

comments directly into the comment field or attach a file for lengthier comments. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202-501-4755 or [GSARegSec@gsa.gov](mailto:GSARegSec@gsa.gov).

**Instructions:** All items submitted must cite Information Collection 9000-0024, Buy American, Trade Agreements, and Duty-Free Entry. Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check [www.regulations.gov](http://www.regulations.gov), approximately two-to-three days after submission to verify posting.

**FOR FURTHER INFORMATION CONTACT:** Zenaida Delgado, Procurement Analyst, at telephone 202-969-7207, or [zenaida.delgado@gsa.gov](mailto:zenaida.delgado@gsa.gov).

**SUPPLEMENTARY INFORMATION:**

**A. OMB Control Number, Title, and Any Associated Form(s)**

9000-0024, Buy American, Trade Agreements, and Duty-Free Entry.

**B. Need and Uses**

This clearance covers the information that an offeror must submit in response to the requirements of the provisions and clauses in Federal Acquisition Regulation (FAR) part 25 that relate to the following:

\* The Buy American statute (41 U.S.C. chapter 83 and Executive Order 10582).

\* The Trade Agreements Act (19 U.S.C. 2501-2515), including the World Trade Organization Government Procurement Agreement and various free trade agreements.

\* The American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (Recovery Act).

\* Subchapters VIII and X of Chapter 98 of the Harmonized Tariff Schedule of the United States (19 U.S.C. 1202).

a. 52.225-2, Buy American Certificate. This provision requires the offeror to identify in its proposal supplies that do not meet the definition of domestic end product.

b. 52.225-4, Buy American—Free Trade Agreements—Israeli Trade Act Certificate. This provision requires a separate list of foreign products that are eligible under a trade agreement, and a list of all other foreign end products.

c. 52.225-6, Trade Agreements Certificate. This provision requires the offeror to certify that all end products are either U.S.-made or designated country end products, except as listed in paragraph (b) of the provision.

Offerors are not allowed to provide other than a U.S.-made or designated country end product, unless the requirement is waived.

d. 52.225-8, Duty-Free Entry. This clause requires contractors to notify the contracting officer when they purchase foreign supplies, in order to determine whether the supplies should be duty-free. The notice shall identify the foreign supplies, estimate the amount of duty, and the country of origin. The contractor is not required to identify foreign supplies that are identical in nature to items purchased by the contractor or any subcontractor in connection with its commercial business, and segregation of these supplies to ensure use only on Government contracts containing duty-free entry provisions is not economical or feasible. In addition, all shipping documents and containers must specify certain information to assure the duty-free entry of the supplies.

e. Construction provisions and clauses:

- 52.225-9, Buy American—Construction Materials
- 52.225-10, Notice of Buy American Requirement—Construction Materials
- 52.225-11, Buy American—Construction Materials Under Trade Agreements
- 52.225-12, Notice of Buy American Requirement—Construction Materials under Trade Agreements
- 52.225-21, Required Use of American Iron, Steel and Manufactured Goods—Buy American—Construction Materials
- 52.225-23, Required Use of American Iron, Steel and Manufactured Goods—Buy American—Construction Materials Under Trade Agreements

The listed provisions and clauses provide that an offeror or contractor requesting to use foreign construction material due to unreasonable cost of domestic construction material shall provide adequate information to permit evaluation of the request.

**C. Annual Burden**

*Respondents:* 8,771.

*Total Annual Responses:* 43,891.

*Total Burden Hours:* 40,738.

**Obtaining Copies:** Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202-501-4755 or emailing [GSARegSec@gsa.gov](mailto:GSARegSec@gsa.gov). Please cite OMB Control No. 9000-0024, Buy American, Trade Agreements, and Duty-Free Entry.

**William F. Clark,**

*Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.*

[FR Doc. 2020-22151 Filed 10-6-20; 8:45 am]

**BILLING CODE 6820-EP-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2020-D-1137]

**Investigational COVID-19 Convalescent Plasma; Guidance for Industry; Withdrawal of Guidance; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that published in the **Federal Register** of September 21, 2020. The document announced the withdrawal of a final guidance for industry entitled “Investigational COVID-19 Convalescent Plasma,” which was issued in April 2020 and updated in May 2020. FDA withdrew the guidance because the Agency issued a new guidance for industry of the same title. The document was published with the incorrect docket number for the guidance for industry that was withdrawn. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Shruti Modi, 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:**

*Correction*

In the **Federal Register** of September 18, 2020 (85 FR 593120), appearing on page 59320 in FR Doc. 2020-20801, the following correction is made:

On page 59320, in the third column, the Docket No. “FDA-2020-D-1825” is corrected to read “FDA-2020-D-1137.”

