

ALL PURPOSE TABLE

| (Dollars in Thousands) | FY 2018 Enacted | | FY 2018 Actuals | | FY 2019 Annualized CR | | FY 2020 President's Budget | | FY 2020 President's Budget +/- FY 2019 Annualized CR | |
|--|-------------------|------------------|------------------|------------------|-----------------------|------------------|----------------------------|------------------|--|----------------|
| | FTE | \$000 | FTE | \$000 | FTE | \$000 | FTE | \$000 | FTE | \$000 |
| | Foods..... | 3,861 | 1,070,187 | 3,861 | 1,059,291 | 3,905 | 1,070,187 | 4,008 | 1,122,047 | 103 |
| <i>Budget Authority.....</i> | <i>3,861</i> | <i>1,059,316</i> | <i>3,861</i> | <i>1,059,291</i> | <i>3,861</i> | <i>1,059,316</i> | <i>3,912</i> | <i>1,084,636</i> | <i>51</i> | <i>25,320</i> |
| <i>User Fees.....</i> | <i>---</i> | <i>10,871</i> | <i>---</i> | <i>---</i> | <i>44</i> | <i>10,871</i> | <i>96</i> | <i>37,411</i> | <i>52</i> | <i>26,540</i> |
| Center..... | 1,147 | 327,044 | 1,147 | 326,210 | 1,150 | 327,044 | 1,230 | 361,678 | 80 | 34,634 |
| Budget Authority..... | 1,147 | 326,212 | 1,147 | 326,210 | 1,147 | 326,212 | 1,175 | 334,712 | 28 | 8,500 |
| User Fees..... | --- | 832 | --- | --- | 3 | 832 | 55 | 26,966 | 52 | 26,134 |
| <i>Food and Feed Recall.....</i> | --- | 243 | --- | --- | 1 | 243 | 1 | 253 | --- | 10 |
| <i>Voluntary Qualified Importer Program.....</i> | --- | 243 | --- | --- | 1 | 243 | 1 | 253 | --- | 10 |
| <i>Third Party Auditor Program.....</i> | --- | 346 | --- | --- | 1 | 346 | 1 | 360 | --- | 14 |
| <i>Innovative Food Products (Proposed).....</i> | --- | --- | --- | --- | --- | --- | 52 | 26,100 | 52 | 26,100 |
| Field..... | 2,714 | 743,143 | 2,714 | 733,081 | 2,755 | 743,143 | 2,778 | 760,369 | 23 | 17,226 |
| Budget Authority..... | 2,714 | 733,104 | 2,714 | 733,081 | 2,714 | 733,104 | 2,737 | 749,924 | 23 | 16,820 |
| User Fees..... | --- | 10,039 | --- | --- | 41 | 10,039 | 41 | 10,445 | --- | 406 |
| <i>Food and Feed Recall.....</i> | --- | 1,000 | --- | --- | 4 | 1,000 | 4 | 1,040 | --- | 40 |
| <i>Food Reinspection.....</i> | --- | 4,575 | --- | --- | 19 | 4,575 | 19 | 4,760 | --- | 185 |
| <i>Voluntary Qualified Importer Program.....</i> | --- | 4,320 | --- | --- | 18 | 4,320 | 18 | 4,495 | --- | 175 |
| <i>Third Party Auditor Program.....</i> | --- | 144 | --- | --- | --- | 144 | --- | 150 | --- | 6 |
| Human Drugs..... | 6,335 | 1,633,743 | 6,335 | 1,755,609 | 6,560 | 1,713,629 | 6,715 | 1,980,030 | 155 | 266,401 |
| <i>Budget Authority.....</i> | <i>2,003</i> | <i>495,395</i> | <i>2,003</i> | <i>495,384</i> | <i>2,003</i> | <i>495,395</i> | <i>2,097</i> | <i>713,895</i> | <i>94</i> | <i>218,500</i> |
| <i>User Fees.....</i> | <i>4,332</i> | <i>1,138,348</i> | <i>4,332</i> | <i>1,260,225</i> | <i>4,557</i> | <i>1,218,234</i> | <i>4,618</i> | <i>1,266,135</i> | <i>61</i> | <i>47,901</i> |
| Center..... | 5,261 | 1,432,054 | 5,261 | 1,554,711 | 5,502 | 1,510,169 | 5,624 | 1,749,191 | 122 | 239,022 |
| Budget Authority..... | 1,239 | 359,226 | 1,239 | 359,222 | 1,239 | 359,226 | 1,301 | 551,084 | 62 | 191,858 |
| User Fees..... | 4,022 | 1,072,828 | 4,022 | 1,195,489 | 4,263 | 1,150,943 | 4,323 | 1,198,107 | 60 | 47,164 |
| <i>Prescription Drug (PDUFA).....</i> | 2,627 | 658,620 | 2,627 | 790,598 | 2,603 | 732,096 | 2,648 | 770,854 | 45 | 38,758 |
| <i>Generic Drug (GDUFA).....</i> | 1,282 | 376,601 | 1,282 | 366,873 | 1,463 | 382,803 | 1,463 | 391,330 | --- | 8,527 |
| <i>Biosimilars (BsUFA).....</i> | 105 | 37,028 | 105 | 36,605 | 195 | 35,416 | 210 | 35,001 | 15 | -415 |
| <i>Outsourcing Facility.....</i> | 8 | 579 | 8 | 1,413 | 2 | 628 | 2 | 922 | --- | 294 |
| Field..... | 1,074 | 201,689 | 1,074 | 200,898 | 1,058 | 203,460 | 1,091 | 230,839 | 33 | 27,379 |
| Budget Authority..... | 764 | 136,169 | 764 | 136,162 | 764 | 136,169 | 796 | 162,811 | 32 | 26,642 |
