated: September 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20626 Filed 9–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0317]

Roy Tuccillo, Jr.: 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) debarring Roy Tuccillo, Jr. for a period of 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Mr. Tuccillo was convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Tuccillo was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of July 15, 2022 (30 days after receipt of the notice), Mr. Tuccillo has not responded. His failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable September 23, 2022.

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

1061, Rockville, MD 20852, 240–402–7500, or at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM–4029), 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)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) 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 food.

On November 9, 2021, Mr. Tuccillo was convicted as defined in section 306(J)(1)(A) of the FD&C Act, in the U.S. District Court for the Eastern District of New York, when the court accepted his plea of guilty and entered judgment against him for the offense of conspiracy to commit wire fraud in violation of 18 U.S.C. 371 and 1343.

FDA’s finding that the debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As stated in the indictment, filed September 26, 2018, transcript of guilty pleas, filed December 26, 2019, and Magistrate Judge Steven Locke’s report and recommendation, filed May