

AMENDMENT TO THE COMMITTEE PRINT
OFFERED BY MR. TOWNS

[REMS]

Page 42, beginning on line 9, strike “(1) Any person who” and all that follows through line 22 and insert the following: “(1) With respect to a person who is a holder of an approved application under section 505 for a drug subject to section 503(b) or under section 351 of the Public Health Service Act, any such person who disseminates a direct-to-consumer advertisement that is false or misleading shall be liable to the United States for a civil penalty in an amount not to exceed \$250,000 for the first such violation in any 3-year period, and not to exceed \$500,000 for each subsequent violation in any 3-year period. No other civil monetary penalties in this Act (including the civil penalty in section 303(f)(3)) shall apply to a violation regarding direct-to-consumer advertising. For purposes of this paragraph: (A) Repeated dissemination of the same or similar advertisement prior to the receipt of the written notice referred to in paragraph (2) for such advertisements shall be considered one violation. (B) On and after the date of the receipt of such a notice,

all violations under this paragraph occurring in a single day shall be considered one violation.”.

Page 41, strike the closing quotation marks.

Page 41, insert after line 8 the following subsection:

1 “(f) RULE OF CONSTRUCTION.—Nothing in this sec-
2 tion may be construed as having any effect on the author-
3 ity of the Secretary under section 314.550, 314.640,
4 601.45, or 601.94 of title 21, Code of Federal Regulations
5 (or successor regulations).”.