| User Fees..... | 310 | 65,520 | 310 | 64,736 | 294 | 67,291 | 295 | 68,028 | 1 | 737 |
| <i>Prescription Drug (PDUFA).....</i> | 54 | 8,101 | 54 | 7,753 | 38 | 9,003 | 38 | 8,801 | --- | -202 |
| <i>Generic Drug (GDUFA).....</i> | 245 | 55,915 | 245 | 55,355 | 247 | 56,808 | 248 | 57,430 | 1 | 622 |
| <i>Biosimilars (BsUFA).....</i> | 7 | 1,150 | 7 | 1,158 | 7 | 1,100 | 7 | 1,363 | --- | 263 |
| <i>Outsourcing Facility.....</i> | 4 | 354 | 4 | 470 | 2 | 380 | 2 | 434 | --- | 54 |
| Biologics..... | 1,434 | 363,766 | 1,434 | 381,890 | 1,394 | 379,144 | 1,422 | 431,561 | 28 | 52,417 |
| <i>Budget Authority.....</i> | <i>806</i> | <i>217,138</i> | <i>806</i> | <i>217,135</i> | <i>806</i> | <i>217,138</i> | <i>826</i> | <i>262,138</i> | <i>20</i> | <i>45,000</i> |
| <i>User Fees.....</i> | <i>628</i> | <i>146,628</i> | <i>628</i> | <i>164,755</i> | <i>588</i> | <i>162,006</i> | <i>596</i> | <i>169,423</i> | <i>8</i> | <i>7,417</i> |
| Center..... | 1,206 | 320,146 | 1,206 | 338,310 | 1,163 | 335,355 | 1,191 | 387,812 | 28 | 52,457 |
| Budget Authority..... | 583 | 175,132 | 583 | 175,131 | 583 | 175,132 | 603 | 220,132 | 20 | 45,000 |
| User Fees..... | 623 | 145,014 | 623 | 163,179 | 580 | 160,223 | 588 | 167,680 | 8 | 7,457 |
| <i>Prescription Drug (PDUFA).....</i> | 553 | 130,171 | 553 | 151,195 | 520 | 144,529 | 527 | 151,782 | 7 | 7,253 |
| <i>Medical Device (MDUFA).....</i> | 70 | 13,602 | 70 | 11,887 | 54 | 14,444 | 54 | 14,117 | --- | -327 |
| <i>Generic Drug (GDUFA).....</i> | --- | 1,055 | --- | 78 | 4 | 1,072 | 4 | 1,085 | --- | 13 |
| <i>Biosimilars (BsUFA).....</i> | --- | 186 | --- | 19 | 2 | 178 | 3 | 696 | 1 | 518 |
| Field..... | 228 | 43,620 | 228 | 43,580 | 231 | 43,789 | 231 | 43,749 | --- | -40 |
| Budget Authority..... | 223 | 42,006 | 223 | 42,004 | 223 | 42,006 | 223 | 42,006 | --- | --- |
| User Fees..... | 5 | 1,614 | 5 | 1,576 | 8 | 1,783 | 8 | 1,743 | --- | -40 |
| <i>Prescription Drug (PDUFA).....</i> | 4 | 1,410 | 4 | 1,370 | 7 | 1,566 | 7 | 1,532 | --- | -34 |
| <i>Medical Device (MDUFA).....</i> | 1 | 204 | 1 | 206 | 1 | 217 | 1 | 211 | --- | -6 |
| Animal Drugs and Feed..... | 944 | 200,465 | 944 | 210,732 | 956 | 220,030 | 983 | 239,515 | 27 | 19,485 |
| <i>Budget Authority.....</i> | <i>774</i> | <i>174,434</i> | <i>774</i> | <i>174,430</i> | <i>774</i> | <i>174,434</i> | <i>801</i> | <i>192,314</i> | <i>27</i> | <i>17,880</i> |
| <i>User Fees.....</i> | <i>170</i> | <i>26,031</i> | <i>170</i> | <i>36,302</i> | <i>182</i> | <i>45,596</i> | <i>182</i> | <i>47,201</i> | <i>---</i> | <i>1,605</i> |
| Center..... | 627 | 133,595 | 627 | 145,181 | 632 | 152,942 | 659 | 166,904 | 27 | 13,962 |
| Budget Authority..... | 457 | 108,919 | 457 | 108,918 | 457 | 108,919 | 484 | 121,199 | 27 | 12,280 |
| User Fees..... | 170 | 24,676 | 170 | 36,263 | 175 | 44,023 | 175 | 45,705 | --- | 1,682 |
| <i>Animal Drug (ADUFA).....</i> | 117 | 16,095 | 117 | 24,865 | 115 | 27,267 | 115 | 27,706 | --- | 439 |
| <i>Animal Generic Drug (AGDUFA).....</i> | 53 | 8,469 | 53 | 11,375 | 60 | 16,644 | 60 | 17,882 | --- | 1,238 |
| <i>Third Party Auditor Program.....</i> | --- | 112 | --- | 23 | --- | 112 | --- | 117 | --- | 5 |
| Field..... | 317 | 66,870 | 317 | 65,551 | 324 | 67,088 | 324 | 72,611 | --- | 5,523 |
| Budget Authority..... | 317 | 65,515 | 317 | 65,512 | 317 | 65,515 | 317 | 71,115 | --- | 5,600 |
| User Fees..... | --- | 1,355 | --- | 39 | 7 | 1,573 | 7 | 1,496 | --- | -77 |
| <i>Animal Drug (ADUFA).....</i> | --- | 310 | --- | 36 | 2 | 431 | 2 | 440 | --- | 9 |
| <i>Animal Generic Drug (AGDUFA).....</i> | --- | 238 | --- | 3 | 2 | 335 | 2 | 216 | --- | -119 |
| <i>Food Reinspection.....</i> | --- | 807 | --- | --- | 3 | 807 | 3 | 840 | --- | 33 |
| <i>Third Party Auditor Program.....</i> | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |

ALL PURPOSE TABLE

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|---|--|----------------|-----------------|----------------|-----------------------|----------------|----------------------------|----------------|--|----------------|
| | FTE | \$000 | FTE | \$000 | | \$000 | FTE | \$000 | FTE | \$000 |
| | Devices and Radiological Health | 2,159 | 512,901 | 2,159 | 479,930 | 2,328 | 522,838 | 2,399 | 631,718 | 71 |
| <i>Budget Authority</i> | <i>1,539</i> | <i>332,893</i> | <i>1,539</i> | <i>332,885</i> | <i>1,539</i> | <i>332,893</i> | <i>1,565</i> | <i>423,893</i> | <i>26</i> | <i>91,000</i> |
| <i>User Fees</i> | <i>620</i> | <i>180,008</i> | <i>620</i> | <i>147,045</i> | <i>789</i> | <i>189,945</i> | <i>834</i> | <i>207,825</i> | <i>45</i> | <i>17,880</i> |
| Center | 1,647 | 411,791 | 1,647 | 381,463 | 1,816 | 421,598 | 1,887 | 529,978 | 71 | 108,380 |
| Budget Authority | 1,045 | 247,888 | 1,045 | 247,884 | 1,045 | 247,888 | 1,071 | 338,888 | 26 | 91,000 |
| User Fees | 602 | 163,903 | 602 | 133,579 | 771 | 173,710 | 816 | 191,090 | 45 | 17,380 |
| <i>Prescription Drug (PDUFA)</i> | 5 | 1,320 | 5 | 987 | 10 | 1,460 | 15 | 4,272 | 5 | 2,812 |
| <i>Medical Device (MDUFA)</i> | 569 | 156,148 | 569 | 126,998 | 729 | 165,815 | 769 | 180,125 | 40 | 14,310 |
| <i>Mammography Quality Standards Act (MQSA)</i> | 28 | 6,435 | 28 | 5,594 | 32 | 6,435 | 32 | 6,693 | --- | 258 |
| Field | 512 | 101,110 | 512 | 98,467 | 512 | 101,240 | 512 | 101,740 | --- | 500 |
| Budget Authority | 494 | 85,005 | 494 | 85,001 | 494 | 85,005 | 494 | 85,005 | --- | --- |
| User Fees | 18 | 16,105 | 18 | 13,466 | 18 | 16,235 | 18 | 16,735 | --- | 500 |
| <i>Medical Device (MDUFA)</i> | 11 | 2,110 | 11 | 2,086 | 10 | 2,240 | 10 | 2,179 | --- | -61 |
| <i>Mammography Quality Standards Act (MQSA)</i> | 7 | 13,995 | 7 | 11,380 | 8 | 13,995 | 8 | 14,556 | --- | 561 |
| National Center for Toxicological Research (BA Only) | 301 | 64,512 | 301 | 64,512 | 301 | 64,512 | 301 | 66,512 | --- | 2,000 |
| Tobacco | 874 | 626,663 | 874 | 625,406 | 991 | 626,663 | 1,053 | 761,739 | 62 | 135,076 |
| Center | 821 | 611,979 | 821 | 614,794 | 932 | 611,979 | 992 | 747,055 | 60 | 135,076 |
| <i>Family Smoking Prevention and Tobacco Control Act</i> | 821 | 611,979 | 821 | 614,794 | 932 | 611,979 | 992 | 647,055 | 60 | 35,076 |
| <i>Expand tobacco product (Proposed)</i> | --- | --- | --- | --- | --- | --- | --- | 100,000 | --- | 100,000 |
| Field | 53 | 14,684 | 53 | 10,612 | 59 | 14,684 | 61 | 14,684 | 2 | --- |
| <i>Family Smoking Prevention and Tobacco Control Act</i> | 53 | 14,684 | 53 | 10,612 | 59 | 14,684 | 61 | 14,684 | 2 | --- |
| FDA Headquarters | 943 | 290,638 | 943 | 315,684 | 1,001 | 299,587 | 1,018 | 320,164 | 17 | 20,577 |