Dated: October 1, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2020-22142 Filed 10-6-20; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2020-N-1720]

**Labeling of Foods Comprised of or Containing Cultured Seafood Cells; Request for Information**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for information.

**SUMMARY:** The Food and Drug Administration (FDA or we) is requesting information pertaining to the labeling of foods comprised of or containing cultured seafood cells. Foods comprised of or containing cultured seafood cells are being developed and may soon enter the marketplace. Therefore, we intend to use information and data resulting from this notice to determine what type(s) of action, if any, we should take to ensure that these foods are labeled properly.

**DATES:** Submit either electronic or written comments on the notice by March 8, 2021.

**ADDRESSES:** You may submit comments and information as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 8, 2021]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 8, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

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

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2020-N-1720 for "Labeling of Foods Comprised of or Containing Cultured Seafood Cells; Request for Information." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Andrea Krause, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371.

#### **SUPPLEMENTARY INFORMATION:**

#### **I. Background**

##### *A. FDA Jurisdiction Over Cultured Animal Cells*

Efforts are underway to develop various food products comprised of or containing cultured animal cells, including cells from livestock, poultry, and seafood<sup>1</sup> species, using a process often referred to as animal cell culture technology. Animal cell culture technology involves the controlled growth of animal cells, their subsequent differentiation into various cell types, and their harvesting and processing into food. Once produced, the harvested cells could potentially be processed into or combined with other foods and marketed in the same, or similar, manner as conventionally produced meat, poultry, and seafood. In this document we refer to these foods as "foods comprised of or containing cultured animal cells." Many companies, both domestic and foreign, are developing products using this technology. Given these technological advances, it is appropriate to consider what actions, if any, may be needed to ensure the safe production and accurate labeling of these products.

FDA will be involved in the regulation of foods generated by animal cell culture technology consistent with our current legal authorities. We are responsible for implementing and enforcing the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 301 *et seq.*), the Public Health Service Act (42 U.S.C. 201 *et seq.*), and the Fair Packaging and Labeling Act (15 U.S.C. 1451 *et seq.*). In carrying out our responsibilities under these laws, we maintain responsibility for ensuring that food is safe and not misbranded.

##### *B. Relevant Misbranding Provisions Under the FD&C Act*

This document primarily pertains to representations about the identity of foods comprised of or containing cultured seafood cells. Such representations include the name of the food and descriptions about its nature, source, or characteristics. There are

<sup>1</sup> The use of the term "seafood" refers to all fish (freshwater and saltwater) and other seafood species (e.g., molluscs, crustaceans) under FDA jurisdiction.

several provisions in the FD&C Act under which food may be misbranded with respect to representations about identity. In general, the representations made or suggested must not cause the labeling to be misleading, either affirmatively or by omission of material facts (21 U.S.C. 343(a)(1) and 321(n)). The FD&C Act prohibits offering a food for sale under the name of another food (21 U.S.C. 343(b)). It requires the labels of non-standardized foods to bear the common or usual name of the food if such a name exists (21 U.S.C. 343(i)(1)). Common or usual names are generally established by common usage, though in some cases may be established by regulation pursuant to the principles in 21 CFR 102.5(a)–(c) (see 21 CFR 102.5(d)). In the absence of a common or usual name or other name established by federal law or regulation, food sold in packaged form is required to be labeled with an accurate description of the food or a fanciful name commonly used by the public (§ 101.3(b)(3) (21 CFR 101.3(b)(3))). Such description or name must not be false or misleading (21 U.S.C. 343(a)(1)) and is referred to as the statement of identity (§ 101.3(b)). Finally, the FD&C Act provides that words or statements required to appear on the label or labeling be in such terms as to render them likely to be understood by the ordinary individual under customary conditions of purchase and use (21 U.S.C. 343(f)).

