documentation that the terms and conditions of the adjustment were established and known to the customer at the time of sale. This rulemaking would be effective for proceedings initiated on or after 30 days following the date of publication of the final rule.

The Department invites parties to comment on this proposed rule and the proposed effective date. Further, any party may submit comments expressing its disagreement with the Department's proposal and may propose an alternative approach.

Classifications

Executive Order 12866

It has been determined that this proposed rule is not significant for purposes of Executive Order 12866.

Paperwork Reduction Act

This proposed rule contains no new collection of information subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

Executive Order 13132

This proposed rule does not contain policies with federalism implications as that term is defined in section 1(a) of Executive Order 13132, dated August 4, 1999 (64 FR 43255 (August 10, 1999)).

Regulatory Flexibility Act

The Chief Counsel for Regulation has certified to the Chief Counsel for Advocacy of the Small Business Administration under the provisions of the Regulatory Flexibility Act, 5 U.S.C. 605(b), that the proposed rule would not have a significant economic impact on a substantial number of small business entities. A summary of the need for, objectives of and legal basis for this rule is provided in the preamble, and is not repeated here.

The entities upon which this rulemaking could have an impact include foreign exporters and producers, some of whom are affiliated with U.S. companies, and U.S. importers. Enforcement & Compliance currently does not have information on the number of entities that would be considered small under the Small Business Administration's size standards for small businesses in the relevant industries. However, some of these entities may be considered small entities under the appropriate industry size standards. Although this proposed rule may indirectly impact small entities that are parties to individual antidumping duty proceedings, it will not have a significant economic impact on any entities.

The proposed action is merely a continuation of the Department's practice based on its interpretation of current Department regulations. If the proposed rule is implemented, no entities would be required to undertake additional compliance measures or expenditures. Rather, the regulations, both in their current form and in this proposed rulemaking, instruct the Department on what adjustments to make to export price or constructed export price and normal value under certain factual scenarios in the course of an antidumping duty proceeding. Because the proposed rule only impacts the way in which the Department makes certain calculations in antidumping duty proceedings, it does not directly impact any business entities. The proposed rule merely clarifies the regulations to better align with current Departmental practices. Therefore, the proposed rule would not have a significant economic impact on a substantial number of small business entities. For this reason, an Initial Regulatory Flexibility Analysis is not required and one has not been prepared.

List of Subjects in 19 CFR Part 351

Administrative practice and procedure, Antidumping, Business and industry, Cheese, Confidential business information, Countervailing duties, Freedom of information, Investigations, Reporting and recordkeeping requirements.

Dated: December 19, 2014.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

For the reasons stated, 19 CFR part 351 is proposed to be amended as follows:

PART 351—ANTIDUMPING AND COUNTERVAILING DUTIES

■ 1. The authority citation for 19 CFR part 351 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 1202 note; 19 U.S.C. 1303 note; 19 U.S.C. 1671 *et seq.;* and 19 U.S.C. 3538.

■ 2. In § 351.102, revise paragraph (b)(38) to read as follows:

§ 351.102 Definitions.

* * * * *

(b) * * *

(38) *Price adjustment.* ''Price adjustment'' means a change in the price charged for subject merchandise or the foreign like product, such as a discount or rebate, including, under certain circumstances, a change such as a discount or rebate that is made after the time of sale (*see* § 351.401(c)), that is reflected in the purchaser's net outlay.

* * * * *

■ 3. In § 351.401, revise paragraph (c) to read as follows:

§ 351.401 In general.

* * * * *

(c) *Use of price net of price adjustments.* In calculating export price, constructed export price, and normal value (where normal value is based on price), the Secretary normally will use a price that is net of price adjustments, as defined in § 351.102(b), that are reasonably attributable to the subject merchandise or the foreign like product (whichever is applicable). The Secretary generally will not consider a price adjustment that reduces or eliminates a dumping margin unless the party claiming such price adjustment demonstrates, to the satisfaction of the Secretary, through documentation that the terms and conditions of the adjustment were established and known to the customer at the time of sale.

* * * * *

[FR Doc. 2014–30664 Filed 12–30–14; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1271

[Docket No. FDA–2014–N–1484]

Revisions to Exceptions Applicable to Certain Human Cells, Tissues, and Cellular and Tissue-Based Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing this proposed rule to amend certain regulations regarding donor eligibility, including the screening and testing of donors of particular human cells, tissues, and cellular and tissue-based products (HCT/Ps), and related labeling. FDA is proposing this action in response to our enhanced understanding in this area and in response to comments from stakeholders regarding the importance of embryos to individuals and couples seeking access to donated embryos.

