Establish two different kinds of user fees. Fees are assessed on the following: (1) Application fees are assessed on certain types of applications for the review of human drug and biological products; and (2) prescription drug program fees are assessed on certain approved products (section 736(a) of the FD&C Act). When specific conditions are met, FDA may waive or reduce fees (section 736(d) of the FD&C Act).

For FY 2018 through FY 2022, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA VI. The base revenue amount for FY 2018 is $878,590,000. The FY 2018 base revenue amount is to be adjusted for inflation and for the resource capacity needs for the process for the review of human drug applications (the capacity planning adjustment). An additional dollar amount specified in the statute (see section 736(b)(1)(F) of the FD&C Act) is then added to provide for additional full-time equivalent (FTE) positions to support PDUFA VI initiatives. The FY 2018 revenue amount may be adjusted further, if necessary, to provide for sufficient operating reserves of carryover user fees. Finally, the amount is adjusted to provide for additional direct costs to fund PDUFA VI initiatives. Fee amounts are to be established each year so that revenues from application fees provide 20 percent of the total revenue, and prescription drug program fees provide 80 percent of the total revenue.

This document provides fee rates for FY 2018 for an application requiring clinical data ($2,421,495), for an application not requiring clinical data ($1,210,748), and for the prescription drug program fee ($304,162). These fees are effective on October 1, 2017, and will remain in effect through September 30, 2018. For applications that are submitted on or after October 1, 2017, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2018

The base revenue amount for FY 2018 is $878,590,000 prior to adjustments for inflation, capacity planning, additional FTE, operating reserve, and additional direct costs (see section 736(b)(1) of the FD&C Act).

A. FY 2018 Statutory Fee Revenue Adjustments for Inflation

PDUFA VI specifies that the $878,590,000 is to be adjusted for inflation increases for FY 2018 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 one plus the average annual percent change in the cost of all PC&B paid per FTE positions at FDA for the first three of the preceding four FYs, multiplied by the proportion of PC&B costs to total FDA costs of the process for the review of human drug applications for the first three of the preceding four FYs (see section 736(c)(1)(A) and (c)(1)(B) of the FD&C Act).

Table 1 summarizes the 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 three of the four FYs preceding FY 2018. The 3-year average is 2.2354 percent.

---

### Table 1—Estimated Annual Reporting Burden

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Annual frequency per response</th>
<th>Total annual responses</th>
<th>Hours per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focus Group Interviews</td>
<td>8,800</td>
<td>1</td>
<td>8,800</td>
<td>1.75</td>
<td>15,400</td>
</tr>
</tbody>
</table>

1 There are no capital costs or operating and maintenance costs associated with this collection of information.

---

### Table 1—FDA Personnel Compensation and Benefits (PC&B) Each Year and Percent Changes

<table>
<thead>
<tr>
<th>Fiscal year</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>3-year average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total PC&amp;B</td>
<td>$2,054,937,000</td>
<td>$2,232,304,000</td>
<td>$2,414,728,159</td>
<td></td>
</tr>
<tr>
<td>Total FTE</td>
<td>$14,555</td>
<td>15,484</td>
<td>16,381</td>
<td></td>
</tr>
<tr>
<td>PC&amp;B per FTE</td>
<td>$141,184</td>
<td>$144,168</td>
<td>$147,408</td>
<td></td>
</tr>
<tr>
<td>Percent Change From Previous Year</td>
<td>2.3451</td>
<td>2.1136</td>
<td>2.2474</td>
<td>2.2354</td>
</tr>
</tbody>
</table>
The statute specifies that this 2.2354 percent should be multiplied by the proportion of PC&B costs to the total costs of the process for the review of human drug applications. Table 2 shows the PC&B and the total costs of the process for the review of human drug applications. Table 2—PC&B as a Percent of Fee Revenues Spent on the Process for the Review of Human Drug Applications

