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United States Government Accountability Office
Washington, DC 20548

March 30, 2007

The Honorable Joe Barton
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

Subject: *Food and Drug Administration: Revenue Information on Certain Companies
Participating in the Medical Device User Fee Program*

Dear Mr. Barton:

The Food and Drug Administration (FDA) is responsible for approving medical devices—such as catheters and artificial hearts—to provide reasonable assurance of their safety and effectiveness. As part of this responsibility, FDA, an agency within the Department of Health and Human Services (HHS), reviews applications submitted by medical device companies for devices they wish to market in the United States, including devices that are new or those that constitute modifications to already approved devices. Prior to 2002, members of Congress, representatives of the medical device industry, and others expressed concern that FDA lacked the resources necessary to complete such reviews in a timely manner to ensure that patients have access to useful, possibly life-saving, devices. In response, Congress enacted the Medical Device User Fee and Modernization Act of 2002 (MDUFMA),¹ which authorizes FDA to charge user fees for some device applications and not others. Revenues from the user fees, together with additional appropriations that were also authorized by MDUFMA, were intended to provide additional resources to FDA for improving the timeliness of device review. In fiscal year 2005, FDA collected approximately \$31 million in user fees from device applications.

Under the MDUFMA user fee program, fees for individual medical device applications range from under \$5,000 to more than \$250,000.² Higher fees are charged for applications that require more review. One of the applications with a higher user fee—\$259,600 in fiscal year 2006—is the Original Premarket Approval (PMA) application. A PMA is submitted for a device that supports or sustains human life, is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury. One of the applications with a lower user fee—\$3,833 in fiscal year 2006—is a Premarket Notification. A Premarket Notification is submitted for devices that are substantially equivalent to a legally marketed device that was not subject to premarket approval.

¹Pub. L. No. 107-250, 116 Stat. 1588.

²MDUFMA includes provisions for user fee amounts for fiscal years 2006 and 2007.

To help ensure that user fees are not financially prohibitive for small medical device companies, MDUFMA provides that companies qualifying as small businesses in a given fiscal year can receive fee discounts and, in certain cases, fee waivers. To qualify as a small business under MDUFMA, a company must submit information to FDA demonstrating that its annual revenues—including the revenues of any affiliate, partner, or parent firm³—are at or below a certain threshold. MDUFMA originally set the threshold for small business qualification at \$30 million, and in 2005, the threshold was increased to \$100 million by the Medical Device User Fee Stabilization Act of 2005 (MDUFSA).⁴ All companies qualifying as small businesses under the \$100 million threshold pay reduced fees when submitting applications subject to user fees. In 2006, for example, the discounted PMA fee was \$98,648, or 38 percent of the full fee of \$259,600. Originally, MDUFMA also provided that companies qualifying as small businesses receive a fee waiver the first time ever they submit one of certain applications that generally have higher fees.⁵ While MDUFSA raised the small business threshold to \$100 million, it provided that only companies with annual revenues of \$30 million or less could continue to receive fee waivers.

FDA's authority to collect user fees will sunset October 1, 2007. You asked us to provide annual revenue information for companies participating in the MDUFMA user fee program to assist Congress as it determines whether changes to the threshold for small business qualification are needed. Revenue information is available for companies that qualify as small businesses, which submit annual revenue information to FDA, and publicly traded companies, which register securities with, and submit annual revenue information to, the Securities and Exchange Commission (SEC).⁶ In this report, we provide revenue information for (1) companies that qualified as small businesses under the MDUFMA user fee program in fiscal year 2006 and (2) companies publicly traded in the United States that submitted device applications subject to user fees and did not qualify as small businesses under MDUFMA in fiscal year 2006.

³Specifically, MDUFMA requires companies to submit their most recent federal income tax returns to FDA so that FDA can verify the "gross sales or receipts" reported by the company and any affiliate, partner, or parent firm.

⁴Pub. L. No. 109-43, § 2(a)(3)(B)(iii), 119 Stat. 439, 440.

⁵These applications include the PMA, the Biologics License Application (BLA), the Premarket Report, and the Product Development Protocol (PDP). The user fee for each of these applications was \$259,600 in fiscal year 2006.