| <i>Budget Authority</i> | <i>591</i> | <i>171,195</i> | <i>591</i> | <i>171,001</i> | <i>591</i> | <i>171,195</i> | <i>620</i> | <i>180,195</i> | <i>29</i> | <i>9,000</i> |
| <i>User Fees</i> | <i>352</i> | <i>119,443</i> | <i>352</i> | <i>144,683</i> | <i>410</i> | <i>128,392</i> | <i>398</i> | <i>139,969</i> | <i>-12</i> | <i>11,577</i> |
| <i>Prescription Drug (PDUFA)</i> | 176 | 50,082 | 176 | 60,244 | 186 | 56,391 | 187 | 59,194 | 1 | 2,803 |
| <i>Medical Device (MDUFA)</i> | 16 | 7,811 | 16 | 7,297 | 31 | 8,463 | 31 | 9,209 | --- | 746 |
| <i>Generic Drug (GDUFA)</i> | 50 | 34,489 | 50 | 27,947 | 103 | 35,243 | 103 | 35,784 | --- | 541 |
| <i>Biosimilars (BsUFA)</i> | 7 | 706 | 7 | 1,393 | 5 | 632 | 5 | 1,022 | --- | 390 |
| <i>Animal Drug (ADUFA)</i> | 4 | 446 | 4 | 828 | 4 | 1,004 | 4 | 734 | --- | -270 |
| <i>Animal Generic Drug (AGDUFA)</i> | 1 | 63 | 1 | 73 | 1 | 785 | 1 | 26 | --- | -759 |
| <i>Family Smoking Prevention and Tobacco Control Act</i> | 97 | 24,491 | 97 | 46,921 | 74 | 24,491 | 61 | 30,867 | -13 | 6,376 |
| <i>Mammography Quality Standards Act (MQSA)</i> | 1 | 92 | 1 | -20 | 2 | 92 | 2 | 102 | --- | 10 |
| <i>Innovative Food Products (Proposed)</i> | --- | --- | --- | --- | --- | --- | --- | 1,900 | --- | 1,900 |
| <i>Food and Feed Recall</i> | --- | 75 | --- | --- | --- | 75 | --- | 78 | --- | 3 |
| <i>Food Reinspection</i> | --- | 480 | --- | --- | 2 | 480 | 2 | 499 | --- | 19 |
| <i>Voluntary Qualified Importer Program</i> | --- | 277 | --- | --- | 1 | 277 | 1 | 288 | --- | 11 |
| <i>Third Party Auditor Program</i> | --- | 39 | --- | --- | --- | 39 | --- | 41 | --- | 2 |
| <i>Outsourcing Facility</i> | --- | 392 | --- | --- | 1 | 420 | 1 | 225 | --- | -195 |
| FDA White Oak Consolidation | --- | 50,559 | --- | 49,453 | --- | 50,772 | --- | 58,926 | --- | 8,154 |
| <i>Budget Authority</i> | --- | <i>43,044</i> | --- | <i>43,044</i> | --- | <i>43,044</i> | --- | <i>50,927</i> | --- | <i>7,883</i> |
| <i>User Fees</i> | --- | <i>7,515</i> | --- | <i>6,409</i> | --- | <i>7,728</i> | --- | <i>7,999</i> | --- | <i>271</i> |
| <i>Prescription Drug (PDUFA)</i> | --- | 3,597 | --- | 3,597 | --- | 3,810 | --- | 3,848 | --- | 38 |
| <i>Medical Device (MDUFA)</i> | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| <i>Generic Drug (GDUFA)</i> | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| <i>Biosimilars (BsUFA)</i> | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| <i>Animal Drug (ADUFA)</i> | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| <i>Animal Generic Drug (AGDUFA)</i> | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| <i>Family Smoking Prevention and Tobacco Control Act</i> | --- | 3,918 | --- | 2,812 | --- | 3,918 | --- | 4,151 | --- | 233 |

