

January 6, 2004

Memo for the record

**Subject: Correction of Calculation of cost of living increases in FDA Civil Monetary Penalties**

6037 '04 FEB -4 P1:42

On December 1, 2003 the FDA published the proposed rule Civil Money Penalties Hearings; Maximum Penalty Amounts and Compliance With the Federal Civil Penalties Inflation Adjustment Act, 68 FR 67094-67097. The purpose of the proposed rule is to adjust for inflation the maximum civil money penalty amounts for the various civil money penalty authorities within our jurisdiction, in accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended.

Curtis Copeland of the Government Accounting Office has pointed out (via a phone conversation on or about 12/08/2003) that certain calculations for CMP inflation adjustments and prescribed rounding in FDA's proposed rule are in error. Specifically, there are four proposed penalties that are not consistent with the law regarding inflation increases. These are the result of applying the specified 10% cap prior to rounding instead of after the prescribed rounding. Thus, since all 14 rounded CPI adjustments exceeded the specified 10 percent cap, each penalty will be increased by exactly 10 percent to be consistent with the Federal Civil Penalties Improvement Act of 1990 as amended by the Debt Collection Improvement Act of 1996.

Consistent with the above, the right most column of Table 1, Adjusted Maximum Penalty Amount (in dollars), in the proposed rule is changed as follows:

\$55,000  
\$1,100,000  
\$110,000  
**\$16,500**  
\$1,100,000  
\$55,000  
\$275,000  
\$550,000  
\$275,000  
\$1,100,000  
**\$1,100**  
**\$330,000**  
**\$11,000**  
\$110,000

The figures in double-underline bold text were changed from those shown in the proposed rule.

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