

is to provide employment, a recipient may not, directly or through contractual or other arrangements, subject an individual to discrimination on the ground of race, color, or national origin in its employment practices under the program including recruitment or recruitment advertising, employment, layoff or termination, upgrading, demotion, or transfer, rates of pay or other forms of compensation, and use of facilities. This paragraph (c) applies to programs where a primary objective of the Federal financial assistance is:

- (1) To reduce unemployment;
- (2) To assist individuals in meeting expenses incident to the commencement or continuation of their education or training; or
- (3) To provide work experience which contributes to education or training.

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Stephen Vaden,

Deputy Secretary, U.S. Department of Agriculture.

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CONSUMER FINANCIAL PROTECTION BUREAU

12 CFR Part 1002

Equal Credit Opportunity (Regulation B); Special Purpose Credit Programs; Rescission

AGENCY: Consumer Financial Protection Bureau.

ACTION: Advisory opinion; rescission.

SUMMARY: The Consumer Financial Protection Bureau (Bureau) is rescinding an advisory opinion issued in December 2020 regarding Regulation B, which implements the Equal Credit Opportunity Act (ECOA), as it applies to certain aspects of special purpose credit programs designed and implemented by for-profit organizations to meet special social needs.

DATES: The advisory opinion is rescinded on June 17, 2026.

FOR FURTHER INFORMATION CONTACT: Dave Gettler, Paralegal Specialist, Office of Regulations, at 202–435–7700 or <https://reginquiries.consumerfinance.gov/>. If you require this document in an alternative electronic format, please contact CFPB_Accessibility@cfpb.gov.

SUPPLEMENTARY INFORMATION: The Consumer Financial Protection Bureau (Bureau) is charged with administering the Equal Credit Opportunity Act

(ECOA or the Act).¹ ECOA prohibits discrimination by a creditor in any aspect of a credit transaction, on the basis of race, color, religion, national origin, sex, marital status, age, an applicant's receipt of public assistance, or the good faith exercise of an applicant's rights under the Consumer Credit Protection Act.² At the same time, ECOA also states that it is not a violation of the Act for a creditor to refuse to extend credit offered pursuant to any special purpose credit program (SPCP) offered by a profit-making organization to meet special social needs which meets standards prescribed in regulations by the Bureau if such refusal is required by or made pursuant to such program.³ On December 21, 2020, the Bureau issued an advisory opinion entitled "Equal Credit Opportunity (Regulation B); Special Purpose Credit Programs" (the advisory opinion) to address regulatory uncertainty regarding Regulation B, which implements ECOA, as it applies to certain aspects of SPCPs designed and implemented by for-profit organizations to meet special social needs.⁴

The advisory opinion purported to address regulatory uncertainty regarding Regulation B as it applies to certain aspects of SPCPs designed and implemented by for-profit organizations to meet special social needs. Specifically, the advisory opinion clarified the content that a for-profit organization must include in a written plan that establishes and administers an SPCP under Regulation B. In addition, the advisory opinion clarified the type of research and data that may be appropriate to inform a for-profit organization's determination that an SPCP is needed to benefit a certain class of persons.

In April 2026, the Bureau issued a final rule amending provisions related to, *inter alia*, SPCPs under Regulation B.⁵ The advisory opinion, however, contains statements that conflict with these recent amendments to Regulation B. As one example, the advisory opinion states that all program participants in an SPCP offered or participated in by a for-profit organization may be required "to share one or more common characteristics (for example, *race, national origin, or sex*)";⁶ the April 2026 final rule, however, prohibits any

SPCP offered or participated in by a for-profit organization from using the common characteristic of race, color, national origin, or sex, or any combination thereof, as a factor in determining eligibility for the program. In addition, the advisory opinion addresses SPCP provisions under Regulation B that have since been amended, rendering those discussions out-of-date or, at best, incomplete. The Bureau now hereby rescinds the advisory opinion. This rescission is intended to avoid any confusion about the appropriate standards and related conditions for SPCPs offered or participated in by for-profit organizations.

