makes it possible to evaluate the effectiveness of some process changes and intervention strategies in reducing the risk of listeriosis.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for electronic access to the QRA and related documents.

FOR FURTHER INFORMATION CONTACT: Sherri Dennis, Center for Food Safety and Applied Nutrition (HFS–005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1914.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 11, 2013 (78 FR 9701), we made available a document entitled ''Draft Joint Food and Drug Administration/Health Canada—Santé Canada Quantitative Assessment of the Risk of Listeriosis From Soft-Ripened Cheese Consumption in the United States and Canada.'' We gave interested parties an opportunity to submit comments by April 29, 2013, for us to consider on the approach used, the assumptions made, the modeling techniques, the data used, and the clarity and the transparency of the QRA documentation. We received nearly 100 comments on the draft QRA and have revised the QRA where appropriate (See Refs. 1 to 5).

Elsewhere in this issue of the **Federal Register,** we are issuing a notice requesting comments and scientific data and information that would assist us in understanding potential intervention measures to reduce the risk of foodborne illness from consumption of cheeses manufactured from unpasteurized milk.

II. Electronic Access

The QRA and related documents are available electronically on the FDA Web site at *http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm, http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm,* and *http://www.regulations.gov.*

III. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.)**

1. FDA and Health Canada, ''Joint Food and Drug Administration/Health Canada—Santé Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Interpretative Summary,'' 2015. Accessible at *http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm* and *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm.*
2. FDA and Health Canada, ''Joint Food and Drug Administration/Health Canada—Santé Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Technical Report,'' 2015. Accessible at *http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm* and *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm.*
3. FDA and Health Canada, ''Joint Food and Drug Administration/Health Canada—Santé Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Technical Report Appendices,'' 2015. Accessible at *http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm* and *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm.*
4. FDA and Health Canada, ''Joint Food and Drug Administration/Health Canada—Santé Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Risk Assessment Model,'' 2015. Accessible at *http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm* and *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm.*
5. Joint FDA/Health Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada: Replies to Public Comments, 2015. Accessible at *http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm* and *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm.*

Dated: July 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18960 Filed 7–31–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0007]

Prescription Drug User Fee Rates for Fiscal Year 2016

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2016. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2012 (PDUFA V), authorizes FDA to collect user fees for certain applications for the review of human drug and biological products, on establishments where the products are made, and on such products. This notice establishes the fee rates for FY 2016.

FOR FURTHER INFORMATION CONTACT: Robert J. Marcarelli, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14202F, Silver Spring, MD 20993–0002, 301–796–7223.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 735 and 736 of the FD&C Act (21 U.S.C. 379g and 379h, respectively) establish three different kinds of user fees. Fees are assessed on the following: (1) Certain types of applications and supplements for the review of human drug and biological products; (2) certain establishments where such products are made; and (3) certain products (section 736(a) of the FD&C Act). When certain conditions are met, FDA may waive or reduce fees (section 736(d) of the FD&C Act).

For FY 2013 through FY 2017, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA V. The base revenue amount for FY 2013, which became the base amount for the remaining 4 FYs of PDUFA V, is $718,669,000, as published in the **Federal Register** of August 1, 2012 (77 FR 45639). The FY 2013 base revenue amount is further adjusted each year after FY 2013 for inflation and workload. Fees for applications, establishments, and products are to be established each year by FDA so that revenues from each category will provide one-third of the total revenue to be collected each year.

This document provides fee rates for FY 2016 for an application requiring

clinical data ($2,374,200), for an application not requiring clinical data or a supplement requiring clinical data ($1,187,100), for an establishment ($585,200), and for a product ($114,450). These fees are effective on October 1, 2015, and will remain in effect through September 30, 2016. For applications and supplements that are submitted on or after October 1, 2015, the new fee schedule must be used. Invoices for establishment and product fees for FY 2016 will be issued in August 2015 using the new fee schedule.

