

AMENDMENTS TO THE COMMITTEE PRINT**OFFERED BY _____****[Medical Device User Fee Act]**

Page 8, strike “or tribal organization,” and insert “(as defined in the Indian Self Determination and Educational Assistance Act),”.

Page 11, strike lines 7 through 10 and insert the following:

1 (B) by striking “clauses (i) through (vi) of
2 subsection (a)(2)(A)” and inserting “clauses (i)
3 through (v) and clauses (vii), (ix), and (x) of
4 subsection (a)(2)(A)”.

Page 14, line 6, strike “supplement,” and insert “supplement (other than a 30-day notice)”.

Page 23, line 9, strike “such sums” and all that follows through line 10 and insert the following: “\$7,100,000 for fiscal year 2008, and for each of the fiscal years 2009 through 2012, \$7,100,000 increased by the amount necessary to offset the effects of inflation occurring after October 1, 2007.”

Page 23, lines 12 through 19, strike “this Act” each place such term appears and insert “this title”.

Page 23, line 20, strike “section 4” and insert “section 103”.

Page 24, strike line 23 and all that follows through page 25, line 21, and insert the following:

1 (b) REGISTRATION OF FOREIGN ESTABLISH-
2 MENTS.—Section 510(i)(1) (21 U.S.C. 360(i)(1)) is
3 amended by striking “On or before December 31” and all
4 that follows and inserting the following: “Any establish-
5 ment within any foreign country engaged in the manufac-
6 ture, preparation, propagation, compounding, or proc-
7 essing of a drug or device that is imported or offered for
8 import into the United States shall, through electronic
9 means in accordance with the criteria of the Secretary—
10 “(A) upon first engaging in any such activity,
11 immediately register with the Secretary the name
12 and place of business of the establishment, the name
13 of the United States agent for the establishment, the
14 name of each importer of such drug or device in the
15 United States that is known to the establishment,
16 and the name of each person who imports or offers
17 for import such drug or device to the United States
18 for purposes of importation; and

1 “(B) each establishment subject to the require-
2 ments of subparagraph (A) shall thereafter—

3 “(i) with respect to drugs, register with the
4 Secretary on or before December 31 of each
5 year; and

6 “(ii) with respect to devices, register with
7 the Secretary during the period beginning on
8 October 1 and ending on December 31 of each
9 year.”.

Page 26, line 18, strike “With regard to” and all that follows through “unless the Secretary” on line 25 and insert the following: “Registrations and listings under this section (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary”.

Page 27, strike lines 10 through 19 and insert the following:

10 **SEC. 205. REPORT BY GOVERNMENT ACCOUNTABILITY OF-**

11 **FICE.**

12 (a) IN GENERAL.—The Comptroller General of the
13 United States shall conduct a study on the appropriate
14 use of the process under section 510(k) of the Federal
15 Food, Drug, and Cosmetic Act as part of the device classi-

1 fication process to determine whether a new device is as
2 safe and effective as a classified device.

3 (b) REPORT.—Not later than 1 year after the date
4 of the enactment of this Act, the Comptroller General shall
5 complete the study under subsection (a) and submit to the
6 Congress a report on the results of such study.