⁶While companies seeking small business qualification must submit to FDA "gross sales or receipts" information from their most recent U.S. tax returns, companies that are publicly traded must submit to SEC gross revenue information in a financial income statement. Both gross sales or receipts and gross revenues are general measures of annual revenue. However, annual revenues reported on a company's financial statement filed with SEC may not be identical to gross sales or receipts reported to the Internal Revenue Service for the same period. Taxable income reported on the tax return is computed in accordance with prescribed federal tax regulations and rules, whereas, pretax financial income reported on financial statements filed with SEC is measured in accordance with generally accepted accounting principles (GAAP). Because tax regulations and GAAP are different, taxable income and pretax financial income can differ.

To provide annual revenues for companies qualifying as small businesses under the MDUFMA user fee program in fiscal year 2006, we obtained annual revenue data from FDA on these companies. To gather information about the MDUFMA user fee program, we interviewed FDA officials as well as representatives of the Medical Device Manufacturers Association. To provide annual revenues for companies publicly traded in the United States that submitted device applications subject to user fees and did not qualify as small businesses in fiscal year 2006, we obtained (1) company information from FDA on all device applications the agency received in fiscal year 2006 that were subject to user fees and (2) SEC data compiled by two private data vendors, Mergent and Audit Analytics. We then matched companies submitting device applications to publicly traded companies in the Audit Analytics and Mergent databases.⁷ We assessed the reliability of FDA data by conducting interviews with FDA staff to understand how FDA collects and uses the data. We assessed the reliability of data from the two private data vendors by comparing actual financial information in SEC filings with financial information provided by the vendors for a sample of companies. Our results cannot be generalized to all companies that submitted device applications in fiscal year 2006. Together, companies qualifying as small businesses and publicly traded companies that were not qualified small businesses were responsible for about 50 percent of the approximately 4,500 device applications subject to user fees that were submitted in fiscal year 2006. We were unable to obtain revenue information for companies responsible for submitting the remaining 50 percent of applications. Because we identified applications submitted by companies that qualified as small businesses and publicly traded companies that did not qualify as small businesses, the remaining applications were likely submitted by private companies that did not qualify as small businesses. We were unable to identify the number of these companies. Enclosure I contains a more detailed description of our methodology. We conducted our work from October 2006 through March 2007 according to generally accepted government auditing standards.

Results in Brief

Of the 697 companies that qualified as small businesses under the MDUFMA user fee program in fiscal year 2006, 656, or about 95 percent, had revenues at or below \$30 million—the threshold for small business qualification originally set by MDUFMA in 2002. Of the 41 companies that had revenues above \$30 million but at or below the current threshold of \$100 million, 35 had revenues above \$30 million but at or below \$70 million. Of the 697 companies that qualified as small businesses in fiscal year 2006, two-thirds submitted at least one device application subject to user fees during that year. These companies were responsible for about 20 percent of the approximately 4,500 device applications subject to user fees that were submitted to FDA in fiscal year 2006.

We identified annual revenues for 258 publicly traded companies that submitted applications subject to user fees and did not qualify as small businesses in fiscal year 2006. Of these companies, 155, or about 60 percent, had annual revenues that were higher than \$500 million. Another 47 companies had annual revenues above \$100 million but at or below \$500 million.

⁷Companies that register their securities with SEC, which are referred to as registrants, may have direct or indirect control of other companies, which are referred to as their subsidiaries. For the remainder of this report, “publicly traded company” refers to either a registrant or a subsidiary of a registrant.

The remaining 56 companies had revenues at or below the current \$100 million threshold for small business qualification. We did not determine why these companies were not qualified as small businesses. In total, the 258 publicly traded companies were responsible for about 30 percent of the approximately 4,500 applications subject to user fees that were submitted to FDA in fiscal year 2006.

HHS reviewed a draft of this report and provided technical comments, which we incorporated as appropriate.

Background

Under the Federal Food, Drug, and Cosmetic Act,⁸ FDA is responsible for ensuring that medical devices are reasonably safe and effective, among other things, before they become commercially available.⁹ Two FDA centers, the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER), are responsible for reviewing applications to market medical devices.¹⁰ CDRH reviews applications for the majority of these devices, such as artificial hearts, dialysis machines, and radiological devices. CBER reviews applications for devices used in the testing and manufacture of biological products, including diagnostic tests intended to screen blood donors (such as for human immunodeficiency virus (HIV)), as well as therapeutic devices used in cell and gene therapies.