II. Fee Revenue Amount for FY 2016

The base revenue amount for FY 2016 is $718,669,000 prior to adjustments for inflation and workload (see section 736(c)(1) and (c)(2) of the FD&C Act).

A. FY 2016 Statutory Fee Revenue Adjustments for Inflation

PDUFA V specifies that the $718,669,000 is to be further adjusted for inflation increases for FY 2016 using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 736(c)(1) of the FD&C Act).

The component of the inflation adjustment for payroll costs shall be 1 plus the average annual percent change in the cost of all PC&B paid per full-time equivalent (FTE) position at FDA for the first 3 of the preceding 4 FYs, multiplied by the proportion of PC&B costs to total FDA costs of process for the review of human drug applications for the first 3 of the preceding 4 FYs (see section 736(c)(1)(A) and (c)(1)(B) of the FD&C Act).

Table 1 summarizes that actual cost and FTE data for the specified FYs, and provides the percent changes from the previous FYs and the average percent changes over the first 3 of the 4 FYs preceding FY 2016. The 3-year average is 2.2328 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGES

Fiscal year	2012	2013	2014	3-Year average
Total PC&B	$1,824,703,000	$1,927,703,000	$2,054,937,000	
Total FTE	13,382	13,974	14,555	
PC&B per FTE	$136,355	$137,949	$141,184	
Percent Change From Previous Year	3.1843%	1.1690%	2.3451%	2.2328%

The statute specifies that this 2.2328 percent should be multiplied by the proportion of PC&B costs to total FDA costs of the process for the review of human drug applications. Table 2 shows the PC&B and the total obligations for the process for the review of human drug applications for 3 FYs.

TABLE 2—PC&B AS A PERCENT OF FEE REVENUES SPENT ON THE PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS

Fiscal year	2012	2013	2014	3-Year average
Total PC&B	$592,642,252	$568,206,210	$585,260,720	
Total Costs	$1,032,419,218	$966,169,007	$1,077,263,695	
PC&B Percent	57.4033%	58.8102%	54.3285%	56.8473%

The payroll adjustment is 2.2328 percent from table 1 multiplied by 56.8473 percent (or 1.2693 percent).

The statute specifies that the portion of the inflation adjustment for non-payroll costs is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC–MD–VA–WV; not seasonally adjusted; all items; annual index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total costs of the process for the review of human drug applications for the first 3 years of the preceding 4 FYs (see section 736(c)(1)(C) of the FD&C Act). Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Baltimore area. The data are published by the Bureau of Labor Statistics and can be found on their Web site at *http://data.bls.gov/cgi-bin/surveymost?cu* by checking the box marked ''Washington-Baltimore All Items, November 1996=100—CUURA311SA0'' and then clicking on the ''Retrieve Data'' button.

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-BALTIMORE AREA

Year	2012	2013	2014	3-Year average
Annual CPI	150.212	152.500	154.847	
Annual Percent Change	2.2024%	1.5232%	1.5390%	1.7549%

To calculate the inflation adjustment for non-payroll costs, we multiply the 1.7549 percent by the proportion of all costs other than PC&B to total costs of the process for the review of human drug applications obligated. Since 56.8473 percent was obligated for PC&B as shown in table 2, 43.1527 percent is the portion of costs other than PC&B (100 percent minus 56.8473 percent equals 43.1527 percent). The non-payroll adjustment is 1.7549 percent times 43.1527 percent, or 0.7573 percent.

Next, we add the payroll adjustment (1.2693 percent) to the non-payroll adjustment (0.7573 percent), for a total inflation adjustment of 2.0266 percent (rounded) for FY 2016.

PDUFA V provides for this inflation adjustment to be compounded after FY 2013 (see section 736(c)(1) of the FD&C Act). This factor for FY 2016 (2.0266 percent) is compounded by adding 1

and then multiplying by 1 plus the compound inflation adjustment factor for FY 2015 (4.327 percent), as published in the **Federal Register** of August 1, 2014 (79 FR 44807 at 44809), which equals to 1.064414 (rounded) (1.020266 times 1.04327) for FY 2016. We then multiply the base revenue amount for FY 2016 ($718,669,000) by 1.064414, yielding an inflation-adjusted amount of $764,961,345.