<table>
<thead>
<tr>
<th>Fiscal year</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>3-year average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total PC&amp;B</td>
<td>$585,260,720</td>
<td>$615,483,892</td>
<td>$652,508,273</td>
<td></td>
</tr>
<tr>
<td>Total Costs</td>
<td>$1,077,263,695</td>
<td>$1,127,664,528</td>
<td>$1,157,817,695</td>
<td></td>
</tr>
<tr>
<td>PC&amp;B Percent</td>
<td>54.3285</td>
<td>54.5804</td>
<td>56.3567</td>
<td>55.0885</td>
</tr>
</tbody>
</table>

The payroll adjustment is 2.2354 percent from table 1 multiplied by 55.0885 percent (or 1.2314 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 three years of the preceding four FYs (see section 736(c)(1)(B) of the FD&C Act). Table 3 provides the summary data for the percent changes in the specified costs other than PC&B costs to total costs of the process that the statute specifies that this 2.0139 percent should be multiplied 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 55.0885 percent was obligated for PC&B (as shown in table 2), 44.9115 percent is the portion of costs other than PC&B (100 percent minus 55.0885 percent equals 44.9115 percent). The non-payroll adjustment is 1.0139 percent times 44.9115 percent, or 0.4554 percent.

Next, we add the payroll adjustment (1.2314 percent) to the non-payroll adjustment (0.4554 percent), for a total inflation adjustment of 1.6868 percent (rounded) for FY 2018.

We then multiply the base revenue amount for FY 2018 ($878,590,000) by 1.016868, yielding an inflation-adjusted amount of $893,410,056.

B. FY 2018 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that after $878,590,000 has been adjusted for inflation, the inflation-adjusted amount shall be further adjusted to reflect changes in the resource capacity needs for the process of human drug application reviews (see section 736(c)(2) of the FD&C Act). The statute prescribes an interim capacity planning adjustment be utilized until a new methodology can be developed through a process involving an independent evaluation as well as obtaining public comment. The interim capacity planning adjustment is applied to FY 2018 fee setting.

To determine the FY 2018 capacity planning adjustment, FDA calculated the average number of each of the five elements specified in the capacity planning adjustment provision: (1) Human drug applications (new drug applications (NDAs)/biologics license applications (BLAs)); (2) active commercial investigational new drug applications (INDs) (IND applications that have at least one submission during the previous 12 months); (3) efficacy supplements; (4) manufacturing supplements; and (5) formal meetings, type A, B, B(EoP), C, and written responses only (WRO) issued in lieu of such formal meetings, over the 3-year period that ended on June 30, 2016, and the average number of each of these elements over the most recent 3-year period that ended June 30, 2017.

The calculations are summarized in table 4. The 3-year averages for each element are provided in column 1 ("3-Year Average Ending 2016") and column 2 ("3-Year Average Ending 2017"). Column 3 reflects the percent change from column 1 to column 2. Column 4 shows the weighting factor for each element. The weighting factor methodology has been updated for PDUFA VI. The previous methodology relied on the relative value of the standard costs for the elements included in the adjuster, and summed to 100 percent. The weighting factor now is the time invested in activities related to the element expressed as a percentage of total time invested in PDUFA activities, and will adjust only the costs attributed to the elements included in the model (hence the weighting factor does not now sum to 100 percent). Column 5 is the weighted percent change in each element. This is calculated by multiplying the weighting factor in each line in column 4 by the percent change in column 3. The values in column 5 are summed, reflecting an adjustment of 2.5090 percent (rounded).
### Table 4—Capacity Planning Adjuster (Interim Methodology) Calculation for FY 2018

<table>
<thead>
<tr>
<th>Element</th>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
<th>Column 4</th>
<th>Column 5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3-year average ending 2016</td>
<td>3-year average ending 2017</td>
<td>Percent change (column 1 to column 2)</td>
<td>Weighting factor (percent)</td>
<td>Weighted percent change</td>
</tr>
<tr>
<td>NDAs/BLAs</td>
<td>147.3333</td>
<td>153.0000</td>
<td>3.8462</td>
<td>18.0915</td>
<td>0.6958</td>
</tr>
<tr>
<td>Active Commercial INDs</td>
<td>7,596.0000</td>
<td>7,846.6667</td>
<td>3.2728</td>
<td>23.3890</td>
<td>0.7655</td>
</tr>
<tr>
<td>Efficacy Supplements</td>
<td>196.3333</td>
<td>212.3333</td>
<td>8.1494</td>
<td>4.1848</td>
<td>0.3410</td>
</tr>
<tr>
<td>Manufacturing Supplements</td>
<td>2,368.0000</td>
<td>2,482.6667</td>
<td>4.8423</td>
<td>4.3690</td>
<td>0.2116</td>
</tr>
<tr>
<td>Meetings Scheduled and WROs</td>
<td>2,720.6667</td>
<td>2,940.0000</td>
<td>8.0617</td>
<td>6.1417</td>
<td>0.4951</td>
</tr>
</tbody>
</table>