DATES: Submit either electronic or written comments on the proposed rule by March 31, 2015.

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA–2014–N–1484 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Melissa Segal, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Regulatory Action

FDA is issuing this proposed rule to amend certain regulations regarding donor eligibility, including the screening and testing of donors of particular HCT/Ps, and related labeling. We are proposing these changes in response to our enhanced understanding in this area and in response to comments from stakeholders regarding the importance of embryos to individuals and couples seeking access to donated embryos.

FDA is proposing this rulemaking under the authority of section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264). Under section 361 of the PHS Act, FDA may issue and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable disease between the States or from foreign countries into the States.

Summary of the Major Provisions of the Regulatory Action

FDA is proposing to amend existing regulations to provide additional flexibility to HCT/P establishments to make available for reproductive use embryos originally intended for reproductive use for a specific individual or couple when those embryos are subsequently intended for directed or anonymous donation. Specifically, this proposed rulemaking would redesignate the current Title 21 of the Code of Federal Regulations (CFR) 1271.90(b) (§ 1271.90(b)) to new § 1271.90(c), and would insert a new § 1271.90(b) entitled ''Exceptions for Reproductive Use'' to clarify that if an embryo was originally intended for reproductive use for a specific individual or couple, its use for directed or anonymous donation, would not be prohibited under § 1271.45(c), even when the applicable donor eligibility requirements under part 1271, subpart C, are not met. FDA also clarifies that we are not creating 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.

The proposed rule also would require appropriate labeling for embryos that would describe the donor eligibility status of the individual donors whose gametes were used to form the embryo. The content of the labeling is not different from that required under current regulations. Consistent with current regulations, the intent of the proposed labeling is to help ensure that physicians have specific and accurate information to provide to recipients for use in making informed medical decisions.

Costs and Benefits

The proposed rule would ensure that any related costs and burdens are kept to a minimum.

I. Background

Under the authority of section 361 of the PHS Act, by delegation from the Surgeon General and the Secretary of Health and Human Services, FDA may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases. Communicable diseases include, but are not limited to, those transmitted by viruses, bacteria, fungi, parasites, and transmissible spongiform encephalopathy agents. Certain diseases are transmissible through implantation, transplantation, infusion, or transfer of HCT/Ps derived from donors infected with those diseases. To prevent the introduction, transmission, or spread of such communicable diseases, we consider it necessary to require establishments to take appropriate measures to prevent the use of cells or tissues from infected donors. FDA regulates HCT/Ps intended for implantation, transplantation, infusion, or transfer into a human recipient under part 1271 that was issued under the authority of section 361 of the PHS Act. Part 1271 requires HCT/P establishments to screen and test donors for relevant communicable disease agents and diseases, to prepare and follow written standard operating procedures for the prevention of the spread of communicable diseases, and to maintain records. Part 1271 also requires that for most HCT/Ps, the cell or tissue donor must be determined to be eligible, based on the results of screening and testing for relevant communicable disease agents and diseases. In most cases, a donor who tests reactive for a particular communicable disease, or who possesses clinical evidence of, or risk factors for, communicable disease agents and diseases, would be considered ineligible, and cells or tissues from that donor would not ordinarily be used.

FDA has published three final rules that make up part 1271. In the **Federal Register** of January 19, 2001 (66 FR 5447), FDA published regulations requiring HCT/P establishments to register and list their HCT/Ps with FDA (registration final rule). In the **Federal Register** of May 25, 2004 (69 FR 29786), we published regulations requiring most cell and tissue donors to be tested and screened for relevant communicable disease agents and diseases (donor eligibility final rule). In the **Federal Register** of November 24, 2004 (69 FR 68612), we published regulations requiring HCT/P establishments to follow current good tissue practice (CGTP), which governs the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps, recordkeeping, and the establishment of a quality program (CGTP final rule). These regulations apply to HCT/Ps recovered on or after May 25, 2005.

As part of our ongoing effort to implement our framework for regulating HCT/Ps, in the **Federal Register** of May 25, 2005 (70 FR 29949), we issued an interim final rule entitled ''Human Cells, Tissues, and Cellular and Tissue-Based Products; Donor Screening and

Testing, and Related Labeling'' (2005 interim final rule), which had an effective date simultaneous with publication. This interim final rule was then adopted without change in the **Federal Register** of June 19, 2007, in the final rule entitled ''Human Cells, Tissues, and Cellular and Tissue-Based Products; Donor Screening and Testing, and Related Labeling'' (72 FR 33667) (2007 final rule). The 2007 final rule amended regulations regarding the screening and testing of donors of HCT/Ps, timing of specimen collection, record retention requirements, and related labeling requirements in response to public comments concerning the importance of cryopreserved embryos to individuals seeking access to donated embryos. The 2007 final rule also added an exception to the donor eligibility requirements in § 1271.90(a)(4) for cryopreserved embryos that, while originally exempt from the donor eligibility requirements because the donors were sexually intimate partners, are later intended for directed or anonymous donation.

