

- \* 7. FDA, P210016 Summary of Safety and Effectiveness Data, January 17, 2025. (Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P210016>.)
- \* 8. FDA, "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Guidance for Industry and FDA Staff," May 29, 2025. (Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program>.)
- \* 9. FDA, "Deciding When to Submit a 510(k) for a Change to an Existing Device; Guidance for Industry and Food and Drug Administration Staff," October 25, 2017. (Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device>.)
- \* 10. FDA, "Deciding When to Submit a 510(k) for a Software Change to an Existing Device; Guidance for Industry and Food and Drug Staff," October 25, 2017. (Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-software-change-existing-device>.)

#### List of Subjects in 21 CFR Part 890

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*, as amended) and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 890 is amended as follows:

#### PART 890—PHYSICAL MEDICINE DEVICES

- 1. The authority citation for part 890 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

- 2. Add § 890.5870 to subpart F to read as follows:

#### § 890.5870 Non-invasive bone growth stimulator.

(a) *Identification.* A non-invasive bone growth stimulator is a prescription device that provides stimulation through electrical, magnetic, or ultrasonic fields. The device is intended to be used externally to promote osteogenesis as an adjunct to primary treatments for fracture fixation and spinal fusion or as a treatment for established nonunions or failed fusions.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical data must demonstrate that the device performs as intended under anticipated conditions of use. Imaging data must demonstrate fusion at the treatment site.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Critical performance and safety characteristics of the device, considering the operational modality of the device, must be verified and validated to ensure:

(i) Intended design outputs are delivered to the patient;

(ii) Thermal safety and thermal reliability;

(iii) Signal characteristics are within safe physiologic limits; and

(iv) Device reliability is consistent with the expected use-life.

(3) Patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the electrical safety and electromagnetic compatibility of the device.

(5) Appropriate software verification, validation, and hazard analysis must be performed.

(6) Labeling comprehension testing must demonstrate the patient can correctly use the device based solely on reading the instructions for use.

(7) Labeling for the device must include the following:

(i) Warning against use on compromised skin or when there are known skin sensitivities;

(ii) Appropriate warnings for patients with implanted medical devices;

(iii) A detailed summary of the supporting clinical data, which includes the clinical outcomes associated with the use of the device, and a summary of adverse events and complications that occurred with the device;

(iv) A clear description of the device;

(v) Instructions on appropriate usage, duration, and frequency of use;

(vi) Instructions for maintenance and safe disposal;

(vii) Validated instructions for appropriate cleaning of any reusable components;

(viii) Specific warnings regarding user burns, electrical shock, and skin irritation; and

(ix) The risks and benefits associated with use of the device when used as intended.

#### Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-07366 Filed 4-15-26; 8:45 am]

BILLING CODE 4164-01-P

## DEPARTMENT OF THE TREASURY

### Financial Crimes Enforcement Network

#### 31 CFR Part 1010

#### Imposition of Special Measure Prohibiting Certain Transmittals of Funds Involving CIBanco S.A., Institución de Banca Multiple; Amendment

**AGENCY:** Financial Crimes Enforcement Network (FinCEN), Treasury.

**ACTION:** Order; amendment of order.

**SUMMARY:** FinCEN is issuing notice of an order amending its June 2025 order finding that CIBanco S.A., Institución de Banca Multiple (CIBanco), is a financial institution operating outside of the United States that is of primary money laundering concern in connection with illicit opioid trafficking and imposing a special measure prohibiting certain transmittals of funds involving CIBanco. This amendment allows for certain transmittals of funds to facilitate payments necessary for the Government of Mexico to liquidate CIBanco.

**DATES:** FinCEN is amending the order published at 90 FR 27770 (June 30, 2025), as amended by 90 FR 30826 (July 11, 2025) and 90 FR 40974 (August 22, 2025), as of April 16, 2026.

**FOR FURTHER INFORMATION CONTACT:** The FinCEN Resource Center at <http://www.fincen.gov/contact>.

#### SUPPLEMENTARY INFORMATION:

#### I. Statutory Authority

In 2024, Congress enacted the FEND Off Fentanyl Act,<sup>1</sup> which, among other things, added 21 U.S.C. 2313a<sup>2</sup> (section 2313a). Section 2313a grants the Secretary of the Treasury (Secretary) the authority to make a finding that "reasonable grounds exist for concluding" that any of the following is of primary money laundering concern in connection with illicit opioid trafficking:

- (1) One or more financial institutions operating outside of the United States;
- (2) One or more classes of transactions within, or involving, a jurisdiction outside of the United States; or
- (3) One or more types of accounts within, or involving, a jurisdiction outside of the United States.<sup>3</sup>

Upon making such a finding, the Secretary is authorized to require

<sup>1</sup> The FEND Off Fentanyl Act is Division E of Public Law 118-50 (Apr. 24, 2024).

<sup>2</sup> Section 2313a codifies section 7213A of the Fentanyl Sanctions Act, as amended by section 3201(a) of the FEND Off Fentanyl Act. The Fentanyl Sanctions Act is Title LXXII of Public Law 116-92 (Dec. 20, 2019).