| FY 2018 Capacity Planning Adjuster | | | | | 2.5090 |

Table 5 shows the calculation of the inflation and capacity planning adjusted amount for FY 2018. The FY 2018 base revenue amount, $878,590,000, shown on line 1 is multiplied by the inflation adjustment factor of 1.016868, resulting in the inflation-adjusted amount of $893,410,056 shown on line 3. That amount is then multiplied by one plus the capacity planning adjustment of 2.5090 percent, resulting in the inflation and capacity planning adjusted amount of $915,825,714 shown on line 5.

### Table 5—PDUFA Inflation and Capacity Planning Adjusted Amount for FY 2018, Summary Calculation

| FY 2018 Revenue Amount | $878,590,000 | Line 1 |
| Inflation Adjustment Factor for FY 2018 (1 plus 1.6868 percent) | 1.016868 | Line 2 |
| Inflation Adjusted Amount | $893,410,056 | Line 3 |
| Capacity Planning Adjustment Factor for FY 2018 (1 plus 2.5090 percent) | 1.025090 | Line 4 |
| Inflation and Capacity Planning Adjusted Amount | $915,825,714 | Line 5 |

The capacity planning adjustment adds $22,415,658 to the fee revenue amount for FY 2018. This increase is driven by the fact that the counts of elements for 2017 (year ending June 30) are at or near the highest levels since the first incorporation of the workload adjuster in 2003. The NDA/BLA count in 2017 is equal to the highest annual number recorded since the advent of the workload adjuster methodology in 2003. Active commercial INDs, efficacy supplements, and meetings/WROs are higher in 2017 than in any previous year recorded in the workload adjuster (note: Meetings/WROs are only counted back to 2014 while the other elements are counted back to 2003). The manufacturing supplement count is approximately 2 percent below the highest number recorded in the history of the workload adjuster. Comparing 2017 to 2014, the first year included in the average in column 1 in the adjustment, NDA/BLAs are 12 percent higher, active commercial INDs are 10 percent higher, efficacy supplements are 25 percent higher, manufacturing supplements are 15 percent higher, and meetings scheduled and WROs are 27 percent higher. This significant and across the board increase in submission activity is the driver of the $22,415,658 upward adjustment to the fee revenue amount.

Per the commitments made in PDUFA VI, this increase in the revenue amount will be allocated and used by organizational review components engaged in direct review work to enhance resources and expand staff capacity and capability (see II.A.4 on p.37 of the PDUFA VI commitment letter).1

C. FY 2018 Statutory Fee Revenue Adjustments for Additional Dollar Amounts

PDUFA VI provides an additional dollar amount for each of the next five fiscal years for additional FTE to support PDUFA VI enhancements outlined in the PDUFA VI commitment letter. The amount for FY 2018 is $20,077,793 (see section 736(b)(1)(F) of the FD&C Act). Adding this amount to the inflation and capacity planning adjusted revenue amount, $915,825,714, equals $935,904,000 (rounded to the nearest thousand dollars).

D. FY 2018 Statutory Fee Revenue Adjustments for Operating Reserve

PDUFA VI provides for an operating reserve adjustment to allow FDA to increase the fee revenue and fees for any given fiscal year during PDUFA VI to maintain up to 14 weeks of operating reserve of carryover user fees. If the carryover balance exceeds 14 weeks of operating reserves, FDA is required to decrease fees to provide for not more than 14 weeks of operating reserves of carryover user fees.

