

## SPECIAL ORDERS

The SPEAKER pro tempore. Under the Speaker's announced policy of January 7, 2003, and under a previous order of the House, the following Members will be recognized for 5 minutes each.

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Kansas (Mr. MORAN) is recognized for 5 minutes.

(Mr. MORAN of Kansas addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

## PUBLICATION OF THE GMPs

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from New Jersey (Mr. PALLONE) is recognized for 5 minutes.

Mr. PALLONE. Mr. Speaker, I rise on the House floor this evening to express my appreciation for the publication of the proposed rule for dietary supplement current good manufacturing practices, or GMPs. After many years of delay and inquiry, I am pleased that the Food and Drug Administration finally put forth this proposed rule earlier this year as required by the Dietary Supplement Health and Education Act, also known as DSHEA. This is truly a step forward in health care and will help to ensure that the public has access to high-quality, safe dietary supplements.

Overall, Mr. Speaker, I have found that the FDA's proposed rule works in favor of both consumers and the industry. The public should expect nothing less than safe and effective supplements, and it is encouraging to witness the government and industry joining together to provide consumers great confidence that supplements are free from contamination, accurately labeled and effective in improving personal health.

The GMPs also provide guidelines that assist the dietary supplement industry in manufacturing safe, effective, unadulterated products. The industry fully appreciates the economic consequences of these proposed regulations and is prepared to invest in the future of the natural products that they sell.

However, there are some concerns that will be expressed by both the public and the industry during the comment period, and I am hopeful that the FDA will be responsive, given the FDA's shared commitment to deliver products with only optimum health benefits. For example, Mr. Speaker, although the GMPs steer dietary supplement manufacturers down the right path, there are several outstanding issues that must be raised.

Mr. Speaker, I am concerned about finished product testing and the scientifically validated measures to be used. It is crucial that the FDA and the dietary supplement industry agree on the methods and scientific criteria required of product testing in order for consumers to compare products based upon the same standards.

I recognize that the best standards are those developed from scientific and clinical research, and I have always supported efforts to promote research and development of dietary supplement products. It is imperative that the GMPs include incentives for stimulating clinical and scientific research. This research is important for establishing scientifically validated methods for dietary supplement testing and for providing uniform standards that can be accessed and utilized by consumers when comparing the health benefits of supplements.

In addition, Mr. Speaker, the economic pressure that the GMPs will place on small companies, manufacturers and raw material suppliers with less than 500 employees, troubles me. Analysis shows that the cost of compliance for small companies is estimated at \$100,000 the year of implementation and \$61,000 the following years. The intent of this financial burden is to rid the market of unscrupulous players. However, small companies and mom-and-pop shops comprise approximately 90 percent of the dietary supplement industry, and I fear that many operations will be forced to go out of business due to the high cost of compliance.

As currently proposed, it is estimated that up to 50 percent of the very small companies could go out of business and that product prices could increase by 35 percent. Retailers, small business manufacturers and consumers will ultimately have to absorb these costs, which will most likely result in fewer consumers being able to purchase dietary supplements.

Mr. Speaker, I would also like to note that GMPs also place a fair amount of pressure, economic or otherwise, on the FDA once they are finalized. Enforcement of the rules will be costly. One way for the U.S. Government to minimize these costs will be to allow independent, third-party organizations to conduct inspections and certify establishments as if they were government inspectors.

This is not a unique concept. For instance, the Joint Commission on Accreditation of Health Care Organizations accredits nearly all the hospitals in the United States.

Another good example of industry and government cooperation is the memorandum of understanding that was established between the American Council for Food Safety and Quality, formerly the Dried Food Association of California, and the FDA. The MOU allows the association to inspect member facilities as if they were government inspectors. The program has paid benefits for all involved. The agency would realize reduced administrative cost burdens as inspection costs could be borne by the manufacturer, while also providing expertise and guidance, thereby allowing manufacturers to come into compliance with the new GMP regulations.

Again, Mr. Speaker, I am pleased with the FDA for finally coming forth

with this proposed rule, and I remain hopeful that the benefits will include improved health as a result of better access to quality dietary supplements. It is imperative that the FDA use the instructive recommendations it receives during the comment period and that the public and the industry play a significant role in ensuring improved access to safe and effective dietary supplement products.