Under MDUFMA, FDA is authorized to collect user fees from device companies for some device applications and not others.¹¹ Companies that are not qualified small businesses pay the standard user fee for the applications they submit. Companies that qualify as small businesses by demonstrating that they meet the \$100 million threshold pay a percentage of the standard user fee, with the amount of the discount depending on the application. In addition, the subset of companies that qualify as small businesses and have demonstrated annual revenues at or below \$30 million receive a fee waiver the first time ever they submit one of certain applications that would have higher fees. Table 1 provides a description of the applications subject to user fees and the standard and discounted small business fees for fiscal year 2006.

⁸Ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301 et seq. (2000)).

⁹Under the act, FDA is also responsible for ensuring that medical devices remain safe after they become commercially available. For example, FDA inspects medical device companies' manufacturing establishments to assess compliance with good manufacturing practices.

¹⁰In general, an application to market a medical device includes information on the device and its components. It also contains proposed labeling for the device and, when applicable, clinical and nonclinical studies that provide reasonable assurance of the device's safety and effectiveness.

¹¹For example, FDA may charge a user fee for BLAs, which companies submit to FDA in order to introduce and license biological products for interstate commerce. MDUFMA does not authorize FDA to charge a fee for a BLA manufacturing supplement, which is a request to change the manufacture of an approved biological product and generally does not require submission of substantive clinical data.

Table 1: Device Applications Subject to User Fees under MDUFMA in Fiscal Year 2006

Application	Purpose of application	Standard user fee	Small business discount user fee^a
PMA	Request for approval of a device that supports or sustains human life, is of substantial importance in preventing impairment of human health, or which presents a potential unreasonable risk of illness or injury	\$259,600	\$98,648
Product Development Protocol (PDP)	An alternative review process for a device that would otherwise require a PMA; a key feature is that the applicant and FDA agree in advance concerning the data that must be developed to demonstrate that the device is safe and effective	259,600	98,648
Premarket Report	Request for approval of a high-risk device originally approved for single use—that is, use on a single patient during a single procedure—that a manufacturer has reprocessed for additional use	259,600	98,648
Panel-track PMA Supplement	Request for approval of a significant change in the design or performance of an approved device, or for a new purpose for using the approved device, when demonstration of reasonable assurance of safety and effectiveness requires significant clinical data	259,600	98,648
180-day PMA Supplements	Request for approval of a significant change in aspects of an approved device, such as its design, specifications, or labeling, when demonstration of reasonable assurance of safety and effectiveness either does not require new clinical data or requires only limited clinical data	55,814	21,209
Real-time PMA Supplement	Request for approval of a minor change to an approved device, such as a minor change in the design or labeling	18,691	7,103
Premarket Notification/510(k) ^b	Request for approval of a device that is substantially equivalent to a legally marketed device that was not subject to premarket approval	3,833	3,066
Biologics License Application (BLA)	Request for approval to introduce and license biological products for interstate commerce	259,600	98,648
BLA Efficacy Supplement	A supplement to an approved premarket application that requires substantive clinical data	259,600	98,648

Source: FDA.

Note: Companies with annual revenues at or below \$30 million receive a fee waiver the first time ever they submit a PMA, PDP, Premarket Report, or BLA as a qualified small business.

^aThe amount of the discounted user fee for a particular application is determined by multiplying the standard user fee for that application by a percentage amount specified by MDUFMA for that application. For PMAs, PDPs, Premarket Reports, Panel-track PMA Supplements, 180-day PMA Supplements, Real-time PMA Supplements, BLAs, and BLA Efficacy Supplements, the percentage is 38 percent. For Premarket Notifications, the percentage is 80 percent.