To determine the 14-week operating reserve amount, the FY 2018 annual base revenue adjusted for inflation and capacity planning, $915,825,714, is divided by 52, and then multiplied by 14. The 14-week operating reserve amount for FY 2018 is $246,568,461.

To determine the end of year operating reserve amount, the Agency must assess actual operating reserve at the end of the third quarter of FY 2017, and forecast collections and obligations in the fourth quarter of FY 2017. The estimated end of year FY 2017 operating reserve is $279,856,044.

Because the estimated end of year FY 2017 PDUFA operating reserve exceeds the 14-week operating reserve for FY 2018, FDA will reduce the FY 2018 PDUFA fee revenue of $935,903,507 by $33,287,582, resulting in an adjusted fee revenue of $902,615,925.

E. FY 2018 Statutory Fee Revenue Adjustments for Additional Direct Cost

PDUFA VI specifies that $8,730,000 be added in addition to the operating reserve adjustment to account for additional direct costs in FY 2018. This additional direct cost adjustment will be adjusted for inflation each year beginning in FY 2019.

The final FY 2018 PDUFA fee revenue is $911,346,000 (rounded to the nearest thousand dollars).

III. Application Fee Calculations

A. Application Fee Revenues and Application Fees

Application fees will be set to generate 20 percent of the total revenue amount, or $182,269,200 in FY 2018.

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

FDA will estimate the total number of fee-paying full application equivalents (FAEs) it expects to receive during the next FY by averaging the number of fee-paying FAEs received in the three most recently completed FYs. Prior year FAE totals are 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. An application that is withdrawn before filing, 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. Prior to PDUFA VI, the FAE amount also included supplements; supplements have been removed from the FAE calculation as the supplement fee has been discontinued in PDUFA VI.

As table 6 shows, the average number of fee-paying FAEs received annually in the most recent 3-year period is 75,271,347 FAEs. FDA will set fees for FY 2018 based on this estimate as the number of full application equivalents that will pay fees.

<table>
<thead>
<tr>
<th>FY</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>3-year average</th>
</tr>
</thead>
<tbody>
<tr>
<td>FAEs</td>
<td>73,375,000</td>
<td>81,955,603</td>
<td>70,483,437</td>
<td>75,271,347</td>
</tr>
</tbody>
</table>

Note: Prior year FAE totals are updated annually to reflect refunds and waivers processed after the close of the FY.

The FY 2018 application fee is estimated by dividing the average number of full applications that paid fees over the latest 3 years, 75,271,347, into the fee revenue amount to be derived from application fees in FY 2018, $182,269,200. The result is a fee of $2,421,495 per full application requiring clinical data, and $1,210,748 per application not requiring clinical data.

IV. Fee Calculations for Prescription Drug Program Fees

PDUFA VI renamed the product fee the “prescription drug program fee”; in addition, PDUFA VI introduced a limitation that an applicant will be assessed more than five program fees for a fiscal year for prescription drug products identified in a single approved NDA or BLA (see section 736(a)(2)(C)). The program fee was also modified so that applicants are assessed a program fee only for prescription drug products identified in a human drug application approved as of October 1 of such fiscal year.

FDA estimates 2,461 program fees will be invoiced in FY 2018 before factoring in waivers, refunds, and exemptions. FDA approximates that there will be 27 waivers and refunds granted. In addition, FDA approximates that another 37 program fees will be exempted in FY 2018 based on the orphan drug exemption in section 736(k) of the FD&C Act. FDA estimates 2,397 program fees in FY 2018, after allowing for an estimated 64 waivers and reductions, including the orphan drug exemptions. The FY 2018 prescription drug program fee rate is calculated by dividing the adjusted total revenue from program fees ($729,076,800) by the estimated 2,397 program fees, for a FY 2018 program fee of $304,162.

V. Fee Schedule for FY 2018

The fee rates for FY 2018 are displayed in table 7:

<table>
<thead>
<tr>
<th>Fee category</th>
<th>Fee rates for FY 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application:</td>
<td></td>
</tr>
<tr>
<td>Requiring clinical data</td>
<td>$2,421,495</td>
</tr>
<tr>
<td>Not requiring clinical data</td>
<td>1,210,748</td>
</tr>
<tr>
<td>Program</td>
<td>304,162</td>
</tr>
</tbody>
</table>

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 subject to fees under PDUFA that is received on or after October 1, 2017. Payment must be made in U.S. currency by electronic check, check, bank draft, wire transfer, 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) or credit card (Discover, VISA, MasterCard, American Express). 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. 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.