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The SPEAKER pro tempore (Mr. CARTER). Under a previous order of the House, the gentleman from Indiana (Mr. BURTON) is recognized for 5 minutes.

(Mr. BURTON of Indiana addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Ohio (Mr. RYAN) is recognized for 5 minutes.

(Mr. RYAN of Ohio addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Michigan (Mr. MCCOTTER) is recognized for 5 minutes.

(Mr. MCCOTTER addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Illinois (Mr. EMANUEL) is recognized for 5 minutes.

(Mr. EMANUEL addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Pennsylvania (Mr. SHUSTER) is recognized for 5 minutes.

(Mr. SHUSTER addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Ohio (Mr. BROWN) is recognized for 5 minutes.

(Mr. BROWN of Ohio addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Oregon (Mr. DEFAZIO) is recognized for 5 minutes.

(Mr. DEFAZIO addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

**STATUS REPORT ON CURRENT SPENDING LEVELS OF ON-BUDGET SPENDING AND REVENUES FOR FY 2004 AND THE 5-YEAR PERIOD FY 2004 THROUGH FY 2008**

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Iowa (Mr. NUSSLE) is recognized for 5 minutes.

Mr. NUSSLE. Mr. Speaker, I am transmitting a status report on the current levels of on-budget spending and revenues for fiscal year 2004 and for the 5-year period of fiscal years 2004 through 2008. This report is necessary to facilitate the application of sections 302 and 311 of the Congressional Budget Act and section 501 of the conference report on the concurrent resolution on the budget for fiscal year 2004 (H. Con. Res. 95). This status report is current through September 3, 2003.

The term "current level" refers to the amounts of spending and revenues estimated for each fiscal year based on laws enacted or awaiting the President's signature.

The first table compares the current levels of total budget authority, outlays, and revenues with the aggregate levels set forth by H. Con. Res. 95. This comparison is needed to enforce section 311(a) of the Budget Act, which creates a point of order against measures that would breach the budget resolution's aggregate levels. The table does not show budget authority and outlays for fiscal years 2004 through 2008, because appropriations for those years have not yet been considered.

The second table compares the current levels of budget authority and outlays for discretionary action by each authorizing committee with the "section 302(a)" allocations made under H. Con. Res. 95 for fiscal year 2004 and fiscal years 2004 through 2008. "Discretionary action" refers to legislation enacted after the adoption of the budget resolution. A separate allocation for the Medicare program,

as established under section 401(a)(3) of the budget resolution, is shown for fiscal year 2004 and fiscal years 2004 through 2013. This comparison is needed to enforce section 302(f) of the Budget Act, which creates a point of order against measures that would breach the section 302(a) discretionary action allocation of new budget authority for the committee that reported the measure. It is also needed to implement section 311(b), which exempts committees that comply with their allocations from the point of order under section 311(a).

The third table compares the current levels of discretionary appropriations for fiscal year 2004 with the "section 302(b)" suballocations of discretionary budget authority and outlays among Appropriations subcommittees. The comparison is needed to enforce section 302(f) of the Budget Act because the point of order under that section equally applies to measures that would breach the applicable section 302(b) suballocation.

The last table gives the current level for 2005 of accounts identified for advance appropriations under section 501 of H. Con. Res. 95. This list is needed to enforce section 501 of the budget resolution, which creates a point of order against appropriation bills that contain advance appropriations that are: (i) not identified in the statement of managers or (ii) would cause the aggregate amount of such appropriations to exceed the level specified in the resolution.

**REPORT TO THE SPEAKER FROM THE COMMITTEE ON THE BUDGET—STATUS OF THE FISCAL YEAR 2004 CONGRESSIONAL BUDGET ADOPTED IN H. CON. RES. 95**

(Reflecting action completed as of September 3, 2003—on-budget amounts, in millions of dollars)

	Fiscal year 2004	Fiscal years 2004–2008
Appropriate Level:		
Budget Authority .....	1,880,555	(1)
Outlays .....	1,903,502	(1)
Revenues .....	1,325,452	8,168,933

**REPORT TO THE SPEAKER FROM THE COMMITTEE ON THE BUDGET—STATUS OF THE FISCAL YEAR 2004 CONGRESSIONAL BUDGET ADOPTED IN H. CON. RES. 95—Continued**