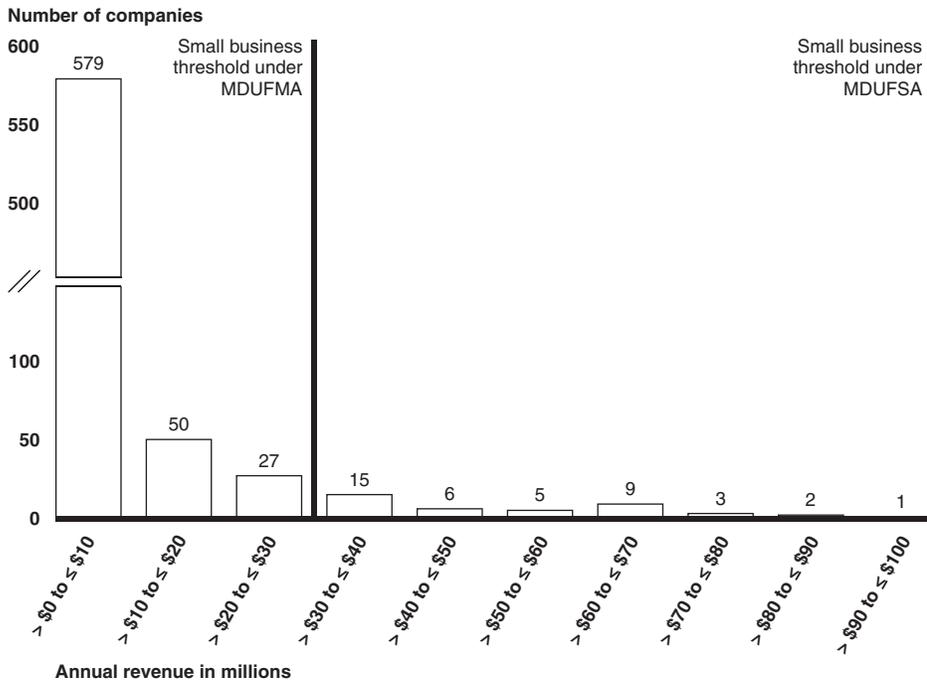
^bFDA refers to a Premarket Notification submission as a 510(k) because the requirement for it is set out in § 510(k) of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 360(k) (2000).

In order to evaluate a company for small business qualification, MDUFMA requires that FDA verify the “gross sales or receipts” reported on the most recent federal income tax returns by the company and any affiliate, partner, or parent firm. Companies must certify that they have furnished accurate copies of their income tax returns and those of any affiliate, partner, or parent firm. If a company cannot provide a copy of its most recent federal income tax return or that of any affiliate, partner, or parent firm—for example, if the company operates overseas and does not report some or all of its revenues on federal income tax returns—the company cannot qualify as a small business.

Most Companies Qualifying as Small Businesses under the MDUFMA User Fee Program in Fiscal Year 2006 Had Annual Revenues at or below \$30 Million

We obtained annual revenues for 697 companies qualifying as small businesses in fiscal year 2006. (See fig. 1.) According to FDA data, 656 of these companies, or about 95 percent, had revenues at or below \$30 million—the threshold for small business qualification originally set by MDUFMA in 2002. Of the 41 companies that had revenues above \$30 million but at or below the current threshold of \$100 million set by MDUFSA in 2005, 35 had revenues above \$30 million but at or below \$70 million.

Figure 1: Annual Revenues of Companies Qualifying as Small Businesses under the MDUFMA User Fee Program in Fiscal Year 2006



Source: GAO analysis of FDA data.

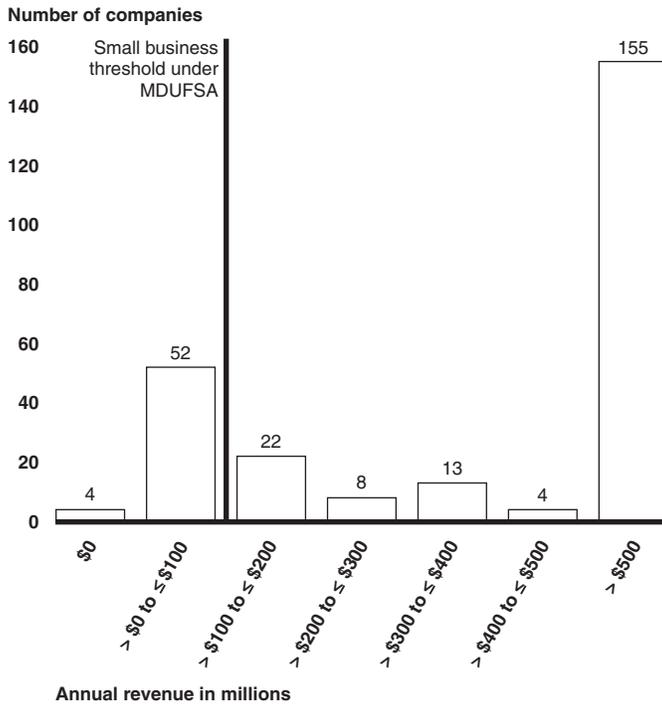
Note: MDUFMA originally set the threshold for small business qualification at \$30 million. In 2005, MDUFSA modified MDUFMA by, among other things, raising the threshold for small business qualification to \$100 million.

