

**AMENDMENT TO COMMITTEE PRINT**  
**OFFERED BY MR. PALLONE OF NEW JERSEY**  
**(PDUFA\_004, June 19, 2007)**

Page 17, redesignate subsection (f) as subsection (g)  
and insert after line 17 the following:

1       (f) EXEMPTION FOR ORPHAN DRUGS.—Section 736  
2 (21 U.S.C. 379h) is further amended by adding at the  
3 end the following:

4       “(k) ORPHAN DRUGS.—A drug designated under sec-  
5 tion 526 and approved for marketing by the Food and  
6 Drug Administration for one or more of the designated  
7 orphan indications shall be exempt from product and facil-  
8 ity fees under this section, provided that the drug meets  
9 all of the following:

10           “(1) The orphan drug had United States sales  
11 in the previous year of less than \$25,000,000 for the  
12 active moiety, for all indications, dosage forms, and  
13 strengths for which the drug is approved and for  
14 any off-label uses.

15           “(2) The orphan drug meets the public health  
16 requirements contained in this Act as such require-  
17 ments are applied to requests for waivers for prod-  
18 uct and facility fees.

1           “(3) The orphan drug is owned or licensed and  
2           marketed by a company that had less than  
3           \$100,000,000 in gross worldwide revenue during the  
4           previous year.”.