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**

<table>
<thead>
<tr>
<th>Identified risk</th>
<th>Mitigation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Tissue Reaction.</td>
<td>Biocompatibility Testing.</td>
</tr>
<tr>
<td></td>
<td>Sterilization Testing.</td>
</tr>
<tr>
<td></td>
<td>Shelf Life/Stability Testing.</td>
</tr>
<tr>
<td></td>
<td>Performance Testing.</td>
</tr>
<tr>
<td></td>
<td>Labeling.</td>
</tr>
<tr>
<td>Ineffective Marking ...</td>
<td>Performance Testing.</td>
</tr>
<tr>
<td></td>
<td>Shelf Life/Stability Testing.</td>
</tr>
<tr>
<td></td>
<td>Labeling.</td>
</tr>
<tr>
<td>Improper Use</td>
<td>Labeling.</td>
</tr>
</tbody>
</table>

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 0910–0483.

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.


**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  

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.

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  
etermination.

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  
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 public 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 kalinowskijdoug@  
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  
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