B. FY 2016 Statutory Fee Revenue Adjustments for Workload

The statute specifies that after the $718,669,000 has been adjusted for inflation, the inflation-adjusted amount shall be further adjusted for workload (see section 736(c)(2) of the FD&C Act).

To calculate the FY 2016 workload adjustment, FDA calculated the average number of each of the four types of applications specified in the workload adjustment provision: (1) Human drug applications; (2) active commercial investigational new drug applications (INDs) (applications that have at least one submission during the previous 12 months); (3) efficacy supplements; and (4) manufacturing supplements received over the 3-year period that ended on June 30, 2012 (base years), and the average number of each of these types of applications over the most recent 3 year period that ended June 30, 2015.

The calculations are summarized in table 4. The 3-year averages for each application category are provided in column 1 (''3-Year Average Base Years 2010–2012'') and column 2 (''3-Year Average 2013–2015''). Column 3 reflects the percent change in workload from column 1 to column 2. Column 4 shows the weighting factor for each type of application, estimating how much of the total FDA drug review workload was accounted for by each type of application in the table during the most recent 3 years. Column 5 is the weighted percent change in each category of workload. This was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. The sum of the values in column 5 is added, reflecting an increase in workload of 11.31 percent (rounded) for FY 2016 when compared to the base years.

TABLE 4—WORKLOAD ADJUSTER CALCULATION FOR FY 2016

Application type	Column 1 3-Year average base years 2010–2012	Column 2 3-Year average 2013–2015	Column 3 Percent change (column 1 to column 2)	Column 4 Weighting factor (percent)	Column 5 Weighted percent change
New Drug Applications/Biologics License Applications	124.3	148.3	19.3081	38.9	7.51
Active Commercial INDs	6830.0	7375.3	7.9839	39.2	3.13
Efficacy Supplements	136.3	175.0	28.3933	6.0	1.69
Manufacturing Supplements	2548.3	2386.7	−6.3415	16.0	−1.01
FY 2016 Workload Adjuster					11.31

Table 5 shows the calculation of the revenue amount for FY 2016. The $718,669,000 subject to adjustment on Line 1 is multiplied by the inflation adjustment factor of 1.064414, resulting in the inflation-adjusted amount on Line 3, $764,961,345. That amount is then multiplied by one plus the workload adjustment of 11.31 percent, resulting in the inflation and workload adjusted amount of $851,481,000 on Line 5, rounded to the nearest thousand dollars.

TABLE 5—PDUFA REVENUE AMOUNT FOR FY 2016, SUMMARY CALCULATION

FY 2013 Revenue Amount and Base Subsequent FYs as published in the **Federal Register** of August 1, 2012 (77 FR 45639) (Rounded to nearest thousand dollars).	$718,669,000	Line 1.
Inflation Adjustment Factor for FY 2016 (1 plus 6.4414 percent)	1.064414	Line 2.
Inflation Adjusted Amount	$764,961,345	Line 3.
Workload Adjustment Factor for FY 2016 (1 plus 11.31 percent)	1.1131	Line 4.
Inflation and Workload Adjusted Amount (Rounded to nearest thousand dollars)	$851,481,000	Line 5.

PDUFA specifies that one-third of the total fee revenue is to be derived from application fees, one-third from establishment fees, and one-third from product fees (see section 736(b)(2) of the FD&C Act). Accordingly, one-third of the total revenue amount ($851,481,000), or a total of $283,827,000, is the amount of fee revenue that will be derived from each of these fee categories: Application Fees, Establishment Fees, and Product Fees.

III. Application Fee Calculations

A. Application Fee Revenues and Application Fees

Application fees will be set to generate one-third of the total fee revenue amount, or $283,827,000 in FY 2016.