About two-thirds of the 697 companies qualifying as small businesses in fiscal year 2006 submitted a device application subject to user fees during that year. Specifically, 439 companies submitted at least one application that year, and these companies were responsible for about 20 percent of the approximately 4,500 applications subject to user fees that were submitted to FDA in fiscal year 2006.

Most Publicly Traded Companies That Submitted Device Applications and Were Not Qualified Small Businesses Had Annual Revenues above \$500 Million in Fiscal Year 2006

We obtained annual revenues for 258 publicly traded companies that submitted device applications subject to user fees and did not qualify as small businesses in fiscal year 2006. (See fig. 2.) Using SEC data we obtained from two private data vendors, we found that 155 of these companies, or about 60 percent, had annual revenues above \$500 million. An additional 47 companies had annual revenues above \$100 million but at or below \$500 million for fiscal year 2006. The remaining 56 companies had annual revenues at or below the current small business threshold of \$100 million, including 4 companies that reported revenues of \$0.¹² Altogether, these 258 publicly traded companies were responsible for about 30 percent of the approximately 4,500 applications subject to user fees that were submitted to FDA in fiscal year 2006. Enclosure II contains more information on the types and numbers of device applications the companies submitted.

Figure 2: Annual Revenues for Publicly Traded Companies That Submitted Device Applications Subject to MDUFMA User Fees in Fiscal Year 2006 and Did Not Qualify as Small Businesses



Source: GAO analysis of FDA, Audit Analytics, and Mergent data.

¹²A company may report annual revenues of \$0 if, for example, the company was new and at the time it filed its report with SEC it had not yet generated revenues.

We did not determine why each of the 56 publicly traded companies with annual revenues at or below \$100 million was not qualified as a small business. One possible explanation provided by a medical device industry representative is that some companies that meet the current threshold for small business qualification may not apply if the discount in user fees for the device applications they are likely to submit is relatively small. Among the 56 companies we found with annual revenues at or below \$100 million, all but one of the applications they submitted in fiscal year 2006 were Premarket Notifications. The Premarket Notification is the least expensive application and subject to the smallest discount. For fiscal year 2006, the standard user fee amount for the Premarket Notification was \$3,833. In contrast, the user fee for companies qualifying as small businesses was \$3,066.

Agency Comments

HHS reviewed a draft of this report and provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the Secretary of Health and Human Services, the Commissioner of FDA, appropriate congressional committees, and other interested parties. We will also make copies available to others on request. In addition, the report will be available at no charge on GAO's Web site at <http://www.gao.gov>. If you or your staff have questions about this report, please contact me at (206) 287-4860 or williamsonr@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in enclosure III.

Sincerely yours,



Randall B. Williamson
Acting Director, Health Care

Enclosures—3

Scope and Methodology

To provide annual revenues for the 697 companies that qualified as small businesses under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) user fee program in fiscal year 2006, we obtained from the Food and Drug Administration (FDA) the number of these companies falling into \$10-million increments of gross sales and receipts from \$0 to \$100 million. FDA collects and tabulates annual revenue information from tax returns that these companies provide to FDA as part of the small business qualification process. In order to qualify as a small business in fiscal year 2006, a company had to demonstrate that its total annual revenue—specifically, its gross sales or receipts and that of any affiliate, partner, or parent firm as recorded on the most recent U.S. federal income tax returns—did not exceed \$100 million.