<sup>3</sup> 21 U.S.C. 2313a(a).

domestic financial institutions and domestic financial agencies to take certain “special measures.” Those special measures are safeguards that may be employed to defend the United States financial system from money laundering risks connected to illicit opioid trafficking.<sup>4</sup> Pursuant to section 2313a, the Secretary may impose one or more of six special measures.<sup>5</sup> The authority of the Secretary to administer section 2313a has been delegated to FinCEN.<sup>6</sup>

## II. Background

On June 25, 2025, FinCEN issued an order (“June 2025 Order”) identifying CIBanco, a Mexico-based commercial bank, as being a financial institution operating outside of the United States of primary money laundering concern in connection with illicit opioid trafficking—specifically, through its provision of financial services that facilitate illicit opioid trafficking by Mexico-based drug trafficking organizations, including the Gulf Cartel, the Beltran-Leyva Organization Cartel, and the Cartel Jalisco Nueva Generación—and imposed a prohibition on certain transmittals of funds involving CIBanco by any covered financial institution.<sup>7</sup> The June 2025 Order was published in the **Federal Register** on June 30, 2025, and through two subsequent orders, the effective date was extended to October 20, 2025.<sup>8</sup> The Government of Mexico has intervened in CIBanco’s operations, including taking over management of CIBanco, to safeguard the Mexican financial system. Through this process, the Government of Mexico oversaw the sale of CIBanco’s major assets and has taken steps to ensure that the sales of CIBanco’s assets did not create additional money laundering risks to

the U.S. financial system. To facilitate the Government of Mexico’s efforts to liquidate and dissolve CIBanco, FinCEN finds it appropriate to amend the order to permit certain transmittals of funds. Therefore, FinCEN amends its order, published on June 30, 2025 (as amended by 90 FR 30826 (July 11, 2025) and 90 FR 40974 (August 22, 2025)).

### III. Order

#### A. Definitions

##### 1. The June 25, 2025 Order

This order defines the June 25, 2025 Order as the order published on June 30, 2025 in the **Federal Register**<sup>9</sup> prohibiting certain transmittals of funds involving CIBanco S.A., Institución De Banca Multiple (as amended by 90 FR 30826 (July 11, 2025) and 90 FR 40974 (August 22, 2025)).

##### 2. Meaning of Other Terms

All terms used but not otherwise defined herein shall have the meaning set forth in 31 CFR Chapter X, 31 U.S.C. 5312, and 21 U.S.C. 2302.

#### B. Amendment of Order

This order amends Section B (“Prohibition on Transmittals of Funds Involving CIBanco”) of the June 25, 2025 Order to read:

A covered financial institution is prohibited from engaging in any transmittal of funds from or to CIBanco. Effective beginning April 16, 2026, all transmittals of funds prohibited by this order, that are ordinarily incident and necessary for the Government of Mexico to liquidate CIBanco, are authorized, provided that (1) the Government of Mexico’s appointed liquidator has determined that such transmittal of funds is necessary to liquidate CIBanco, and (2) the transmittal of funds is not otherwise prohibited by law.

All other provisions of the June 25, 2025 Order remain unchanged.

**Jimmy L. Kirby,**

*Deputy Director, Financial Crimes Enforcement Network.*

[FR Doc. 2026–07416 Filed 4–15–26; 8:45 am]

**BILLING CODE 4810–02–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA–R09–OAR–2025–0058; FRL–12609–03–R9]

### Air Plan Approval; California; Eastern Kern Air Pollution Control District; Portland Cement Kilns

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is taking final action to approve a revision to the Eastern Kern Air Pollution Control District (EKAPCD or “District”) portion of the California State Implementation Plan (SIP). This revision concerns emissions of oxides of nitrogen (NO<sub>x</sub>) from Portland cement kilns. We are approving a local rule that regulates these emission sources under the Clean Air Act (CAA or “Act”).

**DATES:** This rule is effective May 18, 2026.

**ADDRESSES:** The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2025–0058. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through <https://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. **FOR FURTHER INFORMATION CONTACT:** Elijah Gordon, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105; telephone number: (415) 972–3158; email address: [gordon.elijah@epa.gov](mailto:gordon.elijah@epa.gov).

### SUPPLEMENTARY INFORMATION:

Throughout this document, “we,” “us,” and “our” refer to the EPA.

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<sup>4</sup> See 21 U.S.C. 2313a(a).

<sup>5</sup> 21 U.S.C. 2313a(a).

<sup>6</sup> In accordance with Treasury Order 101–05 and 31 U.S.C. 321(b)(2), the authority vested in the Secretary under section 2313a has been delegated to the Director of FinCEN.

<sup>7</sup> *Imposition of Special Measure Prohibiting Certain Transmittals of Funds Involving CIBanco S.A., Institución De Banca Multiple*, 90 FR 27770 (June 30, 2025).

<sup>8</sup> *Imposition of Special Measure Prohibiting Certain Transmittals of Funds Involving CIBanco S.A., Institución De Banca Multiple*, 90 FR 27770 (June 30, 2025); *Imposition of Special Measures Prohibiting Certain Transmittals of Funds Involving CIBanco S.A., Institución de Banca Multiple, Intercam Banco S.A., Institución de Banca Multiple, and Vector Casa de Bolsa, S.A. de C.V.; Extension of Effective Date*, 90 FR 30826 (July 11, 2025); *Imposition of Special Measures Prohibiting Certain Transmittal of Funds Involving CIBanco S.A., Institución de Banca Multiple, Intercam Banco S.A., Institución de Banca Multiple, and Vector Casa de Bolsa, S.A. de C.V.; Extension of Effective Date*, 90 FR 40974 (August 22, 2025).

<sup>9</sup> *Imposition of Special Measure Prohibiting Certain Transmittals of Funds Involving CIBanco S.A., Institución De Banca Multiple*, 90 FR 27770 (June 30, 2025).