In recent years, industry and the medical community have raised concerns that the current regulations restrict the use of embryos that were intended for personal reproductive use and therefore impose limitations on individuals and couples involved in family building. In response to these concerns, we are proposing this rulemaking to clarify and further develop the current exceptions to the donor eligibility requirements. If finalized, the proposed rule will provide HCT/P establishments with the flexibility to make available any embryos originally formed for reproductive use for a specific individual or couple and now intended for reproductive use, provided that specific criteria are met, including requirements for labeling.

II. Description of the Proposed Rule

The proposed rule is intended to allow the use of all embryos for reproductive use by expanding the current exceptions to the prohibition on use under § 1271.90. This proposal is in response to our enhanced understanding in this area and to increase the options for individuals and couples seeking access to these HCT/Ps.

A. Current Exceptions to Prohibition on Use

As set forth in the donor eligibility final rule, an HCT/P must not be implanted, transplanted, infused, or transferred until the donor has been determined to be eligible (§ 1271.45(c)) based on the results of donor screening (§ 1271.75) and testing (§§ 1271.80 and 1271.85) for relevant communicable disease agents and diseases. These donor eligibility requirements apply to all donors of HCT/Ps, including donors of reproductive cells or tissues. In the case of an embryo or of cells derived from an embryo, a donor eligibility determination is required for both the oocyte donor and the semen donor (§ 1271.45(b)).

Section 1271.90(a) contains exceptions from the requirement of determining donor eligibility for the following HCT/Ps: (1) Cells and tissues for autologous use; (2) reproductive cells or tissue donated by a sexually intimate partner of the recipient for reproductive use; (3) cryopreserved cells or tissues for reproductive use that are for autologous use or donated by a sexually intimate partner and are subsequently intended for directed donation; and (4) a cryopreserved embryo that is formed from gametes of sexually intimate partners and is subsequently intended for directed or anonymous donation.

The 2007 final rule added the § 1271.90(a)(4) exception to allow for directed or anonymous donation of cryopreserved embryos originally intended for use by a sexually intimate partner, without the need for a donor eligibility determination. This exception addresses the situation where sexually intimate partners who were not screened and tested at the time of cryopreservation of their embryos later wish to make a directed or anonymous donation of their cryopreserved embryos. As explained in the preamble to the 2005 interim final rule, we recognize that because the embryos were intended for use in a sexually intimate relationship, the donors would not have been required to be screened and tested for communicable disease agents and diseases at the time that the oocytes and semen were recovered. While the 2005 interim final rule recommended that appropriate measures be taken to screen and test the semen and oocyte donors before transfer of the embryo to a recipient, the rule also specifically stated that ''[I]f screening and testing of the semen and oocyte donors are not performed, this rule would not prohibit the transfer of the embryo into a recipient'' (70 FR 29949 at 29951).

The Agency provided additional guidance on this point in the guidance entitled, ''Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' dated August 2007. The guidance states that, as in other cases involving directed donations of reproductive tissue, the regulatory language in § 1271.90(a)(4) allows for the use of embryos from a directed, ineligible donor. In the guidance, FDA also clarified that we intend to apply this policy to a sexually intimate couple's cryopreserved embryos where one of the gametes is from a qualified (*i.e.,* eligible) third party gamete donor, and the other gamete is from the sexually intimate partner of the intended recipient. As specifically stated in the guidance in section VIII.A, ''. . . although FDA requires appropriate screening and testing when possible, if appropriate screening and testing are not possible (*e.g.,* because one of the donors is unavailable), you may still transfer the embryo into a recipient.'' In this proposed rulemaking, our intent is to expand this exception beyond the current exception in § 1271.90(a) for reproductive cells or tissue donated by a sexually intimate partner of the recipient for reproductive use. Under this proposed rule, an embryo, originally intended for reproductive use for a specific individual or couple, may be subsequently used for directed or anonymous donation even when the applicable donor eligibility requirements under part 1271, subpart C are not met. As stated in the new § 1271.90(b), 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.