To provide total annual revenues for publicly traded companies that submitted device applications subject to user fees and did not qualify as small businesses in fiscal year 2006, we conducted a multistep analysis:

- First, we obtained from FDA information on all 4,454 device applications the agency received that year that were subject to user fees.
- Second, we obtained from FDA the names and addresses of the 697 companies that qualified as small businesses under the MDUFMA user fee program in fiscal year 2006 and identified the 783 device applications they submitted by comparing company names and addresses between the 4,454 device applications and the list of 697 companies.¹³ This left 3,671 applications subject to user fees that were submitted to FDA in fiscal year 2006 by companies that did not qualify as small businesses.
- Third, we used two private databases containing information on publicly traded companies to identify 258 publicly traded companies that were responsible for 1,417 of the remaining 3,671 applications. The first database we used, Audit Analytics, contains the names, addresses, and annual revenues of publicly traded companies that register their securities with the Securities and Exchange Commission (SEC), known as registrants. We identified 125 registrants that were responsible for 677 of the 3,671 applications by comparing company names and addresses between the Audit Analytics database and the 3,671 device applications. The second private database we used, Mergent, contains the names of companies that are subsidiaries of registrants. (Audit Analytics does not contain this information.) We used Mergent to identify applications submitted by companies that were subsidiaries of registrants. We did this by comparing subsidiary names with the company names on the remaining applications.¹⁴ In total, we identified 133 subsidiary companies that were responsible for 740 of the remaining 2,994 applications.

¹³To determine whether an application belonged to a company on the list of qualified small businesses, we compared the names and addresses listed on the application and the list. If the names and addresses matched exactly, we considered the application to belong to the company. We also considered an application to belong to a company if we deemed the match was probable in that the two names were very similar. This methodology for comparison of company names and addresses was used throughout our analyses.

¹⁴Subsidiary address information was not available in Mergent. Therefore, we matched applications to the Mergent database using name alone.

- Fourth, we used the Audit Analytics database to obtain annual revenues for the 258 companies we identified as publicly traded. Our methodology was based on FDA’s methodology to assess revenues for small business qualification. FDA defines a company’s annual revenue as the gross sales or receipts for that company and any affiliate, partner, or parent firm. When a company registers its securities with SEC, it must file consolidated financial statements indicating annual revenues—specifically, gross revenues—from all its operations, including those for its subsidiary companies.¹⁵ Therefore, for the 125 companies we matched with registrants in the Audit Analytics database, we used the annual revenue indicated for those companies in the same database. For the 133 companies we identified in Mergent as subsidiaries of registrants, we deemed that their associated registrants would be affiliate, partner, or parent firms; therefore, we used the annual revenue for the registrant indicated in the Audit Analytics database as the annual revenue for the subsidiary company.

Once we identified applications submitted by companies qualifying as small businesses and applications submitted by publicly traded companies, 2,254 applications remained—about 50 percent of all 4,454 applications subject to user fees in fiscal year 2006. These applications are likely from companies that are private.

After assessing the reliability of FDA data and SEC data compiled by Audit Analytics and Mergent, we found that both sets of data were suitable for our purposes. We assessed the reliability of FDA data by conducting interviews with FDA staff to understand how FDA collects and uses the data. We assessed the reliability of data from the two private data vendors by comparing financial information in SEC filings with financial information provided by the vendors for a sample of companies. To gather information about the MDUFMA user fee program, we interviewed officials from FDA, including officials from the two centers within FDA responsible for reviewing applications for medical devices—the Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research. In addition, we interviewed representatives from a national trade association—the Medical Device Manufacturers Association—which represents manufacturers of medical devices. We conducted our work from October 2006 through March 2007 according to generally accepted government auditing standards.

¹⁵Both “gross sales or receipts” as reported on federal income tax returns and gross revenues as reported on a company’s financial statement filed with SEC are general measures of annual revenue. However, they may not be identical for the same period. Taxable income reported on the tax return is computed in accordance with prescribed federal tax regulations and rules, whereas, pretax financial income reported on financial statements filed with SEC is measured in accordance with generally accepted accounting principles (GAAP). Because tax regulations and GAAP are different in many ways, taxable income and pretax financial income can differ.

Information on Device Applications Submitted by Publicly Traded Companies Not Qualified as Small Businesses, Categorized by Annual Company Revenue

Under MDUFMA, medical device companies must pay user fees when they submit certain device applications. These applications are as follows:

- Original Premarket Approvals (PMA)
- Product Development Protocols (PDP)
- Premarket Reports
- Panel-track PMA Supplements
- 180-day PMA Supplements
- Real-time PMA Supplements
- Premarket Notifications/510(k)s
- Biologics License Applications (BLA)
- BLA Efficacy Supplements

In table 2, we provide detailed results of our analysis of device applications from companies publicly traded in the United States that submitted device applications subject to user fees and did not qualify as small businesses. We derived these results by obtaining application information from FDA, excluding applications from companies qualifying for small business discounts and waivers, and matching the companies responsible for the remaining applications to the revenues they reported to SEC, which we obtained from two private data vendors, Audit Analytics and Mergent.