I. ECOA and Regulation B

ECOA makes it unlawful for any creditor to discriminate against any applicant, with respect to any aspect of a credit transaction, on the basis of race, color, religion, national origin, sex, marital status, age, an applicant's receipt of public assistance, or the good faith exercise of an applicant's rights under the Consumer Credit Protection Act.⁷ At the same time, ECOA also states that it is not a violation of the Act for a creditor to refuse to extend credit offered pursuant to "any [SPCP] offered by a profit-making organization to meet special social needs *which meets standards prescribed in regulations by the Bureau*" if such refusal is required by or made pursuant to such program.⁸ ECOA also authorizes the Bureau to write regulations to carry out ECOA's purposes.⁹

In April 2026, the Bureau exercised these authorities by revising the standards for SPCPs under Regulation B to align them with ECOA, including its express statutory purpose, and to prevent unlawful discrimination. Specifically, the Bureau determined that any SPCP that bases eligibility on protected class membership inherently discriminates against ineligible individuals in violation of ECOA, unless the SPCP's use of the otherwise prohibited basis is necessary to overcome a demonstrated inability to access credit that is specifically based on those same characteristics. Finding no evidence (submitted by commenters or otherwise) that SPCPs based on race, color, national origin, or sex remain

⁷ 15 U.S.C. 1691(a).

⁸ 15 U.S.C. 1691(c)(3) (emphasis added).

⁹ 15 U.S.C. 1691b(a). ECOA's express purpose is "to require that financial institutions and other firms engaged in the extension of credit make that credit equally available to all credit-worthy customers without regard to [prohibited bases]." Public Law 93–495, tit. V, sec. 502, 88 Stat. 1521 (1974).

¹ 15 U.S.C. 1691b(a).

² 15 U.S.C. 1691.

³ 15 U.S.C. 1691(c)(3).

⁴ The Bureau published the advisory opinion in the **Federal Register**, 86 FR 3762 (Jan. 15, 2021).

⁵ 91 FR 21620 (Apr. 22, 2026).

⁶ 86 FR 3762 at 3764 (emphasis added).

necessary to serve the narrow original purpose of ECOA's SPCP provisions, the Bureau determined that it is no longer appropriate, necessary, or proper for the SPCP standards in Regulation B to permit such programs to use the common characteristics of race, color, national origin, or sex as eligibility criteria.¹⁰ The Bureau also noted, as discussed below, the constitutional concerns that arise from authorizing such programs.¹¹ Accordingly, the Bureau amended Regulation B by adding new prohibitions, which bar an SPCP offered or participated in by a for-profit organization from using the common characteristic of race, color, national origin, or sex, or any combination thereof, as a factor in determining eligibility for the program.

Independent of and in addition to the above-described prohibitions, the Bureau also determined that additional conditions for SPCPs offered or participated in by for-profit organizations are necessary and appropriate. Specifically, the Bureau amended the SPCP standards to require any such program to be predicated on formal (and regulatorily required) evidence and documentation by the creditor that it is the fact of protected class membership that is causing program participants to be unable to obtain credit. Accordingly, a for-profit organization offering an SPCP must establish and administer the program to extend credit to a class of persons to whom, under the organization's actual credit standards, the organization would actually deny credit in the absence of the SPCP.

The Bureau has determined that the advisory opinion should be rescinded, as it is now outdated and inconsistent with the recent amendments to Regulation B. First, the advisory opinion discusses provisions related to SPCPs that have been modified by the recent amendments to Regulation B. For instance, the recent amendments to the SPCP provisions of Regulation B added new requirements to the written plan requirement that for-profit organizations offering or participating in an SPCP must satisfy. The advisory opinion, of course, does not address these new requirements. Thus, the advisory opinion is no longer current.

Second, the advisory opinion also contains several statements that are inconsistent with these recent amendments to Regulation B's SPCP provisions. For instance, the advisory opinion restated the now-superseded provisions of Regulation B that said all

program participants in an SPCP may be required to share common characteristics such as race, national origin, or sex (so long as the program is not intended to evade the requirements of the ECOA or Regulation B).¹² As explained above, however, recent amendments to Regulation B prohibit an SPCP offered or participated in by a for-profit organization from using the common characteristic of race, color, national origin, or sex, or any combination thereof, as a factor in determining eligibility for the program.