#### *C. FDA–USDA Agreement Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived From Cell Lines of USDA-Amenable Species*

In November 2018, FDA and the U.S. Department of Agriculture (USDA) formally announced that they will jointly oversee the production of cultured cell food products derived from livestock and poultry (Ref. 1). On March 7, 2019, FDA and USDA signed an agreement that described each entity's intended roles with respect to the oversight of human food produced using animal cell culture technology, derived from cell lines of those species<sup>2</sup> covered under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) (Ref. 2). In summary, FDA will oversee the collection, growth and differentiation of livestock and poultry cells until cell harvest. A transition from FDA to USDA's Food Safety and

Inspection Service oversight will occur during the cell harvest stage. USDA then will oversee the processing, packaging, and labeling of the resulting food products derived from the cultured cells of livestock and poultry. FDA will continue to regulate foods comprised of or containing cultured animal cells from other species under FDA's jurisdiction, such as seafood species other than Siluriformes fish.

In the FDA–USDA agreement, FDA and USDA have agreed to develop joint principles for product labeling and claims to ensure that products are labeled consistently and transparently.

#### *D. Public Meetings on Animal Cell Culture Technology*

Participation in public meetings is an important opportunity to share our current thinking on the science surrounding new technologies, how our regulatory framework may apply to new technology, and most importantly, to hear from the public. On July 12, 2018, we held a public meeting, “Foods Produced Using Animal Cell Culture Technology,” to give the public an opportunity to provide comments related to the production of foods using animal cell culture technology. In this meeting, we discussed our expected involvement in the oversight of products of cell culture technology and solicited feedback from stakeholders. Building on this effort, on October 23 to 24, 2018, USDA and FDA hosted a joint public meeting entitled, “Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived From Livestock and Poultry.” This meeting presented the opportunity for FDA and USDA to hear from stakeholders about various issues, including the labeling of food products comprised of or containing cultured livestock and poultry cells.

#### **II. Issues for Consideration and Request for Information**

We invite comment in response to the questions below. Our use of the term “cultured seafood cells” in these questions is intended to distinguish between the foods, which are the subject of this document, and conventionally produced seafood. It is not intended to establish or suggest nomenclature for labeling purposes. The names and descriptions in food labeling should be based on consumer understanding and usage as described in section I.B.

We invite comment, particularly data and other evidence, about: (1) Names or statements of identity for foods comprised of or containing cultured seafood cells; (2) consumer understanding of terms that have been

suggested for the names or statements of identity of foods comprised of or containing cultured seafood cells; and (3) how to assess material differences between the foods that are the subject of this document and conventionally produced foods. In responding to these questions, please identify the question by its associated letter and number (such as “2(a)”) so that we can associate your response with a specific question.

1. Should the name or statement of identity of foods comprised of or containing cultured seafood cells inform consumers about how the animal cells were produced? Please explain your reasoning.

2. What terms should be in the name or statement of identity of a food comprised of or containing cultured seafood cells to convey the nature or source of the food to consumers? (For example, possible terms could be “cell cultured” or “cell based” or “cell cultivated.”) Please explain your reasoning and provide any studies or data about consumer understanding of such terms.

a. How do these terms inform consumers of the nature or source of the food?

b. If foods comprised of or containing cultured seafood cells were to be labeled with the term “culture” or “cultured” in their names or statements of identity (e.g., “cell culture[d]”), would labeling differentiation be necessary to distinguish these products from other types of foods where the term “culture” or “cultured” is used (such as “aquaculture”)? Please explain your reasoning and provide any studies or data about consumer understanding of such terms.

3. The names of many conventionally produced seafood products have been established by common usage or by statute or regulation. Names are also recommended for seafood species in *The Seafood List*.<sup>3</sup> In FDA's view, foods comprised of or containing cultured seafood cells are not yet in the marketplace and, therefore, do not have common or usual names established by common usage.

a. If you disagree with FDA's view, what are these names and what evidence demonstrates that the names are commonly used and understood by the American public for foods derived from cultured animal cells?

b. Should names for conventionally produced seafood products established by common usage, statute, or regulation

<sup>2</sup> Products made from cattle, sheep, swine, goats, and Siluriformes fish are subject to the FMIA. Products made from domesticated chickens, turkeys, ducks, geese, guineas, ratites, and squab are subject to the PPIA.

<sup>3</sup> *The Seafood List* provides guidance to industry about specificity in the naming of seafood sold in interstate commerce and to assist manufacturers in labeling seafood products.

be included in the names or statements of identity of food derived from cultured seafood cells? Please explain your reasoning.

c. If so, is additional qualifying language necessary? What qualifying terms or phrases would be appropriate? Please explain your reasoning.

d. Do these names, with or without qualifying language, clearly distinguish foods derived from seafood cell culture from conventionally produced seafood? Please explain your reasoning.

e. Should FDA update *The Seafood List* to include foods comprised of or containing cultured seafood cells? Please explain your reasoning.

