


List of Subjects in 21 CFR Part 884

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 884 is amended as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

1. The authority citation for part 884 continues to read as follows:


2. Add § 884.4910 to subpart E to read as follows:

   § 884.4910 Specialized surgical instrumentation for use with urogynecologic surgical mesh.

   (a) Identification. Specialized surgical instrumentation for use with urogynecologic surgical mesh is a prescription device specifically intended for use as an aid in the insertion, placement, fixation, or anchoring of surgical mesh during urogynecologic procedures. These procedures include transvaginal pelvic organ prolapse repair, sacrocolpopexy (transabdominal pelvic organ prolapse repair), and treatment of female stress urinary incontinence. Examples of specialized surgical instrumentation include needle passers and trocars, needle guides, fixation tools, and tissue anchors. This device is not a manual gastroenterology-urogynecologic surgical instrument and accessories (§ 876.4730) or a manual surgical instrument for general use (§ 876.4800).

   (b) Classification. Class II (special controls). The special controls for specialized surgical instrumentation for use with urogynecologic mesh are:

   (1) The device must be demonstrated to be biocompatible;

   (2) The device must be demonstrated to be sterile and, if reusable, it must be demonstrated that the device can be adequately reprocessed;

   (3) Performance data must support the shelf life of the device by demonstrating package integrity and device functionality over the requested shelf life;

   (4) Non-clinical performance testing must demonstrate that the device meets all design specifications and performance requirements, and that the device performs as intended under anticipated conditions of use; and

   (5) Labeling must include:

      (i) Information regarding the mesh design that may be used with the device;

      (ii) Detailed summary of the clinical evaluations pertinent to use of the device;

      (iii) Expiration date; and

      (iv) Where components are intended to be sterilized by the user prior to initial use and/or are reusable, validated methods and instructions for sterilization and/or reprocessing of any reusable components.


   Leslie Kux,

   Associate Commissioner for Policy.

   [FR Doc. 2016–31862 Filed 1–5–17; 8:45 am]

   BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81


Air Plan Approval; Ohio; Redesignation of the Cleveland, Ohio Area to Attainment of the 2008 Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) finds that the Cleveland-Akron-Lorain, Ohio area (Cleveland area) is attaining the 2008 ozone National Ambient Air Quality Standard (NAAQS or standard) and is redesignating the area to attainment for the 2008 ozone NAAQS, because the area meets the statutory requirements for redesignation under the Clean Air Act (CAA). The Cleveland area includes Ashitabula, Cuyahoga, Geauga, Lake, Lorain, Medina, Portage, and Summit counties. EPA is also approving, as a revision to the Ohio State Implementation Plan (SIP), the state’s plan for maintaining the 2008 ozone standard through 2030 in the Cleveland area. Finally, EPA finds adequate and is approving the state’s 2020 and 2030 volatile organic compound (VOC) and oxides of nitrogen (NOx) Motor Vehicle Emission Budgets (MVEBs) for the Cleveland area. The Ohio Environmental Protection Agency (Ohio EPA) submitted the final revision and redesignation request on July 6, 2016.

DATES: This final rule is effective January 6, 2017.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R05–OAR–2016–0396. All documents in the docket are listed in the http://www.regulations.gov Web site. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information 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 either through http://www.regulations.gov, or please contact the person identified in the FOR FURTHER INFORMATION CONTACT section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Jenny Liljegren, Physical Scientist, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18),...
III. What action is EPA taking?

EPA finds that the Cleveland nonattainment area is attaining the 2008 ozone standard, based on quality-assured and certified monitoring data for 2013–2015 and that the Ohio portion of this area has met the requirements for redesignation under section 107(d)(3)(E) of the CAA. EPA is thus changing the legal designation of the Cleveland area from nonattainment to attainment for the 2008 ozone standard. EPA is also approving, as a revision to the Ohio SIP, the state’s maintenance plan for the area. The maintenance plan is designed to keep the Cleveland area in attainment of the 2008 ozone NAAQS through 2030. Finally, EPA finds adequate and is approving the newly-established 2020 and 2030 MVEBs for the Cleveland area.

In accordance with 5 U.S.C. 553(d), EPA finds that making these actions become effective immediately upon publication. This is because a delayed effective date is unnecessary due to the nature of a redesignation to attainment, which relieves the area from certain CAA requirements that would otherwise apply to it. The immediate effective date for this action is authorized under both 5 U.S.C. 553(d)(1), which provides that rulemaking actions may become effective less than 30 days after publication if the rule “grants or recognizes an exemption or relieves a restriction,” and section 553(d)(3), which allows an effective date less than 30 days after publication “as otherwise provided by the agency for good cause found and published with the rule.”

The purpose of the 30-day waiting period prescribed in section 553(d) is to give affected parties a reasonable time to prepare before the rule takes effect. Today’s rule, however, does not create any new regulatory requirements such that affected parties would need time to prepare before the rule takes effect. Rather, today’s rule relieves the state of planning requirements for this ozone nonattainment area. For these reasons, EPA finds good cause under 5 U.S.C. 553(d)(3) for these actions to become effective on the date of publication of these actions.

