device use may be associated with: disorientation, confusion, and memory problems.''

(J) Absent performance data demonstrating a beneficial effect of longer term use, generally considered treatment in excess of 3 months, the following statement, prominently placed: ''Warning: When used as intended this device provides short-term relief of symptoms. The long-term safety and effectiveness of ECT treatment has not been demonstrated.''

(ix) Patient labeling must be provided and include:

(A) Relevant contraindications, warnings, precautions.

(B) A summation of the clinical testing, 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.

(C) Information on how the device operates and the typical course of treatment.

(D) The potential benefits.

(E) Alternative treatments.

(F) The following statement, prominently placed: ''Warning: ECT device use may be associated with: disorientation, confusion, and memory problems.''

(G) Absent performance data demonstrating a beneficial effect of longer term use, generally considered treatment in excess of 3 months, the following statement, prominently placed: ''Warning: When used as intended this device provides short-term relief of symptoms. The long-term safety and effectiveness of ECT treatment has not been demonstrated.''

(H) The following statements on known risks of ECT, absent performance data demonstrating that these risks do not apply:

(*1*) ECT treatment may be associated with disorientation, confusion and memory loss, including short-term (anterograde) and long-term (autobiographical) memory loss following treatment. These side effects tend to go away within a few days to a few months after the last treatment with ECT. However, some patients have reported a permanent loss of memories of personal life events (*i.e.,* autobiographical memory). Improvements in the way ECT is applied to patients currently, with controlled electric currents and electrode placement, can minimize but not completely eliminate, these risks.

(*2*) Patients treated with ECT may also experience manic symptoms (including euphoria and/or irritability, impulsivity, racing thoughts, distractibility, grandiosity, increased activity, talkativeness, and decreased need for sleep) or a worsening of the psychiatric symptoms they are being treated for.

(*3*) The physical risks of ECT may include the following (in order of frequency of occurrence):

(*i*) Pain/somatic discomfort (including headache, muscle soreness, and nausea).

(*ii*) Skin burns.

(*iii*) Physical trauma (including fractures, contusions, injury from falls, dental and oral injury).

(*iv*) Prolonged or delayed onset seizures.

(*v*) Pulmonary complications (insufficient, or lack of breathing, or inhalation of foreign substance into the lungs).

(*vi*) Cardiovascular complications (heart attack, high or low blood pressure, and stroke).

(*vii*) Death.

(*viii*) Devices marketed prior to the effective date of this reclassification must have an amendment submitted to their previously cleared premarket notification (510(k)) that demonstrates compliance with these special controls within 60 days after the effective date of this reclassification.

(2) *Classification:* Class III (premarket approval) for the following intended uses: schizophrenia, bipolar manic states, schizoaffective disorder, schizophreniform disorder, and catatonia.

(c) *Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER IN THE **Federal Register**], for any electroconvulsive therapy device with an intended use described in paragraph (b)(2) of this section, that was in commercial distribution before May 28, 1976, or that has, on or before [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER IN THE **Federal Register**], been found to be substantially equivalent to any electroconvulsive therapy device with an intended use described in paragraph (b)(2) of this section, that was in commercial distribution before May 28, 1976. Any other electroconvulsive therapy device with an intended use described in paragraph (b)(2) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: December 18, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–32592 Filed 12–28–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. FDA–2015–D–3719]

Draft Guidances Relating to the Regulation of Human Cells, Tissues, or Cellular or Tissue-Based Products; Public Hearing; Request for Comments; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments; correction.

SUMMARY: The Food and Drug Administration (FDA or Agency) is correcting a notification of a public hearing entitled ''Draft Guidances Relating to the Regulation of Human Cells, Tissues, or Cellular or Tissue-Based Products; Public Hearing; Request for Comments'' that appeared in the **Federal Register** of October 30, 2015 (80 FR 66845). The document announced a public hearing to obtain input on four recently issued draft guidances relating to the regulation of human cells, tissues, or cellular or tissue-based products (HCT/Ps). The document published with conflicting information about who must register for the public hearing. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lori Jo Churchyard, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION: In FR Doc. 2015–27703, appearing on pages 66845 and 66847 in the **Federal Register** of Friday, October 30, 2015, the following corrections are made:

1. On page 66845, in the third column under **DATES**, the third sentence is revised to read: ''Persons seeking to attend (including FDA employees) or to present at the public hearing must register by January 8, 2016.''

2. On page 66847, in the first column under section IV. Attendance and Registration, the third sentence is revised to read: ''Individuals who wish to attend (including FDA employees) or present at the public hearing must

register by sending an email to *CBERPublicEvents@fda.hhs.gov* on or before January 8, 2016, and provide complete contact information, including name, title, affiliation, address, email, and phone number.''

Dated: December 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–32686 Filed 12–28–15; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51, 52, 55, 70, 71 and 124

[EPA–HQ–OAR–2015–0090, FRL–9937–21–OAR]

RIN 2060–AS59

Revisions to the Public Notice Provisions in Clean Air Act Permitting Programs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) proposes to revise the public notice rule provisions for the New Source Review (NSR), title V and Outer Continental Shelf (OCS) permit programs of the Clean Air Act (CAA) and the corresponding onshore area (COA) determinations for implementation of the OCS air quality regulations. This action would remove the mandatory requirement to provide public notice of a draft air permit, as well as certain other program actions, through publication in a newspaper and would instead allow for electronic noticing (e-notice) of these actions. The proposed rule revisions would apply to major source air permits issued by the EPA, by EPA-delegated air agencies, and by air agencies with EPA-approved programs (with the exception of permits that are issued pursuant to the Tribal NSR Rule, which already allows for e-notice methods).

DATES: *Comments.* Comments must be received on or before February 29, 2016.

Public hearing. If anyone contacts us requesting a public hearing on or before January 13, 2016, we will hold a hearing. Additional information about the hearing, if requested, will be published in a subsequent **Federal Register** document.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2015–0090, at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, Cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: For general information on this proposed rule for NSR and OCS programs, please contact Mr. Dave Svendsgaard, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, by phone at (919) 541–2380 or by email at *svendsgaard.dave@epa.gov;* for title V programs please contact Ms. Grecia Castro, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, by phone at (919) 541–1351 or by email at *castro.grecia@epa.gov.* To request a public hearing or information pertaining to a public hearing on this document, contact Ms. Pamela Long, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, by phone at (919) 541–0641 or by email at *long.pam@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. How is this ***Federal Register*** *notice organized?*

The information presented in this document is organized as follows:

B. Does this action apply to me?

Entities potentially affected by this proposed rule include air agencies responsible for the permitting of stationary and OCS sources of air pollution or for determining COA designation for implementation of the OCS Air Regulations. This includes the EPA Regions, and both EPA-delegated air programs and EPA-approved air programs that are operated by state, local and tribal governments. Entities also potentially affected by this proposed rule include owners and operators of stationary and OCS sources that are subject to air pollution permitting under the CAA, as well as the general public who would have an interest in knowing about permitting actions, public hearings and other agency actions.