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–2018–D–1752 for ''Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls; Draft Guidance for Industry and FDA Staff.'' 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.

• 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.'' The Agency will review this copy, including the claimed confidential information, in its 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.gpo.gov/fdsys/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Building, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Chris Henderson, Office of Regulatory Affairs, Division of Operational Policy, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8186, *Christopher.henderson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled ''Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls.'' The draft guidance, when finalized, establishes guidance for industry and FDA staff on how and when FDA intends to publicize retail consignees that may have received recalled foods. FDA's goal is to publicize retail consignee lists for these food recalls, especially those that are likely to be classified as Class I recalls, where providing this additional information will be of the most use to consumers to help them identify recalled food and to determine whether that food is in their possession as effectively and quickly as possible. FDA seeks comment on this draft guidance, including scope of the term ''retail consignee'' as used in this document, the situations where providing retail consignee lists would be of the most use to consumers to identify recalled food in their possession, and additional information that would be of the most use to consumers to help them identify recalled food in their possession.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA regarding publicizing retail consignees to effectuate certain food recalls. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This draft guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Any collections of information under 21 CFR 7.46, 7.49, 7.53, 7.55, and 7.59 have been approved under OMB control number 0910–0249.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Safety/Recalls/default.htm* or *https://www.regulations.gov.*

Dated: September 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21042 Filed 9–26–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0007]

Fee for Using a Rare Pediatric Disease Priority Review Voucher in Fiscal Year 2019

AGENCY: Food and Drug Administration, 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) 2019. 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 the applicants of rare pediatric disease product applications that meet all of the requirements of this program and that 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 of 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 2019 and outlines the payment procedures for such fees.

FOR FURTHER INFORMATION CONTACT: Lola Olajide, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14541B, Silver Spring, MD 20993–0002, 240–402–4244.

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 applicant 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 (including by sale) 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 *https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm511438.pdf.*

The applicant 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 2019 at $2,457,140 and outlines FDA's procedures for payment of rare pediatric disease priority review user fees. This rate is effective on October 1, 2018, and will remain in effect through September 30, 2019.

II. Rare Pediatric Priority Review User Fee for FY 2019

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. Under 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. Under 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 2019, which is to be based on standard cost data from the previous fiscal year, FY 2018. However, the FY 2018 submission cohort has not been closed out yet, thus the cost data for FY 2018 are not complete. The latest year for which FDA has complete cost data is FY 2017. 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. FDA uses data that the Agency estimates and publishes on its website each year—standard costs for review. FDA does not publish a standard cost for ''the review of a human drug application subject to priority review in the previous fiscal year.'' However, we expect all such applications would contain clinical data. The standard cost application categories with clinical data that FDA publishes each year are: (1) New drug applications (NDAs) for a new molecular entity (NME) with clinical data and (2) biologics license applications (BLAs).

The standard cost worksheets for FY 2017 show standard costs of $5,340,560 for an NME NDA, and $4,596,936 for a BLA. Based on these standard costs, the total cost to review the 57 applications in these two categories in FY 2017 (31 NME NDAs with clinical data and 26 BLAs) was $285,077,688. (*Note:* These numbers exclude the President's Emergency Plan for AIDS Relief NDAs; no investigational new drug (IND) review costs are included in this amount.) Thirty-three of these applications (20 NDAs and 13 BLAs) received priority review, which would mean that the remaining 24 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 2017 figures, the costs of a priority and standard review

are estimated using the following formula:

$(33 \alpha \times 1.67) + (24\alpha) = \$285,077,688$

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 $3,603,561 (rounded to the nearest dollar) and the cost of a priority review for NME NDAs and BLAs is 1.67 times that amount, or $6,017,946 (rounded to the nearest dollar). The difference between these two cost estimates, or $2,414,386, represents the incremental cost of conducting a priority review rather than a standard review.

For the FY 2019 fee, FDA will need to adjust the FY 2017 incremental cost by the average amount by which FDA's average costs increased in the 3 years prior to FY 2018, to adjust the FY 2017 amount for cost increases in FY 2018. That adjustment, published in the **Federal Register** on August 1, 2018 (83 FR 37504), setting the FY 2019 PDUFA fee, is 1.7708 percent for the most recent year, not compounded. Increasing the FY 2017 incremental priority review cost of 2,414,386 by 1.7708 percent (or 0.017708) results in an estimated cost of $2,457,140 (rounded to the nearest dollar). This is the rare pediatric disease priority review user fee amount for FY 2019 that must be submitted with a priority review voucher for a human drug application in FY 2019, in addition to any PDUFA fee that is required for such an application.

III. Fee Schedule for FY 2019

The fee rate for FY 2019 is set out in table 1:

TABLE 1—RARE PEDIATRIC DISEASE PRIORITY REVIEW SCHEDULE FOR FY 2019

Fee category	Fee rate for FY 2019
Application submitted with a rare pediatric disease priority review voucher in addition to the normal PDUFA fee	$2,457,140

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 any application that is received on or after October 1, 2018. 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 date on which the sponsor intends to submit the application.

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

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 with a 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 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://faculty.fuqua.duke.edu/~willm/HSM_RA/Documents/HA2006_Ridley_Vouchers.pdf.*

Dated: September 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21033 Filed 9–26–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0329]

Dilip Patel; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is denying a request for a hearing submitted by Dilip Patel and is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Patel for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Patel was convicted of a conspiracy to commit a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act and that the conduct underlying the conviction undermines the process for the regulation of drugs. In determining the appropriateness and period of Patel's debarment, FDA considered the relevant factors listed in the FD&C Act. Patel failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: The order is applicable September 27, 2018.

ADDRESSES: Any application for termination of debarment by Patel under section 306(d) of the FD&C Act (application) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application 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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: Your application must include the Docket No. FDA–2009–N–0329. An application will be placed in the docket and, unless 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.

- Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application 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.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. 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 application 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.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket, 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 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240–402–5931.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(II) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(II)) permits FDA to debar an individual if it finds: (1) That the individual has been convicted of a conspiracy to commit a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act and (2) that the type of conduct which served as the basis for the conviction undermines the process for the regulation of drugs.

On April 24, 2007, Patel pled guilty to one count of conspiracy to distribute misbranded and adulterated drugs, in violation of 18 U.S.C. 371. On December 9, 2010, the U.S. District Court for the District of New Jersey entered the conviction, sentenced Patel to 2 years of probation, and imposed a $3,000 fine. Patel's conviction stemmed from his employment at Able Laboratories, Inc. (Able), where he was a Supervisor of Analytical Control and later a Quality Control Manager in the Quality Control Department. Patel and his co-conspirators conspired and agreed with others to cause the introduction of misbranded and adulterated drugs into interstate commerce with an intent to defraud and mislead the United States, in violation of sections 301(a) and 303(a)(2) of the FD&C Act (21 U.S.C. 331(a) and 333(a)(2)). Specifically, according to the criminal information to which he pled guilty, Patel supervised the falsification and manipulation of assay test results for atenolol, a prescription medication for cardiac conditions, and he directed a subordinate chemist to falsify and manipulate dissolution test results for methylphenidate hydrochloride