this type of device, as well as the mitigation measures required to mitigate these risks in Table 1.

TABLE 1—INTERNAL TISSUE MARKER RISKS AND MITIGATION MEASURES

| Identified Risks and Mitigation Measures | |
|---|---|
| Identified risk | Mitigation measures |
| Adverse Tissue Reaction. | Biocompatibility Testing.<br>Sterilization Testing.<br>Shelf Life/Stability Testing.<br>Performance Testing.<br>Labeling. |
| Ineffective Marking .... | Performance Testing.<br>Shelf Life/Stability Testing.<br>Labeling. |
| Improper Use ..... | Labeling. |

FDA believes that the following special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness:

- The device must be demonstrated to be biocompatible. Material names and specific designation numbers must be provided.
- Performance testing must demonstrate that the device performs as intended to mark the tissue for which it is indicated.
- Performance data must demonstrate the sterility of the device.
- Performance data must support the shelf life of the device by demonstrating sterility, package integrity, device functionality, and material stability over the requested shelf life.
- Labeling must include:
  - A warning that the device must not be used on a non-sterile surface prior to use internally.
  - An expiration date/shelf life.
  - Single use only labeling must be labeled directly on the device.

Internal tissue marker is a prescription device restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device; see 21 CFR 801.109 (*Prescription devices*).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the internal tissue marker they intend to market.

## II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

## IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.*

1. **DEN130004**: De Novo Request from VasoPrep Surgical (formerly Moerae Matrix, Inc.), dated May 3, 2013.

## List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

## PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for 21 CFR part 878 continues to read as follows:

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

■ 2. Add § 878.4670 to subpart E to read as follows:

### § 878.4670 Internal tissue marker.

(a) *Identification.* An internal tissue marker is a prescription use device that is intended for use prior to or during general surgical procedures to demarcate selected sites on internal tissues.

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

(1) The device must be demonstrated to be biocompatible. Material names and specific designation numbers must be provided.

(2) Performance testing must demonstrate that the device performs as intended to mark the tissue for which it is indicated.

(3) Performance data must demonstrate the sterility of the device.

(4) Performance data must support the shelf life of the device by demonstrating sterility, package integrity, device functionality, and material stability over the requested shelf life.

(5) Labeling must include:

(i) A warning that the device must not be used on a non-sterile surface prior to use internally.

(ii) An expiration date/shelf life.

(iii) Single use only labeling must be labeled directly on the device.

Dated: July 30, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–19177 Filed 8–4–15; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

## 24 CFR Part 5

**[Docket No. FR–5173–C–06]**

**RIN 2501–AD33**

## Affirmatively Furthering Fair Housing; Technical Correction

**AGENCY:** Office of the General Counsel, HUD.

**ACTION:** Final rule, technical correction.

**SUMMARY:** This document corrects a typographical error in HUD's final rule on Affirmatively Furthering Fair Housing, published on July 16, 2015.

**DATES:** *Effective:* August 17, 2015.

**FOR FURTHER INFORMATION CONTACT:** For further information about this technical correction, contact Camille E. Acevedo, Associate General Counsel for Legislation and Regulations, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10282, Washington, DC 20410–0500; telephone

number 202–708–1793 (this is not a toll-free number). Persons who are deaf or hard of hearing and persons with speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

**SUPPLEMENTARY INFORMATION:** On July 16, 2015, at 42271, HUD published a final rule to provide HUD program participants with an approach to help them better incorporate into their planning processes the duty to affirmatively further the purposes and policies of the Fair Housing Act, so they can more effectively meet their long-standing fair housing obligations. Under this rule, recipients of HUD funds will prepare an Assessment of Fair Housing (AFH), developed in accordance with requirements provided in the rule, and will submit the AFH to HUD. In detailing submission requirements, the rule explains when different program participants must submit to HUD their first AFH. New regulatory § 5.160 contains submission deadlines for program participants to submit their first AFHs to HUD. Section 5.160(a)(1)(i)(C) in the final rule, which describes the deadline by when consolidated plan participants that are Insular Areas or States must submit their first AFH to HUD, inadvertently omitted the word ''year'' after ''program'' and omitted the word ''plan'' after the second occurrence of the word ''consolidated.'' Therefore, this document revises 24 CFR 5.160(a)(1)(i)(C) to include these two missing words.

