under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). Rather, the requirement to label HCT/Ps in accordance with the proposed rule is a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)). Therefore, FDA tentatively concludes that these proposed requirements in this document are not subject to review by OMB because they do not constitute a ''collection of information'' under the PRA.

**IX. Comments**

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

**List of Subjects in 21 CFR Part 1271**

Biologics, Drugs, Human cells and tissue-based products, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Public Health Service Act and under the authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1271 be amended as follows:

## PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

■ 1. The authority citation for 21 CFR part 1271 continues to read as follows:

**Authority:** 42 U.S.C. 216, 243, 263a, 264, 271.

■ 2. In § 1271.90:
■ a. Revise the heading;
■ b. Revise paragraphs (a)(3) and (a)(4) by removing ''exempt'' and by adding in its place ''excepted'';
■ c. Revise paragraph (a)(4) by removing ''paragraph'' and by adding in its place ''paragraphs ''; and by adding ''(a)(1) and'' before ''(a)(2)'';
■ d. Redesignate paragraph (b) as paragraph (c);
■ e. Add a new paragraph (b);
■ f. Revise newly designated paragraph (c) by removing ''paragraph'' and by adding in its place ''paragraphs'' and by adding ''and (b)'' after ''(a)'' in the introductory text;
■ g. Revise newly designated paragraph (c)(2) by removing ''(b)(6)'' and by adding in its place ''(c)(6)''; and
■ h. Revise newly designated paragraph (c)(6) by adding ''recovery or'' before ''cryopreservation''.

The revisions read as follows:

**§ 1271.90 Are there other exceptions and what labeling requirements apply?**

(a) * * *

(3) Cryopreserved cells or tissue for reproductive use, other than embryos, originally excepted under paragraphs (a)(1) or (a)(2) of this section at the time of donation, that are subsequently intended for directed donation, provided that

* * * * *

(4) A cryopreserved embryo, originally excepted under paragraphs (a)(1) and (a)(2) of this section at the time of cryopreservation, that is subsequently intended for directed or anonymous donation. When possible, appropriate measures should be taken to screen and test the semen and oocyte donors before transfer of the embryo to the recipient.

(b) *Exceptions for Reproductive Use.* An embryo originally intended for reproductive use for a specific individual or couple that is subsequently intended for directed or anonymous donation for reproductive use is excepted from the prohibition on use under § 1271.45(c) even when the applicable donor eligibility requirements under part 1271, subpart C are not met. Nothing in this paragraph creates an exception for deficiencies that occurred in making the donor eligibility determination for either the oocyte donor or the semen donor as required under § 1271.45(b), or for deficiencies in performing donor screening or testing, as required under §§ 1271.75, 1271.80, and 1271.85.

(c) *Required labeling.* As applicable, you must prominently label an HCT/P described in paragraphs (a) and (b) of this section as follows:

(1) * * *

(2) ''NOT EVALUATED FOR INFECTIOUS SUBSTANCES,'' unless you have performed all otherwise applicable screening and testing under §§ 1271.75, 1271.80, and 1271.85. This paragraph does not apply to reproductive cells or tissue labeled in accordance with paragraph (c)(6) of this section.

* * * * *

(6) ''Advise recipient that screening and testing of the donor(s) were not performed at the time of recovery or cryopreservation of the reproductive cells or tissue, but have been performed subsequently,'' for paragraphs (a)(3) or (a)(4) of this section.

* * * * *

■ 3. Amend § 1271.370(b)(4) by removing ''§ 1271.90(b)'' and by adding in its place ''§ 1271.90(c)''.

Dated: December 23, 2014.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2014–30528 Filed 12–30–14; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF LABOR

### Mine Safety and Health Administration

### 30 CFR Part 100

**[Docket No. MSHA–2014–0009]**

**RIN 1219–AB72**

## Criteria and Procedures for Assessment of Civil Penalties

**AGENCY:** Mine Safety and Health Administration, Labor.

**ACTION:** Proposed rule; notice of public hearings; extension of comment period; close of record.

**SUMMARY:** The Mine Safety and Health Administration (MSHA) will hold two additional public hearings on the Agency's proposed rule for Criteria and Procedures for Assessment of Civil Penalties.

**DATES:** MSHA will hold public hearings on February 5, 2015, and February 12, 2015, at the locations listed in the **SUPPLEMENTARY INFORMATION** section of this document.

Post-hearing comments must be received or postmarked by midnight Eastern Standard Time on March 12, 2015.

**ADDRESSES:** Submit comments, informational materials, and requests to speak, identified by RIN 1219–AB72 or Docket No. MSHA–2014–0009, by one of the following methods:

- *Federal E-Rulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *E-Mail: zzMSHA-comments@dol.gov.* Include RIN 1219–AB72 or Docket No. MSHA–2014–0009 in the subject line of the message.
- *Mail:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209–3939.
- *Hand Delivery or Courier:* MSHA, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia, between 9:00 a.m. and 5:00 p.m., Monday through Friday,

except Federal holidays. Sign in at the receptionist's desk on the 21st floor.