B. Continued Obligations Under HCT/P Regulations

As discussed previously, this proposed rule would clarify and further develop the current exceptions to the prohibition on use and provide greater accommodation to individuals and couples wanting access to embryos intended for reproductive use, while continuing to emphasize the applicability of the donor eligibility screening and testing requirements for individual gamete donors. FDA reminds industry of its continued obligations under part 1271, subpart C to determine donor eligibility based on the results of donor screening (§ 1271.75) and testing (§§ 1271.80 and 1271.85). Establishments must also continue to comply with part 1271 requirements applicable to reproductive HCT/Ps to prevent the introduction, transmission, or spread of communicable disease.

C. Labeling Requirements

This proposed rule describes the continued applicability of labeling requirements for embryos intended for reproductive use that would be excepted from the prohibition on use. This proposed rule would require prominent labeling that describes the donor eligibility status of the individual donors whose gametes were used to form the embryo. The required labeling would provide information to the treating physician to permit discussion of the potential risks of communicable diseases with the recipient. We expect that a recipient would be fully informed of the risks involved in using an embryo for reproductive purposes as described under proposed § 1271.90(b) even when the donor eligibility requirements under part 1271, subpart C are not met.

Specifically, under proposed § 1271.90(c)(2) through (c)(6), an embryo originally intended for reproductive use for a specific individual or couple that is subsequently intended for directed or anonymous donation must be prominently labeled with the following statements as they are applicable:

- ''NOT EVALUATED FOR INFECTIOUS SUBSTANCES'';
- ''WARNING: Advise recipient of communicable disease risk'';
- the BIOHAZARD legend shown in § 1271.3(h);
- ''WARNING: Reactive test results for (name of disease agent or disease)'';
- ''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.''

The proposed labeling requirements are based on the expectation that a physician will be closely involved in the decision to use an embryo and the recognition that physicians are under legal and ethical obligations that require them to discuss the risks of communicable disease transmission stemming from the use of HCT/Ps. FDA relies on physicians to meet these obligations when discussing procedures involving HCT/Ps with recipients. FDA expects that HCT/P establishments will take appropriate measures to screen and test the semen and oocyte donor(s) before making available for reproductive use the embryo excepted under proposed § 1271.90(b). For this reason, proposed § 1271.90(b) also specifically states that ''[N]othing 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.''

III. Proposed Revisions to FDA Regulations

We are proposing revisions to the following FDA regulations:

A. Proposed Amendments to § 1271.90

Section 1271.90 sets forth exceptions where HCT/P establishments are not required to make a donor eligibility determination under § 1271.50 or to perform donor screening or testing under §§ 1271.75, 1271.80, and 1271.85. We are proposing to add language to the exceptions listed in this section to provide clarity and update the regulation by allowing for an embryo originally intended for reproductive use for a specific individual or couple, to be subsequently used for directed or anonymous donation, even when the donor eligibility requirements under part 1271, subpart C are not met.

We are proposing to amend § 1271.90 as follows:

- Changing the heading of this section by deleting ''from the requirement of determining donor eligibility,'' and inserting ''other'' before ''exceptions.'' If this change is finalized, the heading for § 1271.90 would read ''Are there other exceptions and what labeling requirements apply?'' We made this change for clarity; the new heading would be more accurate.
- Changing § 1271.90(a)(3) by replacing ''exempt'' with ''excepted,'' which is the term used in the introductory title for this provision. Thus, this change would make the language more consistent. If this change is finalized, the beginning of § 1271.90(a)(3) would read, ''Cryopreserved cells or tissues for reproductive use, other than embryos, originally excepted. . . .''
- Changing current § 1271.90(a)(4) by replacing ''exempt'' with ''excepted,'' and by adding ''(a)(1) and'' before ''(a)(2)'' to clarify that as proposed, § 1271.90(a)(4) would refer to a cryopreserved embryo formed for autologous use and the reproductive cells or tissue were donated by a sexually intimate partner of the recipient for reproductive use. If this change is finalized, § 1271.90(a)(4) would read, ''A cryopreserved embryo, originally excepted under paragraphs (a)(1) and (a)(2). . . .''
- Redesignating current § 1271.90(b) as § 1271.90(c) and adding a new paragraph (b) to § 1271.90.
- Changing newly designated § 1271.90(c) by adding ''and (b)'' after ''(a)'' in the introductory text, revising § 1271.90(c)(2) to replace ''(b)(6)'' with ''(c)(6)'', and by adding ''recovery or'' before ''cryopreservation'' in new § 1271.90(c)(6) to clarify that some testing and screening activities may take place before recovery, not just before cryopreservation.

B. Proposed § 1271.90(b)

We are proposing to redesignate the current § 1271.90(b) to § 1271.90(c), and insert a new § 1271.90(b) entitled ''Exceptions for Reproductive Use.'' Under proposed § 1271.90(b), an embryo originally intended for reproductive use for a specific individual or couple that is subsequently intended for directed or anonymous donation 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. Accordingly, when an establishment fails to comply with applicable donor eligibility requirements under part 1271, subpart C, the establishment would not be prohibited from making available for reproductive use such embryos for reproductive purposes in accordance with this section. The proposed exception from the prohibition on use does not create 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.

