adjustment factor, the establishment fee for non-small businesses is to be further adjusted for a small business adjustment factor. Section 744K(c)(3)(B) provides that the small business adjustment factor is the adjustment to the establishment fee for non-small businesses that is necessary to achieve total fees equaling the total fees that FDA would have collected if no entity qualified for the small business exception in section 744K(c)(4) of the FD&C Act.

Therefore, to calculate the small business adjustment to the establishment fee for non-small businesses for FY 2015, FDA must estimate: (1) The number of outsourcing facilities that will pay the reduced fee for small businesses for FY 2015; and (2) the total fee revenue it would have collected if no entity had qualified for the small business exception (i.e., if each outsourcing facility that registers for FY 2015 were to pay the inflation-adjusted fee amount of $15,308). With respect to (1), FDA estimates that 5 entities will qualify for small business exceptions for FY 2015. Accordingly, FDA estimates that 5 entities will pay the reduced fee for small businesses for FY 2015. With respect to (2), to estimate the total number of outsourcing facilities that will register for FY 2015, FDA used data submitted to date by outsourcing facilities through the voluntary registration process, which began in December 2013. Accordingly, FDA estimates that 50 outsourcing facilities, including 5 small businesses, will register with the Agency in FY 2015.

If the projected 50 outsourcing facilities paid the full inflation-adjusted fee of $15,308, this would result in total revenue of $765,400 in FY 2015 ($15,308 times 50). However, because 5 of the outsourcing facilities expected to register for FY 2015 are estimated to qualify for the small business exception and will pay one-third of the full fee ($5,103 × 5), totaling $25,515 instead of paying the full fee ($15,308 × 5), which totals $76,540, this would leave a shortfall of $51,025 ($76,540 − $25,515). Dividing $51,025 by 45 (the number of estimated non-small businesses) yields $1,134 (rounded to the nearest dollar). Therefore, the FY 2015 small business adjustment to the establishment fee for non-small businesses is $1,134.

C. Summary of FY 2015 Fee Rates

TABLE 4—OUTSOURCING FACILITY FEES

Qualified Small Business Establishment Fee	$5,103
Non-Small Business Establishment Fee	16,442
Reinspection Fee	15,308

III. Fee Payment Options and Procedures

A. Establishment Fee

Once an entity submits registration information and FDA has reviewed the information and determined that it is complete, the entity will incur the annual establishment fee. FDA will send an invoice to the entity via email, to the email address indicated in the registration file, or via regular mail if email is not an option. The invoice will contain information regarding the obligation incurred, the amount owed, and payment procedures. A facility will not be deemed registered as an outsourcing facility until it has paid the annual establishment fee under section 744K of the FD&C Act. Accordingly, it is important that facilities seeking to operate as registered outsourcing facilities pay all fees immediately upon receiving an invoice. If an entity does not pay the full invoiced amount within fifteen calendar days after FDA issues the invoice, FDA will consider the submission of registration information to have been withdrawn and adjust the invoice to reflect that no fee is due.

Outsourcing facilities that registered in FY 2014 and wish to maintain their status as an outsourcing facility in FY 2015 must register during the annual registration period that lasts from October 1, 2014 to December 31, 2014. Failure to register and complete payment by December 31, 2014, will result in a loss of status as an outsourcing facility on January 1, 2015. Entities should submit their registration information no later than December 10, 2014 to allow enough time for review of the registration information, invoicing, and payment of fees before the end of the registration period.

B. Reinspection Fee

FDA will issue invoices for each reinspection via email, to the email address indicated in the registration file, or via regular mail if email is not an option.

C. Fee Payment Procedures

Entities may remit payments via check or wire transfer.

1. If paying with a paper check: Checks must be in U.S. currency from a U.S. bank and made payable to the Food and Drug Administration. Payments can be mailed to: Food and Drug Administration, P.O. Box 956733, St. Louis, MO 63195–6733. If a check is sent by a courier that requests a street address, the courier can deliver the check to: U.S. Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (**Note:** This U.S. Bank address is for courier delivery only; do not send mail to this address.)

2. If paying with a wire transfer: Use the following account information when sending a wire transfer: New York Federal Reserve Bank, U.S. Dept of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Road, Silver Spring, MD 20993. The originating financial institution may charge a wire transfer fee. An outsourcing facility should ask its financial institution about the fee and add it to the payment to ensure that the order is fully paid. The tax identification number of FDA is 53–0196965.

Dated: July 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–18111 Filed 7–31–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0007]

Prescription Drug User Fee Rates for Fiscal Year 2015

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) 2015. 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 2015.

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 2015 for an application requiring clinical data ($2,335,200), for an application not requiring clinical data or a supplement requiring clinical data ($1,167,600), for an establishment ($569,200), and for a product ($110,370). These fees are effective on October 1, 2014, and will remain in effect through September 30, 2015. For applications and supplements that are submitted on or after October 1, 2014, the new fee schedule must be used. Invoices for establishment and product fees for FY 2015 will be issued in August 2014 using the new fee schedule.