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|--|------------------------------------|-----------|-----------------|-----------|-----------------------|-----------|----------------------------|-----------|--|---------|
| | FTE | \$000 | FTE | \$000 | | \$000 | FTE | \$000 | FTE | \$000 |
| | Other Rent and Rent Related | --- | 121,919 | --- | 121,530 | --- | 123,881 | --- | 146,251 | --- |
| <i>Budget Authority</i> | --- | 71,943 | --- | 71,943 | --- | 71,943 | --- | 93,444 | --- | 21,501 |
| <i>User Fees</i> | --- | 49,976 | --- | 49,587 | --- | 51,938 | --- | 52,807 | --- | 869 |
| <i>Prescription Drug (PDUFA)</i> | --- | 24,672 | --- | 26,163 | --- | 26,127 | --- | 26,389 | --- | 262 |
| <i>Medical Device (MDUFA)</i> | --- | 5,187 | --- | 8,672 | --- | 5,239 | --- | 5,291 | --- | 52 |
| <i>Generic Drug (GDUFA)</i> | --- | 12,946 | --- | 9,426 | --- | 13,075 | --- | 13,206 | --- | 131 |
| <i>Biosimilars (BsUFA)</i> | --- | 805 | --- | 766 | --- | 1,070 | --- | 1,081 | --- | 11 |
| <i>Animal Drug (ADUFA)</i> | --- | 720 | --- | 720 | --- | 790 | --- | 797 | --- | 7 |
| <i>Animal Generic Drug (AGDUFA)</i> | --- | 273 | --- | 261 | --- | 264 | --- | 266 | --- | 2 |
| <i>Family Smoking Prevention and Tobacco Control Act</i> | --- | 4,898 | --- | 3,579 | --- | 4,898 | --- | 5,283 | --- | 385 |
| <i>Food and Feed Recall</i> | --- | 43 | --- | --- | --- | 43 | --- | 45 | --- | 2 |
| <i>Food Reinspection</i> | --- | 204 | --- | --- | --- | 204 | --- | 212 | --- | 8 |
| <i>Voluntary Qualified Importer Program</i> | --- | 170 | --- | --- | --- | 170 | --- | 177 | --- | 7 |
| <i>Third Party Auditor Program</i> | --- | 24 | --- | --- | --- | 24 | --- | 25 | --- | 1 |
| <i>Outsourcing Facility</i> | --- | 34 | --- | --- | --- | 34 | --- | 35 | --- | 1 |
| GSA Rental Payments | --- | 238,487 | --- | 219,283 | --- | 241,024 | --- | 240,928 | --- | -96 |
| <i>Budget Authority</i> | --- | 170,208 | --- | 170,208 | --- | 170,208 | --- | 171,570 | --- | 1,362 |
| <i>User Fees</i> | --- | 68,279 | --- | 49,075 | --- | 70,816 | --- | 69,358 | --- | -1,458 |
| <i>Prescription Drug (PDUFA)</i> | --- | 33,373 | --- | 20,205 | --- | 35,341 | --- | 35,695 | --- | 354 |
| <i>Medical Device (MDUFA)</i> | --- | 8,229 | --- | 8,229 | --- | 8,312 | --- | 8,395 | --- | 83 |
| <i>Generic Drug (GDUFA)</i> | --- | 12,594 | --- | 12,594 | --- | 12,720 | --- | 12,847 | --- | 127 |
| <i>Biosimilars (BsUFA)</i> | --- | 339 | --- | 339 | --- | 451 | --- | 455 | --- | 4 |
| <i>Animal Drug (ADUFA)</i> | --- | 522 | --- | 522 | --- | 839 | --- | 847 | --- | 8 |
| <i>Animal Generic Drug (AGDUFA)</i> | --- | 376 | --- | 304 | --- | 307 | --- | 310 | --- | 3 |
| <i>Family Smoking Prevention and Tobacco Control Act</i> | --- | 12,030 | --- | 6,882 | --- | 12,030 | --- | 9,960 | --- | -2,070 |
| <i>Food and Feed Recall</i> | --- | 73 | --- | --- | --- | 73 | --- | 76 | --- | 3 |
| <i>Food Reinspection</i> | --- | 348 | --- | --- | --- | 348 | --- | 362 | --- | 14 |
| <i>Voluntary Qualified Importer Program</i> | --- | 290 | --- | --- | --- | 290 | --- | 302 | --- | 12 |
| <i>Third Party Auditor Program</i> | --- | 47 | --- | --- | --- | 47 | --- | 49 | --- | 2 |
| <i>Outsourcing Facility</i> | --- | 58 | --- | --- | --- | 58 | --- | 60 | --- | 2 |
| Color Certification | 36 | 10,125 | 36 | 10,006 | 37 | 10,062 | 37 | 10,534 | --- | 472 |
| Export Certification | 22 | 4,696 | 22 | 4,166 | 26 | 4,696 | 26 | 4,696 | --- | --- |
| Export Certification (Proposed) | --- | --- | --- | --- | --- | --- | --- | 4,280 | --- | 4,280 |
| Priority Review Vouchers (PRV) Tropical Disease | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Priority Review Vouchers (PRV) Pediatric Disease | 1 | 7,686 | 1 | 298 | --- | 7,686 | --- | 7,997 | --- | 311 |
| Over the Counter Monograph (Proposed) | --- | --- | --- | --- | --- | --- | --- | 28,400 | --- | 28,400 |
| Food and Drug Safety -- No Year (P.L. 113-6) | --- | --- | --- | 766 | --- | --- | --- | --- | --- | --- |
| Food Safety | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Drug Safety | --- | --- | --- | 766 | --- | --- | --- | --- | --- | --- |
| 21st Century Cures (BA Only) | 100 | 60,000 | 100 | 41,458 | 72 | 60,000 | 100 | 75,000 | 28 | 15,000 |
| MCMi -- No Year | --- | --- | 5 | 3,554 | --- | --- | --- | --- | --- | --- |
| Opioids -- No Year | 8 | 94,000 | 8 | 12,749 | 8 | 94,000 | --- | --- | -8 | -94,000 |
| Subtotal, Salaries and Expenses | 17,018 | 5,350,347 | 17,023 | 5,356,317 | 17,579 | 5,488,711 | 18,062 | 6,130,298 | 483 | 641,587 |
| Buildings and Facilities (Budget Authority) | --- | 11,788 | --- | 14,618 | --- | 11,788 | --- | 11,788 | --- | --- |
| Total Program Level | 17,018 | 5,362,135 | 17,018 | 5,367,381 | 17,607 | 5,500,499 | 18,062 | 6,142,086 | 483 | 641,587 |