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.

Please include the user fee identification (ID) number on your check, bank draft, or postal money order. Mail your payment to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197-9000. If a check, bank draft, or money order is to be sent by a courier that requests a street address, the courier should deliver your payment 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). 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.

If paying by wire transfer, 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: U.S. Department of the Treasury, TREAUSNYC, 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. If needed, FDA’s tax identification number is 53-0196965.

B. Prescription Drug Program Fees

FDA plans to issue invoices and payment instructions for FY 2018 program fees under the new fee schedule in September 2017. Payment will be due on October 1, 2017. FDA plans to issue invoices in December 2017 for FY 2018 program fees that qualify for fee assessments after the initial 2017 billing.

Dated: September 8, 2017.

Leslie Kux,
Associate Commissioner for Policy.

FOR FURTHER INFORMATION CONTACT: [FR Doc. 2017–19494 Filed 9–13–17; 8:45 am]

BILLING CODE 4164–01–P

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DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Waiver of Compliance With Navigation Laws; Hurricanes Harvey and Irma

AGENCY: Office of the Secretary, Department of Homeland Security.

ACTION: Notice.

Hurricane Harvey striking the United States and Irma Gulf Coast has resulted in severe disruptions in both the midstream and downstream sectors of the oil supply system. Some refineries and pipeline networks are shut-in or running at reduced rates. In addition, conditions exist for a potential imminent shortage of energy supply in areas predicted to be affected by Hurricane Irma. In light of the impact on the affected region’s energy needs, the Department of Energy (DOE) has recommended that the Department of Homeland Security waive the requirements of the Jones Act in the interest of national defense to facilitate the transportation of the necessary volume of petroleum products for a 7-day period. Furthermore, the Department of Defense (DoD) has requested a 7-day waiver of the Jones Act in the interest of national defense, commencing immediately.

The Jones Act, 46 United States Code (U.S.C.) 55102, states “a vessel may not provide any part of the transportation of merchandise by water, or by land and water, between points in the United States to which the coastwise laws apply, either directly or via a foreign port” unless the vessel was built in and documented under the laws of the United States and is wholly owned by persons who are citizens of the United States. Such a vessel, after obtaining a coastwise endorsement from the U.S. Coast Guard, is “coastwise-qualified.” The coastwise laws generally apply to points in the territorial sea, which is defined as the belt, three nautical miles wide, seaward of the territorial sea baseline, and to points located in internal waters, landward of the territorial sea baseline.

The navigation laws, including the coastwise laws, can be waived under the authority provided by 46 U.S.C. 501. The statute provides in relevant part, “On request of the Secretary of Defense, the head of an agency responsible for the administration of the navigation or vessel-inspection laws shall waive compliance with those laws to the extent the Secretary considers necessary in the interest of national defense.” 46 U.S.C. 501(a).

For the reasons stated above, and in light of the request from the Department of Defense and the concurrence of the Department of Energy, I am exercising my authority to waive the Jones Act for a 7-day period, commencing immediately, to facilitate movement of refined petroleum products, including gasoline, diesel, and jet fuel—to be shipped from New York, Pennsylvania, Texas, and Louisiana to South Carolina, Georgia, Florida, and Puerto Rico. This waiver applies to covered merchandise laded on board a vessel within the 7 day period of the waiver.

Executed this 8th day of September, 2017.

Elaine C. Duke,
Acting Secretary of Homeland Security.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration (USCIS) invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the Federal Register to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (i.e. the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until November 13, 2017.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0131 in the body of the letter, the agency name and Docket ID USCIS–2014–0005. To avoid duplicate submissions, please use only one of the following methods to submit comments:
(2) Mail. Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140.


SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: http://www.regulations.gov and enter USCIS–2014–0005 in the search box. Regardless of the method used for submitting comments or material, all...