We note that the language we are proposing to add to the exceptions currently listed in § 1271.90 is additive. It creates an additional exception for the use of certain reproductive HCT/Ps that are not currently excepted, but it does not impact or restrict the exceptions currently provided for in the regulations.

C. Proposed § 1271.90(c)

Under proposed § 1271.90(c), HCT/P establishments must prominently label an HCT/P described in paragraphs (a) and (b) of this section as required in paragraph (c). The labeling requirements are intended to help ensure that physicians have specific and accurate information to provide to recipients for use in making informed medical decisions.

If finalized, the nonsubstantive change to § 1271.90(c)(2) would clarify that the labeling requirements contained in § 1271.90(c)(2) do not apply to reproductive cells or tissue labeled in accordance with § 1271.90(c)(6). The proposed change to § 1271.90(c)(6) would include ''recovery or'' before the word ''cryopreservation''. Thus, the

proposed § 1271.90(c)(6) provision requires HCT/P establishments to prominently label an HCT/P described in § 1271.90(a)(3) or (a)(4) with ''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 HCT/Ps described in § 1271.90(a)(3) or (a)(4). This proposed change is made to recognize that some testing and screening activities may take place even before recovery of HCT/Ps, not just before cryopreservation.

D. Proposed Amendments to § 1271.370

Section 1271.370 sets forth labeling requirements in addition to those that apply under §§ 1271.55, 1271.60, 1271.65, and 1271.90. Because, as discussed previously, this rule is proposing to redesignate the current labeling requirements under § 1271.90(b) to § 1271.90(c), we are proposing to amend § 1271.370(b)(4) to revise the reference from § 1271.90(b) to § 1271.90(c).

IV. Legal Authority

FDA is proposing this rulemaking under the authority of section 361 of the PHS Act. Under section 361 of the PHS Act, FDA may issue and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable disease between the States or from foreign countries into the States. It is important to recognize that HCT/Ps recovered in one State may be sent to another for processing, and then shipped for use throughout the United States, or beyond. FDA has been involved in many recalls where HCT/Ps processed in a single establishment have been distributed in many States. In any event, intrastate transactions affecting interstate communicable disease transmission may also be regulated under section 361 of the PHS Act. (See *Louisiana* v. *Mathews,* 427 F. Supp. 174, 176 (E.D. La. 1977); *Independent Turtle Farmers of Louisiana, Inc.* v. *United States of America, et al.,* 2010 U.S. Dist. LEXIS 31117). This rulemaking proposes changes in response to our enhanced understanding of the uses of certain types of HCT/Ps in specific situations and in response to comments from stakeholders regarding the importance of embryos to individuals and couples seeking access to donated embryos.

V. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). This proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the costs associated with this rule are expected to be minimal, we propose to certify that this rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in a 1-year expenditure that would meet or exceed this amount.

This rule proposes to amend certain regulations regarding donor eligibility and labeling related to the screening and testing of donors of particular HCT/Ps. The proposed rule would provide additional flexibility to HCT/P establishments to make available for reproductive use embryos originally intended for reproductive use for a specific individual or couple and subsequently intended for directed or anonymous donation. Specifically, the proposed rule would clarify that if an embryo was originally intended for reproductive use for a specific individual or couple, its use for directed or anonymous donation would not be prohibited under § 1271.45(c), even when the applicable donor eligibility requirements under part 1271, subpart C are not met. This proposed exception from prohibition for use would not create 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. The proposed rule also requires appropriate labeling that describes the donor eligibility status of the individual donors whose gametes were used to form the embryo.

This rule will provide greater accommodation of individuals and couples wanting access to embryos originally intended for reproductive use, while continuing to emphasize the applicability of the donor eligibility screening and testing requirements for individual gamete donors. If finalized, the proposed rule will provide HCT/P establishments with the flexibility to make available embryos originally intended for reproductive use, provided that specific criteria are met. Consistent with current regulations, the proposed labeling requirements will help ensure that physicians have specific and accurate information to provide to recipients for use in making informed medical decisions. Because this proposed rule would impose no additional regulatory burdens, the costs associated with this rule are expected to be minimal. FDA requests comment on this conclusion.

VI. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) 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.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. The Paperwork Reduction Act of 1995

The labeling requirements contained in this proposed rule are not subject to review by the Office of Management and Budget (OMB) because they do not constitute a ''collection of information''

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,