

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

Purpose: To prohibit approval by the Food and Drug Administration of genetically engineered fish unless the National Oceanic and Atmospheric Administration concurs with such approval.

**IN THE SENATE OF THE UNITED STATES—112th Cong., 2d Sess.**

**S. 3187**

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, 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 Ms. MURKOWSKI

Viz:

1 At the end of title XI, add the following:

2 **SEC. 11 \_\_\_\_ . ANALYSES OF APPLICATION FOR APPROVAL OF**

3 **GENETICALLY-ENGINEERED FISH.**

4 Notwithstanding any other provision of law, approval  
5 by the Secretary of Health and Human Services of an ap-  
6 plication submitted under the Federal Food, Drug, and  
7 Cosmetic Act (21 U.S.C. 301 et seq.) for approval of any  
8 genetically modified marine or anadromous organism shall  
9 not take effect until the date that the Secretary of Com-

1 merce, acting through the Under Secretary for Oceans and  
2 Atmosphere, approves such application using standards  
3 applied by the Under Secretary under the National Envi-  
4 ronmental Policy Act of 1969 (42 U.S.C. 4321 et seq.),  
5 which shall include a Regulatory Impact Review required  
6 by Executive Order 12866 (58 Fed. Reg. 51735) and Ini-  
7 tial Regulatory Flexibility Analyses required under chap-  
8 ter 6 of title 5, United States Code (commonly referred  
9 to as the “Regulatory Flexibility Act”).