

**AMENDMENT TO THE AMENDMENT IN THE  
NATURE OF A SUBSTITUTE TO H.R. 9  
OFFERED BY MRS. MIMI WALTERS OF  
CALIFORNIA**

Page 59, insert the following after line 19 and redesignate the succeeding paragraphs accordingly:

1           (8) RESTRICTION ON CERTAIN INTER PARTES  
2           PROCEEDINGS.—Section 316 of title 35, United  
3           States Code, is amended by adding at the end the  
4           following:  
5           “(f) DRUG OR BIOLOGICAL PRODUCT PATENTS.—An  
6           inter partes review shall not be instituted or maintained  
7           for a patent that claims a drug or biological product,  
8           method of use, or method of manufacturing a drug or bio-  
9           logical product approved under section 505 of the Federal  
10          Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section  
11          351 of the Public Health Service Act (42 U.S.C. 262),  
12          including any patent listed in the Food and Drug Adminis-  
13          tration publication Approved Drug Products with Thera-  
14          peutic Equivalence Evaluations or identified by the patent  
15          owner in a certification in its response to the petition.”.

