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

voucher program is available at: *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm375479.htm.*

This notice establishes the rare pediatric disease priority review fee rate for FY 2021 at $1,360,879 and outlines FDA's payment procedures for rare pediatric disease priority review user fees. This rate is effective on October 1, 2020, and will remain in effect through September 30, 2021.

II. Rare Pediatric Priority Review User Fee Rate for FY 2021

Under section 529(c)(2) of the FD&C Act, the amount of the rare pediatric disease priority review user fee is determined each fiscal year based on the difference between the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous fiscal year, and the average cost incurred by FDA in the review of a human drug application that is not subject to priority review in the previous fiscal year.

A priority review is a review conducted with a PDUFA goal date of 6 months after the receipt or filing date, depending on the type of application. As described in the PDUFA goals letter, FDA has committed to reviewing and acting on 90 percent of the applications granted priority review status within this expedited timeframe. Normally, an application for a human drug or biological product will qualify for priority review if the product is intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. An application that does not receive a priority designation receives a standard review. As described in the PDUFA goals letter, FDA has committed to reviewing and acting on 90 percent of standard applications within 10 months of the receipt or filing date depending on the type of application. A priority review involves a more intensive level of effort and a higher level of resources than a standard review.

FDA is setting a fee for FY 2021, which is to be based on standard cost data from the previous fiscal year, FY 2020. However, the FY 2020 submission cohort has not been closed out yet, thus the cost data for FY 2020 are not complete. The latest year for which FDA has complete cost data is FY 2019. Furthermore, because FDA has never tracked the cost of reviewing applications that get priority review as a separate cost subset, FDA estimated this cost based on other data that the Agency has tracked. The Agency expects all applications that received priority review would contain clinical data. The application categories with clinical data for which FDA tracks the cost of review are: (1) New drug applications (NDAs) for a new molecular entity (NME) with clinical data and (2) biologics license applications (BLAs).

The total cost for FDA to review NME NDAs with clinical data and BLAs in FY 2019 was $199,369,923. There was a total of 70 applications in these two categories (49 NME NDAs with clinical data and 21 BLAs). (*Note:* These numbers exclude the President's Emergency Plan for AIDS Relief NDAs; no investigational new drug review costs are included in this amount.) Forty-four of these applications (32 NDAs and 12 BLAs) received priority review and the remaining 26 (17 NDAs and 9 BLAs) received standard reviews. Because a priority review compresses a review schedule that ordinarily takes 10 months into 6 months, FDA estimates that a multiplier of 1.67 (10 months ÷ 6 months) should be applied to non-priority review costs in estimating the effort and cost of a priority review as compared to a standard review. This multiplier is consistent with published research on this subject, which supports a priority review multiplier in the range of 1.48 to 2.35 (Ref. 1). Using FY 2019 figures, the costs of a priority and standard review are estimated using the following formula:

$$(44\ \alpha \times 1.67) + (26\ \alpha) = \$199{,}369{,}923$$

where ''α'' is the cost of a standard review and ''α times 1.67'' is the cost of a priority review. Using this formula, the cost of a standard review for NME NDAs and BLAs is calculated to be $2,004,121 (rounded to the nearest dollar) and the cost of a priority review for NME NDAs and BLAs is 1.67 times that amount, or $3,346,882 (rounded to the nearest dollar). The difference between these two cost estimates, or $1,342,761, represents the incremental cost of conducting a priority review rather than a standard review.

For the FY 2021 fee, FDA will need to adjust the FY 2019 incremental cost by the average amount by which FDA's average costs increased in the 3 years prior to FY 2020, to adjust the FY 2019 amount for cost increases in FY 2020. That adjustment, published in the **Federal Register** on August 3, 2020 (see 85 FR 46651), setting the FY 2021 PDUFA fees, is 1.3493 percent for the most recent year, not compounded. Increasing the FY 2019 incremental priority review cost of $1,342,761 by 1.3493 percent (or 0.013493) results in an estimated cost of $1,360,879 (rounded to the nearest dollar). This is the rare pediatric disease priority review user fee amount for FY 2021 that must be submitted with a priority review voucher for a human drug application in FY 2021, in addition to any PDUFA fee that is required for such an application.