## Correction

Accordingly, FR Doc. 2015–17032, Affirmatively Furthering Fair Housing (FR–5173–F–04), published in the **Federal Register** on July 16, 2015 (80 FR 42271) is corrected as follows:

On page 42357, revise the first full paragraph in the third column, beginning on the third line of the column (24 CFR 5.160(a)(1)(i)(C)), to read as follows ''(C) For consolidated plan participants that are Insular Areas or States, the program year that begins on or after January 1, 2018 for which a new consolidated plan is due, as provided in 24 CFR 91.15(b)(2); and''

Dated: July 29, 2015.

**Camille E. Acevedo,**

*Association General Counsel for Legislation and Regulations.*

[FR Doc. 2015–19214 Filed 8–4–15; 8:45 am]

BILLING CODE 4210–67–P

## DEPARTMENT OF LABOR

## Occupational Safety and Health Administration

## 29 CFR Part 1956

**[Docket No. OSHA–2015–0003]**

**RIN 1218–AC97**

## Maine State Plan for State and Local Government Employers

**AGENCY:** Occupational Safety and Health Administration (OSHA), Department of Labor.

**ACTION:** Notice of initial approval determination.

**SUMMARY:** The Maine State and Local Government Only State Plan, a state occupational safety and health plan applicable only to public sector employment (employees of the state and its political subdivisions), is approved as a developmental plan under the Occupational Safety and Health Act of 1970 and OSHA regulations. Under the approved Plan, the Maine Department of Labor is designated as the state agency responsible for the development and enforcement of occupational safety and health standards applicable to state and local government employment throughout the state. The Occupational Safety and Health Administration (OSHA) retains full authority for coverage of private sector employees in the State of Maine, as well as for coverage of federal government employees.

**DATES:** *Effective:* August 5, 2015.

**FOR FURTHER INFORMATION CONTACT:** *For press inquiries:* Contact Francis Meilinger, Office of Communications, Room N–3647, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–1999; email *meilinger.francis2@dol.gov.*

*For general and technical information:* Contact Douglas J. Kalinowski, Director, OSHA Directorate of Cooperative and State Programs, Room N–3700, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693–2200; email: *kalinowski.doug@dol.gov.*

**SUPPLEMENTARY INFORMATION:**

### A. Introduction

Section 18 of the Occupational Safety and Health Act of 1970 (the ''OSH Act''), 29 U.S.C. 667, provides that a state which desires to assume responsibility for the development and enforcement of standards relating to any occupational safety and health issue with respect to which a federal standard has been promulgated may submit a State Plan to the Assistant Secretary of Labor for Occupational Safety and Health (''Assistant Secretary'') documenting the proposed program in detail. Regulations promulgated pursuant to the OSH Act at 29 CFR part 1956 provide that a state may submit a State Plan for the development and enforcement of occupational safety and health standards applicable only to employers of the state and its political subdivisions (''public employers'').

Under these regulations the Assistant Secretary will approve a State Plan for State and Local Government Only if the Plan provides for the development and enforcement of standards relating to hazards in employment covered by the Plan, which are or will be at least as effective in providing safe and healthful employment and places of employment as standards promulgated and enforced under Section 6 of the OSH Act, giving due consideration to differences between public and private sector employment. In making this determination the Assistant Secretary will consider, among other things, the criteria and indices of effectiveness set forth in 29 CFR part 1956, subpart B.

A State and Local Government Only State Plan may receive initial approval even though, upon submission, it does not fully meet the criteria set forth in 29 CFR 1956.10 and 1956.11, if it includes satisfactory assurances by the state that the state will take the necessary steps, and establishes an acceptable developmental schedule, to meet the criteria within a three year period (29 CFR 1956.2(b)). The Assistant Secretary may publish a notice of ''certification of completion of developmental steps'' when all of a state's developmental commitments have been met satisfactorily (29 CFR 1956.23; 1902.33 and 1902.34) and the Plan is structurally complete. After certification of a State Plan for State and Local Government Only, OSHA may initiate a period of at least one year of intensive performance monitoring, after which OSHA may make a determination under the procedures of 29 CFR 1902.38, 1902.39, 1902.40 and 1902.41 as to whether, on the basis of actual operations, the criteria set forth in 29 CFR 1956.10 and 1956.11 for ''at least as effective'' State Plan performance are being applied under the Plan.

### B. History of the Present Proceeding

Since 1971, the Maine Department of Labor, Bureau of Labor Standards (Bureau), has adopted standards and performed inspections in the public