II. Fee Revenue Amount for FY 2015

The base revenue amount for FY 2015 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 2015 Statutory Fee Revenue Adjustments for Inflation

PDUFA V specifies that the $718,669,000 is to be further adjusted for inflation increases for FY 2015 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). The total PC&B paid and numbers of FTE paid, from which the average cost per FTE can be derived, are published in FDA's Justification of Estimates for Appropriations Committees.

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 2015. The 3-year average is 1.8829 percent.

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

Fiscal year	2011	2012	2013	3-Year average
Total PC&B	$1,761,655,000	$1,824,703,000	$1,927,703,000	.....
Total FTE	13,331	13,382	13,974	.....
PC&B per FTE	$132,147	$136,355	$137,949	.....
Percent Change from Previous Year	1.2954%	3.1843%	1.1690%	1.8829%

The statute specifies that this 1.8829 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	2011	2012	2013	3-Year average
Total PC&B	$596,627,595	$ 592,642,252	$568,206,210	.....
Total Costs	$1,025,621,707	$1,032,419,218	$966,169,007	.....
PC&B Percent	58.1723%	57.4033%	58.8102%	58.1286%

The payroll adjustment is 1.8829 percent from table 1 multiplied by 58.1286 percent (or 1.0945 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 fiscal years (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 is 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	2011	2012	2013	3-Year average
Annual CPI	146.975	150.212	152.500	.....
Annual Percent Change	3.3449%	2.2024%	1.5232%	2.3568%

To calculate the inflation adjustment for non-payroll costs, we multiply the 2.3568 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 58.1286 percent was obligated for PC&B as shown in table 2, 41.8714 percent is the portion of costs other than PC&B (100 percent minus 58.1286 percent equals 41.8714 percent). The non-payroll adjustment is 2.3568 percent times 41.8714 percent, or 0.9868 percent.

Next, we add the payroll adjustment (1.0945 percent) to the non-payroll adjustment (0.9868 percent), for a total inflation adjustment of 2.0813 percent (rounded) for FY 2015.

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 2015 (2.0813 percent) is compounded by adding 1 and then multiplying by 1 plus the inflation adjustment factor for FY 2014 (2.20 percent), as published in the **Federal Register** of August 2, 2013 (78 FR 46980 at 46982), which equals to 1.043271 (rounded) (1.020813 times 1.0220) for FY 2015. We then multiply the base revenue amount for FY 2015 ($718,669,000) by 1.043271, yielding an inflation-adjusted amount of $749,766,526.

B. FY 2015 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 2015 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, 2014.

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 2012–2014''). 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 7.49 percent (rounded) for FY 2015 when compared to the base years.

TABLE 4—WORKLOAD ADJUSTER CALCULATION FOR FY 2015

Application type	3-Year average base years 2010–2012 Column 1	3-Year average 2012–2014 Column 2	Percent change (column 1 to column 2) Column 3	Weighting factor (percent) Column 4	Weighted percent change Column 5
New Drug Applications/Biologics License Applications	124.3	141.3	13.6766	37.3	5.10
Active Commercial INDs	6830.0	7141.3	4.5578	41.4	1.89
Efficacy Supplements	136.3	156.7	14.9670	7.5	1.12
Manufacturing Supplements	2548.3	2433.7	−4.4971	13.8	−0.62
FY 2015 Workload Adjuster	.....	.....	.....	.....	7.49

Table 5 shows the calculation of the revenue amount for FY 2015. The $718,669,000 subject to adjustment on the first line is multiplied by the inflation adjustment factor of 1.043271, resulting in the inflation-adjusted amount on the third line, $749,766,526. That amount is then multiplied by one plus the workload adjustment of 7.49 percent, resulting in the inflation and workload adjusted amount of $805,924,000 on the fifth line, rounded to the nearest thousand dollars.

TABLE 5—PDUFA REVENUE AMOUNT FOR FY 2015, 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 2015 (1 plus 4.3271 percent)	1.043271	Line 2.
Inflation Adjusted Amount	$749,766,526	Line 3.
Workload Adjustment Factor for FY 2015 (1 plus 7.49 percent)	1.0749	Line 4.
Inflation and Workload Adjusted Amount (Rounded to nearest thousand dollars)	$805,924,000	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 ($805,924,000), or a total of $268,641,333, 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 $268,641,333 in FY 2015.

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.

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 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 115.042 FAEs. FDA will set fees for FY 2015 based on this estimate as the number of full application equivalents that will pay fees.