III. Fee Rate Schedule for FY 2021

The fee rate for FY 2021 is set in table 1:

TABLE 1—RARE PEDIATRIC DISEASE PRIORITY REVIEW SCHEDULE FOR FY 2021

Fee category	Priority review fee rate for FY 2021
Application submitted with a rare pediatric disease priority review voucher in addition to the normal PDUFA fee	$1,360,879

IV. Implementation of Rare Pediatric Disease Priority Review User Fee

Under section 529(c)(4)(A) of the FD&C Act, the priority review user fee is due (*i.e.,* the obligation to pay the fee is incurred) when a sponsor notifies FDA of its intent to use the voucher. Section 529(c)(4)(B) of the FD&C Act specifies that the application will be considered incomplete if the priority review user fee and all other applicable user fees are not paid in accordance with FDA payment procedures. In addition, section 529(c)(4)(C) specifies that FDA may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section of the FD&C Act.

The rare pediatric disease priority review fee established in the new fee schedule must be paid for applications submitted with a priority review voucher received on or after October 1, 2020. In order to comply with this requirement, the sponsor must notify FDA 90 days prior to submission of the human drug application that is the subject of a priority review voucher of

an intent to submit the human drug application, including the estimated submission date.

Upon receipt of this notification, FDA will issue an invoice to the sponsor for the rare pediatric disease priority review voucher fee. The invoice will include instructions on how to pay the fee via wire transfer, check, or online payments.

As noted in section II, if a sponsor uses a rare pediatric disease priority review voucher for a human drug application, the sponsor would incur the rare pediatric disease priority review voucher fee in addition to any PDUFA fee that is required for the application. The sponsor would need to follow FDA's normal procedures for timely payment of the PDUFA fee for the human drug application.

Payment must be made in U.S. currency by electronic check, check, bank draft, wire transfer, credit card, or U.S. postal money order payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (*Note:* Only full payments are accepted. No partial payments can be made online). Once you search for your invoice, select ''Pay Now'' to be redirected to *Pay.gov.* Note that electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S bank accounts as well as U.S. credit cards.

If paying by paper check the invoice number should be included on the check, followed by the words ''Rare Pediatric Disease Priority Review.'' All paper checks must be in U.S. currency from a U.S. bank made payable and mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000.

If checks are sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979107, 1005 Convention Plaza, St. Louis, MO 63101. (*Note:* This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery contact the U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery). The FDA post office box number (P.O. Box 979107) must be written on the check. If needed, FDA's tax identification number is 53–0196965.

If paying by wire transfer, please reference your invoice number when completing your transfer. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee it is required to add that amount to the payment to ensure that the invoice is paid in full. The account information is as follows: U.S. Dept. of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Number: 75060099, Routing Number: 021030004, SWIFT: FRNYUS33.

V. Reference

The following reference is on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is not available electronically at *https://www.regulations.gov* as this reference is copyright protected. FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Ridley, D.B., H.G. Grabowski, and J.L. Moe, ''Developing Drugs for Developing Countries,'' *Health Affairs,* vol. 25, no. 2, pp. 313–324, 2006, available at: *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.25.2.313.*

Dated: October 2, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–22186 Filed 10–2–20; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1987]

Fee Rate for Using a Material Threat Medical Countermeasure 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 material threat medical countermeasure (MCM) priority review voucher for fiscal year (FY) 2021. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to determine and collect material threat MCM priority review user fees for certain applications for review of human drug products when those applications use a material threat MCM priority review voucher. These vouchers are awarded to the sponsors of material threat MCM applications that meet all the requirements of this program and upon FDA approval of such applications. The amount of the fee for using a material threat MCM 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 material threat MCM priority review fee rate for FY 2021 and outlines the payment procedures for such fees.

FOR FURTHER INFORMATION CONTACT: Lola Olajide, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61077B, Beltsville, MD 20705–4304, 240–402–4244.

SUPPLEMENTARY INFORMATION:

I. Background

Section 3086 of the Cures Act (Pub. L. 114–255) added section 565A to the FD&C Act (21 U.S.C. 360bbb–4a). In section 565A of the FD&C Act, Congress encouraged development of material threat MCMs by offering additional incentives for obtaining FDA approval of such products. Under section 565A of the FD&C Act, the sponsor of an eligible material threat MCM application (as defined in section 565A(a)(4)) shall receive a priority review voucher upon approval of the material threat MCM application. The recipient of a material threat MCM 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 PDUFA goals is available at