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| | FTE | \$000 | FTE | \$000 | FTE | \$000 | FTE | \$000 | FTE | \$000 |
| <i>Non-Field Activities</i> | 12,012 | 3,614,266 | 12,012 | 3,755,335 | 12,560 | 3,745,630 | 12,965 | 4,385,201 | 405 | 639,571 |
| <i>Field Activities</i> | 4,898 | 1,171,116 | 4,898 | 1,152,189 | 4,939 | 1,173,404 | 4,997 | 1,223,992 | 58 | 50,588 |
| <i>White Oak, Rent Activities, and B&F</i> | --- | 422,753 | --- | 404,884 | --- | 427,465 | --- | 457,893 | --- | 30,428 |
| <i>Food and Drug Safety -- No Year</i> | --- | --- | --- | 766 | --- | --- | --- | --- | --- | --- |
| <i>Opioids -- No Year</i> | 8 | 94,000 | 8 | 12,749 | 8 | 94,000 | --- | --- | -8 | -94,000 |
| <i>21st Century Cures</i> | 100 | 60,000 | 100 | 41,458 | 100 | 60,000 | 100 | 75,000 | 28 | 15,000 |
| <i>MCMi -- No Year</i> | --- | --- | 5 | 3,554 | --- | --- | --- | --- | --- | --- |
| User Fees: | | | | | | | | | | |
| Current Law | | | | | | | | | | |
| <i>Prescription Drug (PDUFA)</i> | 3,419 | 911,346 | 3,419 | 1,062,112 | 3,364 | 1,010,323 | 3,422 | 1,062,367 | 58 | 52,044 |
| <i>Medical Device (MDUFA)</i> | 667 | 193,291 | 667 | 165,375 | 825 | 204,730 | 865 | 219,527 | 40 | 14,797 |
| <i>Generic Drug (GDUFA)</i> | 1,577 | 493,600 | 1,577 | 472,273 | 1,817 | 501,721 | 1,818 | 511,682 | 1 | 9,961 |
| <i>Biosimilars (BsUFA)</i> | 119 | 40,214 | 119 | 40,280 | 209 | 38,847 | 225 | 39,618 | 16 | 771 |
| <i>Animal Drug (ADUFA)</i> | 121 | 18,093 | 121 | 26,971 | 121 | 30,331 | 121 | 30,524 | --- | 193 |
| <i>Animal Generic Drug (AGDUFA)</i> | 54 | 9,419 | 54 | 12,016 | 63 | 18,335 | 63 | 18,700 | --- | 365 |
| <i>Family Smoking Prevention and Tobacco Control Act</i> | 971 | 672,000 | 971 | 685,600 | 1,065 | 672,000 | 1,114 | 712,000 | 49 | 40,000 |
| Subtotal, Current Law | 6,928 | 2,337,963 | 6,928 | 2,464,627 | 7,464 | 2,476,287 | 7,628 | 2,594,418 | 164 | 118,131 |
| Indefinite | | | | | | | | | | |
| <i>Mammography Quality Standards Act (MQSA)</i> | 36 | 20,522 | 36 | 16,954 | 42 | 20,522 | 42 | 21,351 | --- | 829 |
| <i>Color Certification</i> | 36 | 10,125 | 36 | 10,006 | 37 | 10,062 | 37 | 10,534 | --- | 472 |
| <i>Export Certification</i> | 22 | 4,696 | 22 | 4,166 | 26 | 4,696 | 26 | 4,696 | --- | --- |
| <i>Priority Review Vouchers (PRV) Tropical Disease</i> | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| <i>Priority Review Vouchers (PRV) Pediatric Disease</i> | 1 | 7,686 | 1 | 298 | --- | 7,686 | --- | 7,997 | --- | 311 |
| <i>Food and Feed Recall</i> | --- | 1,434 | --- | --- | 5 | 1,434 | 5 | 1,492 | --- | 58 |