B. Estimate of the Number of Fee-Paying Applications and Setting the Application Fees

For FY 2013 through FY 2017, FDA will estimate the total number of fee-paying full application equivalents (FAEs) it expects to receive the next FY by averaging the number of fee-paying FAEs received in the 3 most recently completed FYs. Beginning with FY 2016, prior year FAE totals will be updated annually to reflect refunds and waivers processed after the close of the FY.

In estimating the number of fee-paying FAEs, a full application requiring clinical data counts as one FAE. An application not requiring clinical data counts as one-half of an FAE, as does a supplement requiring clinical data. An application that is withdrawn, or refused for filing, counts as one-fourth of an FAE if the applicant initially paid a full application fee, or one-eighth of an FAE if the applicant initially paid one-half of the full application fee amount.

As table 6 shows, the average number of fee-paying FAEs received annually in the most recent 3-year period is 119.545 FAEs. FDA will set fees for FY 2016 based on this estimate as the number of

full application equivalents that will pay fees.

TABLE 6—FEE-PAYING FAE 3-YEAR AVERAGE

FY	2012	2013	2014	3-Year average
Fee-Paying FAEs	120.375	109.510	128.750	119.545

Beginning with FY 2016, prior year FAE totals will be updated annually to reflect refunds and waivers processed after the close of the FY.

The FY 2016 application fee is estimated by dividing the average number of full applications that paid fees over the latest 3 years, 119.545, into the fee revenue amount to be derived from application fees in FY 2016, $283,827,000. The result, rounded to the nearest hundred dollars, is a fee of $2,374,200 per full application requiring clinical data, and $1,187,100 per application not requiring clinical data or per supplement requiring clinical data.

IV. Fee Calculations for Establishment and Product Fees

A. Establishment Fees

At the beginning of FY 2015, the establishment fee was based on an estimate that 509 establishments would be subject to and would pay fees. By the end of FY 2015, FDA estimates that 516 establishments will have been billed for establishment fees, before all decisions on requests for waivers or reductions are made. FDA estimates that a total of 15 establishment fee waivers or reductions will be made for FY 2015. In addition, FDA estimates that another 16 full establishment fees will be exempted this year based on the orphan drug exemption in section 736(k) of the FD&C Act. Subtracting 31 establishments (15 waivers, plus the estimated 16 establishments under the orphan exemption) from 516 leaves a net of 485 fee-paying establishments. FDA will use 485 to estimate the FY 2016 establishments paying fees. The fee per establishment is determined by dividing the adjusted total fee revenue to be derived from establishments ($283,827,000) by the estimated 485 establishments, for an establishment fee rate for FY 2016 of $585,200 (rounded to the nearest hundred dollars).

B. Product Fees

At the beginning of FY 2015, the product fee was based on an estimate that 2,434 products would be subject to and would pay product fees. By the end of FY 2015, FDA estimates that 2,554 products will have been billed for product fees, before all decisions on requests for waivers, reductions, or exemptions are made. FDA assumes that there will be 39 waivers and reductions granted. In addition, FDA estimates that another 35 product fees will be exempted this year based on the orphan drug exemption in section 736(k) of the FD&C Act. FDA estimates that 2,480 products will qualify for and pay product fees in FY 2015, after allowing for an estimated 74 waivers and reductions, including the orphan drug products, and will use this number for its FY 2016 estimate. The FY 2016 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees ($283,827,000) by the estimated 2,480 products for a FY 2016 product fee of $114,450 (rounded to the nearest ten dollars).

V. Fee Schedule for FY 2016

The fee rates for FY 2016 are displayed in table 7:

TABLE 7—FEE SCHEDULE FOR FY 2016

Fee category	Fee rates for FY 2016
Applications:	
Requiring clinical data	$2,374,200
Not requiring clinical data	1,187,100
Supplements requiring clinical data	1,187,100
Establishments	585,200
Products	114,450

VI. Fee Payment Options and Procedures

A. Application Fees

The appropriate application fee established in the new fee schedule must be paid for any application or supplement subject to fees under PDUFA that is received on or after October 1, 2015. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. Please include the user fee identification (ID) number on your check, bank draft, or postal money order. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000.

