ISSUES

OGD FUNDING

GPhA Position

Given the critical mission of the FDA to protect the public health, GPhA has been a strong advocate of adequate funding for the Agency to fulfill its mission. GPhA supports providing the Office of Generic Drugs (OGD) an additional $14 million for the specific purpose of reviewing and approving generic drug applications which would ultimately result in greater cost savings for consumers and state and federal governments. This increase would bring total OGD appropriations to approximately $54 million.

Key Points

The number of generic drug applications -- Abbreviated New Drug Applications (ANDAs) -- submitted to the FDA each year for review and approval has more than doubled over the past six years, from 361 in 2002 to 830 in 2008.

This influx of generic drug applications has resulted in an accumulation of about 1,400 unapproved filings, which now are awaiting action by the FDA's Office of Generic Drugs. Median review and approval time for ANDAs has swelled to nearly 21 months – more than a year longer than the statutory six-month review period allowed by federal regulations.

This situation could worsen over the next five years as patents expire on brand-name drugs totaling more than $100 billion in sales, resulting in a surge in submissions of generic drug applications.

The FY2009 budget for the Office of Generic Drugs is approximately $41 million. Over the past eight years, OGD has seen only very minimal increases in funding, and in some years was flat-funded. This has occurred even with a staggering three-fold increase in the OGD workload.

The lack of adequate funding has resulted in delayed approval of new generic drugs, which in turn has cost the government billion of dollars in lost savings. Because generics cost 30% to 80% less than brands, a one percent increase in generic utilization nationwide equates to approximately $4 billion dollars in annual savings.

Background

Generic medicines provide billions of dollars in savings each year to consumers, employers, insurers and state and federal prescription drug benefit programs. Without wide-scale generic drug use, the government could not afford to maintain Medicare, Medicaid, SCHIP, the President's Emergency Plan for AIDS Relief (PEPFAR), TRICARE for military personnel and veterans, and other programs that enable more than 100 million Americans to afford the medicines they need. And without an increased reliance on affordable generics, it will not be possible to implement the much needed healthcare reforms as envisioned by President Obama.

Since 2002, the number of Abbreviated New Drug Applications (ANDAs) submitted to the FDA has more than doubled - from 361 in 2002 to 830 in 2008. While the good news is that the number of generic applications has been increasing as a result of a vibrant generic drug industry, the bad news is that average ANDA (abbreviated new drug application) review time has also dramatically increased to 21 months, far

LATEST ON OGD FUNDING

5.26.2011 - GPhA Calls on House Appropriations Committee to Protect Funding for FDA and the Office of Generic Drugs in FY 2012 Budget

3.21.2011 - GPhA Says Cuts to FDA Generic Drug Program Would Have 'Devastating Impact' on Consumers and Government

7.16.2010 - GPhA Says Senate Increase in FDA Funding is "Step in the Right Direction"

3.09.2010 - GPhA Urges Congress to Strengthen Obama Administration's Call for Increased Funding for FDA

2.01.2010 - GPhA Statement on the Obama Administration's Proposed Fiscal Budget for the Food and Drug Administration

10.22.2009 - GPhA Applauds Increase in Funding for FDA's Office of Generic Drugs

7.09.2009 - GPhA Applauds House Action to Increase Funding for FDA's Office of Generic Drugs

7.13.2007 - GPhA Praises House Subcommittee for Increasing Funding for Office of Generic Drugs

6.20.2006 - GPhA Hails Senate Agricultural Appropriations Subcommittee Proposal for $10 Million Increase in Funding for FDA Office of Generic Drugs

2.17.2006 - Increased OGD Funding, Not User Fees, Will Benefit Consumers, Says GPhA

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exceeding the statutory requirement of six months.

RSS

FDA currently has nearly 1,400 unapproved ANDAs on file. Although a significant sum of these applications cannot be approved due to patent or exclusivity protections or longstanding FDA review process issues (such as citizen petitions and consults), the cumulative impact of this growing number of unapproved ANDAs is that the review and approval times are substantially increasing and the process has become anything but "abbreviated."

And the longer an application is delayed, the longer consumers wait to obtain affordable generic medicines.

Related Information

Letters

May 26, 2011 - Letter to House Appropriations Committee Chairman Hal Rogers and Ranking Member Norm Dicks Regarding FDA 2012 Budget (291.67KB PDF)

March 18, 2011 - Letter to House Speaker Boehner, Senate Leader Reid and Director of the Office of Management and Budget, Jack Lew, Regarding FDA Office of Generic Drugs 2011 Budget (310.29KB PDF)

Testimony & Content

May 18, 2005 - GPhA Testimony before the House Energy and Commerce Committee on Generic Utilization

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Other

February 15, 2009 - FDA FY2009 Budget

February 15, 2009 - FDA Office of Generic Drugs Web Site

February 18, 2006 - OGD Director Gary Buehler, Presentation at GPhA's 2006 Annual Meeting (479.48KB PDF)

May 1, 2005 - FDA Office of Generic Drugs: Approvals and Tentative Approvals of Generic Drugs