Table 2: Annual Revenues for 258 Publicly Traded Companies Not Qualified as Small Businesses, Categorized by the Number of Device Applications per Application Type, in Fiscal Year 2006

Annual revenue (millions of dollars)	Application type (fee in dollars)									510(k) (\$3,833)	
	PMA (\$259,600)	PDP (\$259,600)	Premarket Report (\$259,600)	BLA (\$259,600)	Panel-Track PMA Supplement (\$259,600)	180-Day PMA Supplement (\$55,814)	Real-Time PMA Supplement (\$18,691)	BLA Efficacy Supplement (\$259,600)			
\$0	0	0	0	0	0	0	0	0	0	4	Companies
	0	0	0	0	0	0	0	0	0	13	Applications
>\$1 to ≤\$25	1	0	0	0	0	0	0	0	0	21	Companies
	1	0	0	0	0	0	0	0	0	33	Applications
>\$25 to ≤\$50	0	0	0	0	0	0	0	0	0	11	Companies
	0	0	0	0	0	0	0	0	0	31	Applications
>\$50 to ≤\$75	0	0	0	0	1	0	0	0	0	10	Companies
	0	0	0	0	1	0	0	0	0	20	Applications
>\$75 to ≤\$100	0	0	0	0	0	0	0	0	0	8	Companies
	0	0	0	0	0	0	0	0	0	18	Applications
>\$100 to ≤\$125	0	0	0	0	0	1	1	0	0	8	Companies
	0	0	0	0	0	1	7	0	0	14	Applications
>\$125 to ≤\$150	0	0	0	0	0	0	0	0	0	5	Companies
	0	0	0	0	0	0	0	0	0	7	Applications
>\$150 to ≤\$175	0	0	0	0	1	1	1	0	0	2	Companies
	0	0	0	0	1	1	1	0	0	3	Applications
>\$175 to ≤\$200	0	0	0	0	0	0	0	0	0	4	Companies
	0	0	0	0	0	0	0	0	0	9	Applications
>\$200 to ≤\$300	1	0	0	0	0	2	1	0	0	6	Companies
	1	0	0	0	0	2	1	0	0	25	Applications
>\$300 to ≤\$400	0	0	0	0	0	1	3	0	0	12	Companies
	0	0	0	0	0	2	5	0	0	61	Applications
>\$400 to ≤\$500	0	0	0	0	0	1	0	0	0	4	Companies
	0	0	0	0	0	2	0	0	0	12	Applications
>\$500 to ≤\$600	0	0	0	0	0	0	1	0	0	10	Companies
	0	0	0	0	0	0	1	0	0	22	Applications
>\$600 to ≤\$700	0	0	0	0	0	0	0	0	0	5	Companies
	0	0	0	0	0	0	0	0	0	18	Applications
>\$700 to ≤\$800	0	0	0	0	0	0	0	0	0	1	Companies
	0	0	0	0	0	0	0	0	0	2	Applications
>\$800 to ≤\$900	0	0	0	0	0	0	0	0	0	3	Companies
	0	0	0	0	0	0	0	0	0	4	Applications
>\$900 to ≤\$1,000	0	0	0	0	0	0	0	0	0	0	Companies
	0	0	0	0	0	0	0	0	0	0	Applications
More than \$1,000	12	0	0	2	8	20	22	0	0	129	Companies
	21	0	0	2	8	78	216	0	0	759	Applications

Source: GAO analysis of FDA, Audit Analytics, and Mergent data.

Note: Shading for emphasis only. In addition, individual companies may appear in more than one column in the same row if they submit more than one type of application. As a result, the number of companies in this table does not sum to 258.

GAO Contact and Staff Acknowledgments

GAO Contact

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Acknowledgments

In addition to the contact named above, James Musselwhite, Assistant Director; Donald Neff, Assistant Director; Ramsey Asaly; Cathy Hamann; Jessica Morris; Daniel Ries; and Yorick F. Uzes made key contributions to this report.

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