If checks are to be 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. Contact the U.S. Bank at 314–418–4013 if you have any questions concerning courier delivery.)

Please make sure that the FDA post office box number (P.O. Box 979107) is written on the check, bank draft, or postal money order.

Wire transfer payment may also be used. Please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and add it to your payment to ensure that your fee is fully paid. The account information for wire transfers is as follows: New York Federal Reserve Bank, U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993–0002.

Application fees can also be paid online with an electronic check (ACH). FDA has partnered with the U.S. Department of the Treasury to use Pay.gov, a Web-based payment application, for online electronic payment. The Pay.gov feature is available on the FDA Web site after the user fee ID number is generated.

The tax identification number of FDA is 53–0196965.

B. Establishment and Product Fees

FDA will issue invoices for establishment and product fees for FY 2016 under the new fee schedule in August 2015. Payment will be due on October 1, 2015. FDA will issue invoices in November 2016 for any products and establishments subject to fees for FY 2016 that qualify for fee assessments after the August 2015 billing.

Dated: July 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18914 Filed 7–31–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1358]

Recommendations for Premarket Notification (510(k)) Submissions for Nucleic Acid-Based Human Leukocyte Antigen Test Kits Used for Matching of Donors and Recipients in Transfusion and Transplantation; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled ''Recommendations for Premarket Notification (510(k)) Submissions for Nucleic Acid-Based Human Leukocyte Antigen (HLA) Test Kits Used for Matching of Donors and Recipients in Transfusion and Transplantation; Guidance for Industry.'' The guidance document provides recommendations to submitters and FDA reviewers in preparing and reviewing premarket notification submissions (hereafter referred to as ''510(k) submission'' or ''510(k)'') for HLA in vitro diagnostic (IVD) device test kits. The guidance applies specifically to nucleic acid-based HLA test kits used for the matching of donors and recipients in transfusion and transplantation, whether testing is for a single locus or for multiple loci simultaneously, for which the premarket submission to FDA will be a 510(k). The guidance announced in this notice finalizes the draft guidance of the same title dated November 2013.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, 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:

I. Background

FDA is announcing the availability of a document entitled ''Recommendations for Premarket Notification (510(k)) Submissions for Nucleic Acid-Based Human Leukocyte Antigen Test Kits Used for Matching of Donors and Recipients in Transfusion and Transplantation; Guidance for Industry.'' The guidance provides recommendations to submitters and FDA reviewers in preparing and reviewing 510(k) submissions for IVD device test kits, specifically for nucleic acid-based HLA test kits used for the matching of donors and recipients in transfusion and transplantation, whether testing is for a single locus or for multiple loci simultaneously. The guidance includes detailed information on the types of studies FDA recommends for validation of HLA test kits submitted as 510(k)s. More specifically, the guidance document addresses the types of studies and other information that FDA recommends to be used in designing and conducting studies for validation of nucleic acid-based HLA test kits and preparing a 510(k) submission.

In the **Federal Register** of November 20, 2013 (78 FR 69693), FDA announced the availability of the draft guidance of the same title dated November 2013. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, editorial changes were made for purposes of clarity and accuracy. The guidance announced in this notice finalizes the draft guidance dated November 2013.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on premarket notification (510(k)) submissions for nucleic acid-based HLA test kits used for matching of donors and recipients in transfusion and transplantation. 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.

II. Paperwork Reduction Act of 1995

This 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). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 809 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 812 have been approved under OMB control numbers 0910–0078 and 0910–0582; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 56 have been approved under OMB control number 0910–0130; and the collections of information in 21 CFR part 50 have been approved under OMB control number 0910–0586.

III. 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