4. Should terms that specify a certain type of seafood (such as “fillet” or “steak”) be included in or accompany the name or statement of identity of foods comprised of or containing cultured animal cells?

a. Under what circumstances should these terms be used? What information would they convey to consumers? For example, would such terms convey the physical form or appearance of the food? Please explain your reasoning. Additionally, please provide any studies or data about consumer understanding of such terms when used to describe foods comprised of or containing cultured seafood cells.

b. Would these terms be misleading to consumers? Please explain your reasoning and provide any supporting studies or data.

5. When comparing conventionally produced seafood to foods comprised of or containing cultured seafood cells, what attributes (such as nutrition, taste, texture, or aroma) vary between the foods and should FDA consider to be material to consumers' purchasing and consumption decisions? Please explain your reasoning.

a. Are there other characteristics beyond nutritional attributes or organoleptic properties that may be material differences? These could relate either to cellular constituents or characteristics influenced by the cell culture production process. Please be specific in your response and explain your reasoning.

### III. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the **Federal**

**Register**, but websites are subject to change over time.

1. FDA, Statement from USDA Secretary Perdue and FDA Commissioner Gottlieb on the Regulation of Cell Cultured Food Products from Cell Lines of Livestock and Poultry, Nov. 16, 2018, available at <https://www.fda.gov/news-events/press-announcements/statement-usda-secretary-perdue-and-fda-commissioner-gottlieb-regulation-cell-cultured-food-products>.
2. Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-amenable Species, March 7, 2019, available at <https://www.fda.gov/food/domestic-interagency-agreements-food/formal-agreement-between-fda-and-usda-regarding-oversight-human-food-produced-using-animal-cell>.

Dated: October 1, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2020–22140 Filed 10–6–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2020–N–1989]

#### Fee Rate for Using a Rare Pediatric Disease Priority Review Voucher in Fiscal Year 2021

**AGENCY:** Food and Drug Administration, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the fee rate for using a rare pediatric disease priority review voucher for fiscal year (FY) 2021. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to determine and collect rare pediatric disease priority review user fees for certain applications for review of human drug or biological products when those applications use a rare pediatric disease priority review voucher. These vouchers are awarded to sponsors of rare pediatric disease product applications that meet all the requirements of this program and are submitted 90 days or more after July 9, 2012, upon FDA approval of such applications. The amount of the fee for using a rare pediatric disease priority review voucher is determined each FY, based on the difference between the average cost incurred by FDA to review

a human drug application designated as priority review in the previous FY, and the average cost incurred in the review of an application that is not subject to priority review in the previous FY. This notice establishes the rare pediatric disease priority review fee rate for FY 2021 and outlines the payment procedures for such fees.

#### FOR FURTHER INFORMATION CONTACT:

Misbah Tareen, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61077A, Beltsville, MD 20705–4304, 301–796–3997.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 908 of FDASIA (Pub. L. 112–144) added section 529 to the FD&C Act (21 U.S.C. 360ff). In section 529 of the FD&C Act, Congress encouraged development of new human drugs and biological products for prevention and treatment of certain rare pediatric diseases by offering additional incentives for obtaining FDA approval of such products. Under section 529 of the FD&C Act, the sponsor of an eligible human drug application submitted 90 days or more after July 9, 2012, for a rare pediatric disease (as defined in section 529(a)(3)) shall receive a priority review voucher upon approval of the rare pediatric disease product application. The recipient of a rare pediatric disease priority review voucher may either use the voucher for a future human drug application submitted to FDA under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), or transfer (including by sale) the voucher to another party. The voucher may be transferred repeatedly until it ultimately is used for a human drug application submitted to FDA under section 505(b)(1) of the FD&C Act or section 351(a) of the Public Health Service Act. A priority review is a review conducted with a Prescription Drug User Fee Act (PDUFA) goal date of 6 months after the receipt or filing date, depending on the type of application. Information regarding current PDUFA goals is available at <https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm511438.pdf>.

The sponsor that uses a rare pediatric disease priority review voucher is entitled to a priority review of its eligible human drug application, but must pay FDA a rare pediatric disease priority review user fee in addition to any user fee required by PDUFA for the application. Information regarding the rare pediatric disease priority review