| <i>Food Reinspection</i> | --- | 6,414 | --- | --- | 24 | 6,414 | 24 | 6,673 | --- | 259 |
| <i>Voluntary Qualified Importer Program</i> | --- | 5,300 | --- | --- | 20 | 5,300 | 20 | 5,515 | --- | 215 |
| <i>Third Party Auditor Program</i> | --- | 712 | --- | 23 | 1 | 712 | 1 | 742 | --- | 30 |
| <i>Outsourcing Facility</i> | 12 | 1,417 | 12 | 1,883 | 5 | 1,520 | 5 | 1,676 | --- | 156 |
| Subtotal, Indefinite | 107 | 58,306 | 107 | 33,330 | 160 | 58,346 | 160 | 60,676 | --- | 2,330 |
| Proposed | | | | | | | | | | |
| <i>Export Certification (Proposed)</i> | --- | --- | --- | --- | --- | --- | --- | 4,280 | --- | 4,280 |
| <i>Over the Counter Monograph (Proposed)</i> | --- | --- | --- | --- | --- | --- | --- | 28,400 | --- | 28,400 |
| <i>Innovative Food Products (Proposed)</i> | --- | --- | --- | --- | --- | --- | 52 | 28,000 | 52 | 28,000 |
| <i>Expand tobacco product (Proposed)</i> | --- | --- | --- | --- | --- | --- | --- | 100,000 | --- | 100,000 |
| Subtotal, Proposed | --- | --- | --- | --- | --- | --- | 52 | 160,680 | 52 | 160,680 |
| Total User Fees | 7,035 | 2,396,269 | 7,035 | 2,497,957 | 7,624 | 2,534,633 | 7,840 | 2,815,774 | 216 | 281,141 |
| Total Budget Authority, Pre-Transfer | 9,983 | 2,965,866 | 9,988 | 2,872,978 | 9,983 | 2,965,866 | 10,222 | 3,326,312 | 239 | 360,446 |
| <i>BA, S&E</i> | 9,875 | 2,800,078 | 9,875 | 2,799,833 | 9,875 | 2,800,078 | 10,122 | 3,239,524 | 247 | 439,446 |
| <i>BA, B&F</i> | --- | 11,788 | --- | 14,618 | --- | 11,788 | --- | 11,788 | --- | --- |
| <i>Opioids -- No Year</i> | 8 | 94,000 | 8 | 12,749 | 8 | 94,000 | --- | --- | -8 | -94,000 |
| <i>21st Century Cures</i> | 100 | 60,000 | 100 | 41,458 | 100 | 60,000 | 100 | 75,000 | --- | 15,000 |
| <i>MCMi -- No Year</i> | --- | --- | 5 | 3,554 | --- | --- | --- | --- | --- | --- |
| Total Program Level, Pre-Transfer | 17,018 | 5,362,135 | 17,023 | 5,370,935 | 17,607 | 5,500,499 | 18,062 | 6,142,086 | 455 | 641,587 |
| HHS OIG transfer (BA Only) | --- | -1,500 | --- | -1,500 | --- | -1,500 | --- | --- | --- | 1,500 |
| Total Budget Authority, Post-Transfer | 9,983 | 2,964,366 | 9,988 | 2,871,478 | 9,983 | 2,964,366 | 10,222 | 3,326,312 | 239 | 361,946 |
| Total User Fees | 7,035 | 2,396,269 | 7,035 | 2,497,957 | 7,624 | 2,534,633 | 7,840 | 2,815,774 | 216 | 281,141 |
| Total Program Level, Post-Transfer | 17,018 | 5,360,635 | 17,023 | 5,369,435 | 17,607 | 5,498,999 | 18,062 | 6,142,086 | 455 | 643,087 |
| Nonrecurring Expenses Fund (NEF) (non-add) | | | | | | | | | | |
| Hurricane Funding Transfer to S&E | | | | 187 | | | | | | |