Moreover, in discussing the determination of need for an SPCP offered or participated in by a for-profit organization, the advisory opinion stated that the for-profit organization must be able to show a connection between the research or data informing its analysis and the fact that, under the organization's customary standards of creditworthiness, a class of persons *probably* would not receive credit or would receive it on less favorable terms than are ordinarily available to other applicants applying to the organization for a similar type and amount of credit.¹³ But the recent changes to Regulation B make clear that any SPCP offered by a for-profit organization must be established and administered to extend credit to a class of persons who actually (in lieu of "probably") would not receive such credit. Given these and other inconsistencies, the Bureau has determined that it is appropriate and necessary to rescind the advisory opinion to avoid confusion about the appropriate standards and related conditions for SPCPs offered or participated in by for-profit organizations.

Additionally, in its recent Regulation B Final Rule, the Bureau noted the serious constitutional concerns raised by SPCPs, to the extent they are read as authorizing discrimination on the bases of race, color, sex, or national origin.¹⁴ Unambiguously, the Constitution forbids the government from establishing programs that would discriminate in this fashion on the basis of race or color¹⁵ and sharply limits the circumstances in which government distinctions may be made as to sex or national origin. The advisory opinion not only implicates the overall constitutional propriety of SPCPs limited on such bases, but involves the government in expressly encouraging

private actors to create those very programs.¹⁶ Courts have long held that action by a private party can be attributed to the government when the government "provides significant encouragement" for the action.¹⁷ This concern is especially acute when "the State has significantly involved itself with invidious discriminations," such as those based on race.¹⁸ The Bureau acknowledges the serious constitutional concerns raised by both the underlying SPCP provisions, as they were implemented at the time of the advisory opinion, and with the advisory opinion itself. As with the recent amendment of Regulation B, the Bureau believes that the rescission of the advisory opinion is both necessary and appropriate to avoid these potential constitutional challenges.

II. Regulatory Matters

This rescission is issued under the Bureau's authority to provide guidance regarding ECOA and Regulation B, including under section 1022(b)(1) of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, which authorizes guidance as may be necessary or appropriate to enable the CFPB to administer and carry out the purposes and objectives of Federal consumer financial laws.¹⁹ This rescission does not have the force or effect of law, and it has no legally binding effect, including on persons or entities outside the Federal Government.

The Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) has determined that this action is not a "significant regulatory action" under E.O. 12866.

Pursuant to subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, also known as the Congressional Review Act (CRA),²⁰ the CFPB will submit a report containing this rescission and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to this issuance's effective date. OIRA has determined that this rescission is not a "major rule" within the meaning of the relevant sections of the CRA.

The CFPB has determined that this rescission does not contain any new or substantively revised information

¹⁰ 86 FR 3762 at 3763.

¹⁷ See *San Francisco Arts & Athletics, Inc. v. U.S. Olympic Committee*, 483 U.S. 522, 546 (1987); see also *Reitman v. Mulkey*, 387 U.S. 369 (1967).

¹⁸ *Reitman*, 387 U.S. at 380.

¹⁹ 12 U.S.C. 5512(b)(1).

²⁰ 5 U.S.C. 801 *et seq.*

¹⁰ 91 FR 21620 at 21652.

¹¹ *Id.* at 21653.

¹² 86 FR 3762 at 3764.

¹³ 86 FR 3762 at 3766.

¹⁴ 91 FR 21620 at 21653.

¹⁵ *Students for Fair Admissions, Inc. v. President and Fellows of Harvard College*, 600 U.S. 181, 206–07 (2023).

collection requirements that would require approval by OMB under the Paperwork Reduction Act.²¹

Russell Vought,

Acting Director, Consumer Financial Protection Bureau.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2026–N–6536]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Ingestible Gastrointestinal Blood Detection Capsule

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the ingestible gastrointestinal blood detection capsule into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the ingestible gastrointestinal blood detection capsule. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective June 17, 2026. The classification was applicable on February 24, 2023.

FOR FURTHER INFORMATION CONTACT: Sivakami Venkatachalam, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2676, Silver Spring, MD 20993–0002, 301–796–9103, Sivakami.Venkatachalam@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the ingestible gastrointestinal blood detection capsule into class II (special controls), which we have determined will provide a reasonable assurance of safety and

effectiveness of the device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person

determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining “substantial equivalence”). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On September 29, 2022, FDA received EnteraSense Ltd.'s request for De Novo classification of the Pill Sense System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on February 24, 2023, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21

²¹ 44 U.S.C. 3501 *et seq.*