

AMENDMENT NO. 2

Calendar No. \_\_\_\_\_

Purpose: To require the Secretary of Health and Human Services to issue final guidance to advance the development of interchangeable biosimilar biological products.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

**S. 4348**

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on \_\_\_\_\_ and  
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. MARSHALL

Braun

Viz:

1 At the appropriate place in title V, insert the fol-  
2 lowing:

3 **SEC. 5 \_\_\_\_\_. FDA FINAL GUIDANCE ON INTERCHANGEABLE**

4 **BIOSIMILAR BIOLOGICAL PRODUCTS.**

5 Not later than 1 year after the date of enactment  
6 of this Act, the Secretary of Health and Human Services,  
7 acting through the Commissioner of Food and Drugs,  
8 shall issue final guidance to advance the development of  
9 interchangeable biosimilar biological products by describ-  
10 ing reasonable differences between a biosimilar biological

1 product and the reference product with respect to total  
2 concentration for purposes of meeting the requirements  
3 for licensure of the biosimilar biological product under sec-  
4 tion 351(k) of the Public Health Service Act (42 U.S.C.  
5 262(k)) and determining interchangeability under para-  
6 graph (4) of such section.