*For 2018, the Pre-Transfer levels do not reflect the transfer of \$1.5 million from FDA Headquarters to the HHS Office of Inspector General to support oversight of FDA's expanded authorities.

**FTE figures do not include an estimated 87 reimbursable, 2 CRADA, 2 FOIA, and 36 PEPFAR. The table also excludes Opioids – IMF FTE supported with one-time funding provided via the FY 2018 Omnibus. Table includes additional base funding as part of the Opioids IMF initiative to maintain these staffing levels.

***The Drug Quality and Security Act (P.L. 113-54) authorized FDA to collect fees for the licensure and inspection of certain third-party logistics providers and wholesale drug distributors. 21 U.S.C. §§ 360eee-3(c); 353(e)(3). The program is still under development and a fee estimate is not available at this time.

****Color Certification does not reflect the availability of mandatory funds sequestered in the prior fiscal year.

*****In addition to the funding displayed in FY 2018 Enacted column, the Further Additional Supplemental Appropriations for Disaster Relief and Requirement Act, 2018 included \$7.6 million in one-time, no-year funding for FDA.

*****Does not reflect priority review voucher user fee for Medical Countermeasures as no companies have announced planned use of the voucher.

*****Funding and FTE levels for FYs 2018 - 2020 have been comparably adjusted to reflect the realignment of: intergovernmental affairs (IGA) FTE to FDA HQ; operational support FTE from FDA HQ to the centers and offices as part of implementation of FDA's Working Capital Fund (WCF); and FDA HQ organizations as per the December 2018 Congressional Notification.

*****FY 2020 NEF budget allocations will be provided upon settlement of the FY 2019 NEF Congressional Notification.

*****FY 2019 Enacted reflects the amount specified in the August 2018 FR Notice for Outsourcing Facility Fees.