TABLE 6—FEE-PAYING FAE 3-YEAR AVERAGE

FY	2011	2012	2013	3-Year average
Fee-Paying FAEs	108.250	122.375	114.500	115.042

The FY 2015 application fee is estimated by dividing the average number of full applications that paid fees over the latest 3 years, 115.042, into the fee revenue amount to be derived from application fees in FY 2015, $268,641,333. The result, rounded to the nearest hundred dollars, is a fee of $2,335,200 per full application requiring clinical data, and $1,167,600 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 2014, the establishment fee was based on an estimate that 455 establishments would be subject to and would pay fees. By the end of FY 2014, FDA estimates that 509 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 20 establishment fee waivers or reductions will be made for FY 2014. In addition, FDA estimates that another 17 full establishment fees will be exempted this year based on the orphan drug exemption in section 736(k) of the FD&C Act. Subtracting 37 establishments (20 waivers, plus the estimated 17 establishments under the orphan exemption) from 509 leaves a net of 472 fee-paying establishments. FDA will use 472 to estimate the FY 2015 establishments paying fees. The fee per establishment is determined by dividing the adjusted total fee revenue to be derived from establishments ($268,641,333) by the estimated 472 establishments, for an establishment fee rate for FY 2015 of $569,200 (rounded to the nearest hundred dollars).

B. Product Fees

At the beginning of FY 2014, the product fee was based on an estimate that 2,425 products would be subject to and would pay product fees. By the end of FY 2014, FDA estimates that 2,545 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 69 waivers and reductions granted. In addition, FDA estimates that another 42 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 2,434 products will qualify for product fees in FY 2014, after allowing for an estimated 111 waivers and reductions, including the orphan drug products, and will use this number for its FY 2015 estimate. The FY 2015 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees ($268,641,333) by the estimated 2,434 products for a FY 2015 product fee of $110,370 (rounded to the nearest ten dollars).

V. Fee Schedule for FY 2015

The fee rates for FY 2015 are set out in table 7:

TABLE 7—FEE SCHEDULE FOR FY 2015

Fee category	Fee rates for FY 2015
Applications:	
Requiring clinical data	$2,335,200
Not requiring clinical data	1,167,600
Supplements requiring clinical data	1,167,600
Establishments	569,200
Products	110,370

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, 2014. 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 2015 under the new fee schedule in August 2014. Payment will be due on October 1, 2014. FDA will issue invoices in November 2015 for any products and establishments subject to fees for FY 2015 that qualify for fee assessments after the August 2014 billing.

Dated: July 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–18113 Filed 7–31–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Correction

The National Institutes of Health NIH published in the **Federal Register** on July 18, 2014 a notice titled ''Proposed Collection; 60-Day Comment Request; A Generic Submission for Formative Research, Pre-Testing, Stakeholder Measures and Advocate Forms at NCI'' [79 FR 42023]. The notice contained an incorrect email address for Kelley Landy, Acting Director of the Office of Advocacy Relations. The correct email address is *kelley.landy@nih.gov*.

Dated: July 28, 2014.

Cynthia Chaves,

NIH Federal Register Liaison.

[FR Doc. 2014–18087 Filed 7–31–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Recruitment and Screening for the Insight Into Determination of Exceptional Aging and Longevity (IDEAL) Study

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 2, 2014, Vol. 79, page 18569 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute on Aging (NIA), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Luigi Ferrucci, M.D., Ph.D., NIA Clinical Research Branch, Harbor Hospital, 5th Floor, 3001 S. Hanover, Baltimore, MD 21225 or call non-toll-free number (410) 350–3936 or Email your request, including your address to: *Ferruccilu@grc.nia.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Recruitment and Screening for the Insight into Determination of Exceptional Aging and Longevity (IDEAL) Study (OMB#: 0925–0631). National Institute on Aging (NIA), National Institutes of Health (NIH).

Need and Use of Information Collection

Longevity combined with good health and functionality at the end of life represents a common goal. Although research has examined correlates of long life and functional decline, we still know relatively little about why certain individuals live in excellent health into their eighties while others succumb to failing health at much younger ages. Understanding the mechanisms important to ideal aging may provide new opportunity for health promotion and disability prevention is this rapidly growing segment of the population.

The purpose of IDEAL (Insight into the Determinants of Exceptional Aging and Longevity) is to recruit into the Baltimore Longitudinal Study on Aging (BLSA) exceptionally long lived and healthy individuals and to learn what makes them so resilient and resistant to disease and disability, and to identify potential interventions that may contribute to the IDEAL condition. By enrolling the IDEAL cohort in the BLSA their biologic, physiologic, behavioral and functional characteristics will be evaluated using the same methods used with the current cohort who will serve as a type of control group. The first aim is to identify factors and characteristics that distinguish IDEAL from non-IDEAL individuals. We intend to compare the two groups to identify factors that discriminate IDEAL aging from non-IDEAL aging individuals. The second aim is to identify physiological, environmental and behavioral characteristics that are risk factors for losing the IDEAL condition over several years or longer. We postulate that the mechanisms of extreme longevity probably differ from those associated with delay or escape from disease and disability. As is customary in the BLSA, we plan to follow this cohort for life with yearly visits. This is a request for OMB to approve a reinstatement with change of Recruitment and Screening for the Insight into Determination of Exceptional Aging and Longevity (IDEAL) Study for 3 years.

OMB approval is requested for 3 years. There is no annualized cost to respondents. The total estimated annualized burden hours are 333.