• *Fax:* 202–693–9441.

*Instructions:* All submissions must include ''MSHA'' and ''RIN 1219–AB72'' or ''Docket No. MSHA–2014–0009.'' Do not include personal information that you do not want publicly disclosed; MSHA will post all comments without change to *http://www.regulations.gov* and *http://www.msha.gov/currentcomments.asp,* including any personal information provided. For additional instructions for participation in Public Hearings on this rulemaking, see the ''Public Hearings'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read comments received, go to *http://www.regulations.gov* or *http://www.msha.gov/currentcomments.asp.* To read background documents, go to *http://www.regulations.gov.* Review the docket in person at MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia, between 9:00 a.m. and 5:00 p.m. Monday through Friday, except Federal Holidays. Sign in at the receptionist's desk on the 21st floor.

*Email notification:* To subscribe to receive an email notification when MSHA publishes rules, program information, instructions, and policy, in the **Federal Register**, go to *http://www.msha.gov/subscriptions/subscribe.aspx.*

**FOR FURTHER INFORMATION CONTACT:** Sheila McConnell, Acting Director, Office of Standards, Regulations, and Variances, MSHA, at *mcconnell.sheila.a@dol.gov* (email); 202–693–9440 (voice); or 202–693–9441 (facsimile).

**SUPPLEMENTARY INFORMATION:**

## I. Background

On July 31, 2014, MSHA published a proposed rule (79 FR 44494) to amend its civil penalty regulation to simplify the criteria, which will promote consistency, objectivity, and efficiency in the proposed assessment of civil penalties and facilitate the resolution of enforcement issues. The proposal would place a greater emphasis on the more serious safety and health conditions and provide improved safety and health for miners. MSHA is also proposing alternatives that would address the scope and applicability of its civil penalty regulation.

In response to requests from the public, MSHA held public hearings on December 4, 2014, in Arlington, Virginia, and on December 9, 2014, in Denver, Colorado. The post-hearing comment period was scheduled to close on January 9, 2015.

## II. Public Hearings

In response to requests from the public, MSHA will hold two additional public hearings on the proposed rule to provide the public an opportunity to present their views on this rulemaking. MSHA is holding the hearings on the following dates at the locations indicated:

| Date | Location | Contact No. |
|---|---|---|
| Thursday, February 5, 2015 | Sheraton Birmingham Hotel, 2101 Richard Arrington Jr. Boulevard North, Birmingham, AL 35203. | 205–324–5000 |
| Thursday, February 12, 2015 | Embassy Suites Chicago—Downtown, 600 N. State Street, Chicago, IL 60654 | 312–943–3800 |

The hearings will begin with an opening statement from MSHA, followed by oral presentations from members of the public. The public hearings will begin at 9:00 a.m. and end no later than 5:00 p.m., or earlier if the last person presenting testimony has spoken.

Persons and organizations wishing to speak are encouraged to notify MSHA in advance for scheduling purposes. Persons do not have to make a written request to speak; however, MSHA will give priority to persons who have notified us, in advance, of their intent to speak and will provide others an opportunity to present oral testimony if time allows. MSHA requests that parties making presentations at the hearings submit them no later than five days prior to the hearing. Testimony, presentations, and accompanying documentation will be included in the rulemaking record.

The hearings will be conducted in an informal manner. Formal rules of evidence and cross examination will not apply. The hearing panel may ask questions of speakers and speakers may ask questions of the hearing panel. Verbatim transcripts of the proceedings will be prepared and made a part of the rulemaking record. Copies of the transcripts will be available to the public on *http://www.regulations.gov* and on MSHA's Web site at *http://www.msha.gov/tscripts.htm.*

Commenters are requested to be specific in their comments and submit detailed rationale and supporting documentation for any comment or suggested alternative as MSHA cannot sufficiently evaluate general comments. All comments must be received or postmarked by March 12, 2015.

Dated: December 23, 2014.

**Joseph A. Main,**

*Assistant Secretary of Labor for Mine Safety and Health.*

[FR Doc. 2014–30578 Filed 12–30–14; 8:45 am]

**BILLING CODE 4510–43–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 50, 51, 52, 53, and 58

**[EPA–HQ–OAR–2008–0699; FRL–9921–26–OAR]**

**RIN 2060–AP38**

### National Ambient Air Quality Standards for Ozone

**AGENCY:** Environmental Protection Agency.

**ACTION:** Announcement of public hearings.

**SUMMARY:** The Environmental Protection Agency (EPA) is announcing three public hearings for the proposed rule titled, ''National Ambient Air Quality Standards for Ozone,'' that was published in the **Federal Register** on December 17, 2014. The hearings will be held in Washington, DC, Arlington, Texas, and Sacramento, California.

Based on its review of the air quality criteria for ozone ($O_3$) and related photochemical oxidants and national ambient air quality standards (NAAQS) for $O_3$, the EPA proposes to make revisions to the primary and secondary NAAQS for $O_3$ to provide requisite