IV. Statutory and Executive Order Reviews

Under the CAA, redesignation of an area to attainment and the accompanying approval of a maintenance plan under section 107(d)(3)(E) are actions that affect the status of a geographical area and do not impose any additional regulatory requirements on sources beyond those imposed by state law. A redesignation to attainment does not in and of itself create any new requirements, but rather results in the applicability of requirements contained in the CAA for areas that have been redesignated to attainment. Moreover, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a).

Thus, in reviewing SIP submissions, EPA’s role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

• Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
• Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.);
• Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.);
• Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
• Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land on any other area where EPA or an Indian tribe has demonstrated that the tribe has jurisdiction. In those areas of
Indian country, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because redesignation is an action that affects the status of a geographical area and does not impose any new regulatory requirements on tribes, impact any existing sources of air pollution on tribal lands, nor impair the maintenance of ozone national ambient air quality standards in tribal lands.

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the Federal Register. A major rule cannot take effect until 60 days after it is published in the Federal Register.

This action is not a “major rule” as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 7, 2017. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

§ 52.1885 Control strategy: Ozone.

(3) Approval—On July 6, 2016, the Ohio Environmental Protection Agency submitted a request to redesignate the Cleveland area to attainment of the 2008 ozone NAAQS. As part of the redesignation request, the State submitted a maintenance plan as required by section 175A of the Clean Air Act. Elements of the section 175 maintenance plan include a contingency plan and an obligation to submit a subsequent maintenance plan revision in eight years as required by the Clean Air Act. The 2020 motor vehicle emissions budgets for the Cleveland area are 38.85 tons per summer day (TPSD) for VOC and 61.56 TPSD for NOX. The 2030 motor vehicle emissions budgets for the Cleveland area are 30.80 TPSD for VOC and 43.82 TPSD for NOX.

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

3. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7401 et seq.

4. Section 81.336 is amended by revising the entry for Cleveland-Akron-Lorain, OH in the table entitled “Ohio—2008 8-Hour Ozone NAAQS (Primary and secondary)” to read as follows:

§ 81.336 Ohio.

<table>
<thead>
<tr>
<th>Designated area</th>
<th>Date</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleveland, OH: 2 Ashtabula County, Cuyahoga County, Geauga County, Lake County, Lorain County, Medina County, Portage County, Summit County.</td>
<td>1/6/2017</td>
<td>Attainment.</td>
</tr>
</tbody>
</table>

1 This date is July 20, 2012, unless otherwise noted.

2 Excludes Indian country located in each area, unless otherwise noted.
AmeriCorps, Senior Corps, Social Community Service (CNCS) is a federal agency that engages more than five million Americans in service through its AmeriCorps, Senior Corps, Social Innovation Fund, and Volunteer Generation Fund programs to further its mission to improve lives, strengthen communities, and foster civic engagement through service and volunteering. For more information, visit NationalService.gov.

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114–74) (the “Act”), which is intended to improve the effectiveness of civil monetary penalties and to maintain the deterrent effect of such penalties, requires agencies to adjust the civil monetary penalties for inflation annually.

II. Method of Calculation

CNCS has two civil monetary penalties in its regulations. A civil monetary penalty under the Act is a penalty, fine, or other sanction that is for a specific monetary amount as provided by Federal law or has a maximum amount provided for by Federal law and is assessed or enforced by an agency pursuant to Federal law and is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts. (See 28 U.S.C. 2461 note).

The inflation adjustment for each applicable civil monetary penalty is determined using the percent increase in the Consumer Price Index for all Urban Consumers (CPI–U) for the month of October of the year in which the amount of each civil money penalty was most recently established or modified. In the December 16, 2016, OMB Memo for the Heads of Executive Agencies and Departments, M–17–11, Implementation of the 2017 annual adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, OMB published the multiplier for the required annual adjustment. The cost-of-living adjustment multiplier for 2017, based on the CPI–U for the month of October 2016, not seasonally adjusted, is 1.01636.

CNCS identified two civil penalties in its regulations: (1) The penalty associated with Restrictions on Lobbying (45 CFR 1230.400) and (2) the penalty associated with the Program Fraud Civil Remedies Act (45 CFR 2554.1).

The civil monetary penalties related to Restrictions on Lobbying (Section 319, Pub. L. 101–121; 31 U.S.C. 1352) range from $18,936 to $189,361. Using the 2017 multiplier, the new upper limit of the civil monetary penalty is $19,246 to $192,459.

The civil monetary penalties for the Program Fraud Civil Remedies Act of 1986 (Pub. L. 99–509) civil monetary penalty has an upper limit of $10,781. Using the 2017 multiplier, the new upper limit of the civil monetary penalty is $10,957.

III. Summary of Final Rule

This final rule applies to civil penalties assessed on or after January 15, 2017, when the violation occurred after November 2, 2015. If the violation occurred prior to November 2, 2015, or a penalty was assessed prior to August 1, 2016, the pre-adjustment civil penalty amounts in effect prior to August 1, 2016, will apply.