



AMENDMENT NO. \_\_\_\_\_ Calendar No. \_\_\_\_\_

Purpose: To require summary approval information with respect to certain approved drugs and 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. HICKENLOOPER

Viz:

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

3 **SEC. 5 \_\_\_\_\_. SUMMARY APPROVAL INFORMATION.**

4 With respect to each new drug application for a new  
5 molecular entity approved under section 505(c) of the  
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c))  
7 or biological product licensed under section 351(a) of the  
8 Public Health Service Act (42 U.S.C. 262(a)) pursuant  
9 to accelerated approval under section 506(c) of the Fed-  
10 eral Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)),  
11 the Secretary of Health and Human Services shall provide

1 for the drug or biologic action package a summary of the  
2 basis for approval, including, as relates to such new molec-  
3 ular entity, whether an advisory committee meeting was  
4 held and a rationale for a determination by the Secretary  
5 that a surrogate endpoint is reasonably likely to predict  
6 clinical benefit.