(Reflecting action completed as of September 3, 2003—on-budget amounts, in millions of dollars)

	Fiscal year 2004	Fiscal years 2004–2008
Current Level:		
Budget Authority .....	1,101,447	(1)
Outlays .....	1,424,936	(1)
Revenues .....	1,331,075	8,377,042
Current Level or (+)/under/ (–) Appropriate Level:		
Budget Authority .....	–779,108	(1)
Outlays .....	–478,566	(1)
Revenues .....	5,623	208,109

<sup>1</sup> Not applicable because annual appropriations Acts for fiscal years 2005 through 2008 will not be considered until future sessions of Congress.

**BUDGET AUTHORITY**

Enactment of measures providing new budget authority for FY 2004 in excess of \$779,108,000,000 (if not already included in the current level estimate) would cause FY 2004 budget authority to exceed the appropriate level set by H. Con. Res. 95.

**OUTLAYS**

Enactment of measures providing new outlays for FY 2004 in excess of \$478,566,000,000 (if not already included in the current level estimate) would cause FY 2004 outlays to exceed the appropriate level set by H. Con. Res. 95.

**REVENUES**

Enactment of measures that would result in revenue reduction for FY 2004 in excess of \$5,623,000,000 (if not already included in the current level estimate) would cause revenues to fall below the appropriate level set by H. Con. Res. 95.

Enactment of measures resulting in revenue reduction for the period FY 2004 through 2008 in excess of \$208,109,000,000 (if not already included in the current level estimate) would cause revenues to fall below the appropriate levels set by H. Con. Res. 95.

**DIRECT SPENDING LEGISLATION—COMPARISON OF CURRENT LEVEL WITH AUTHORIZING COMMITTEE 302(a) ALLOCATIONS FOR DISCRETIONARY ACTION, REFLECTING ACTION COMPLETED AS OF SEPTEMBER 3, 2003**

(Fiscal years, in million of dollars)

House Committee	2004		2004–2008 total		2004–2013 total	
	BA	Outlays	BA	Outlays	BA	Outlays
<b>Agriculture:</b>						
Allocation .....	0	0	0	0	(1)	(1)
Current Level .....	0	0	0	0	(1)	(1)
Difference .....	0	0	0	0	(1)	(1)
<b>Armed Services:</b>						
Allocation .....	70	34	70	70	(1)	(1)
Current Level .....	0	0	0	0	(1)	(1)
Difference .....	–70	–34	–70	–70	(1)	(1)
<b>Education and the Workforce:</b>						
Allocation .....	39	47	201	245	(1)	(1)
Current Level .....	0	0	0	0	(1)	(1)
Difference .....	–39	–47	–201	–245	(1)	(1)
<b>Energy and Commerce:</b>						
Allocation .....	–170	–170	439	439	(1)	(1)
Current Level .....	1,325	100	685	795	(1)	(1)
Difference .....	1,495	270	246	356	(1)	(1)
<b>Financial Services:</b>						
Allocation .....	0	375	0	1,250	(1)	(1)
Current Level .....	–1	–1	–2	–2	(1)	(1)
Difference .....	–1	376	–2	–1,252	(1)	(1)
<b>Government Reform:</b>						
Allocation .....	–1	0	–3	–1	(1)	(1)
Current Level .....	0	0	0	0	(1)	(1)
Difference .....	1	0	3	1	(1)	(1)
<b>House Administration:</b>						
Allocation .....	0	0	0	0	(1)	(1)
Current Level .....	1	1	3	3	(1)	(1)
Difference .....	1	1	3	3	(1)	(1)
<b>International Relations:</b>						
Allocation .....	0	0	0	0	(1)	(1)
Current Level .....	0	0	0	0	(1)	(1)
Difference .....	0	0	0	0	(1)	(1)
<b>Judiciary—</b>						
Allocation .....	19	19	95	95	(1)	(1)
Current Level .....	0	0	0	0	(1)	(1)
Difference .....	–19	–19	–95	–95	(1)	(1)
<b>Resources:</b>						
Allocation .....	24	24	522	342	(1)	(1)
Current Level .....	0	0	0	0	(1)	(1)
Difference .....	–24	–24	–522	–342	(1)	(1)