AMENDMENT NO._____ Calendar No._____

Purpose: To improve the bill.

IN THE SENATE OF THE UNITED STATES—115th Cong., 2d Sess.

S. 974

To promote competition in the market for drugs and biological products by facilitating the timely entry of lower cost generic and biosimilar versions of those drugs and biological products.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENTS intended to be proposed by _____

Viz:

On page 7, line 21, insert ''that is subject to an approved risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1), where such approved risk evaluation and mitigation strategy contains one or more elements to assure safe use under subsection (f)(3) of that section'' after ''(42 U.S.C. 262)''.

On page 11, beginning on line 9, strike ''by a preponderance of the evidence'' and insert ''by clear and convincing evidence''.

On page 12, line 23, strike ''31 days'' and insert ''60 days''.

On page 13, between lines 16 and 17, insert ''Such request shall contain—

(I) a statement identifying the covered product and the quantity of such covered product being sought;

(II) a statement about whether such covered product is intended for development and testing that involves human clinical trials, protocols, informed consent documents, and informational materials for testing that include protections that provide safety protections comparable to those provided by the risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) for the covered product;

(III) a description of how the eligible product developer will ensure that testing activities involving such covered product include safety meas-

ures comparable to the elements of the risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) for the covered product and provide an equivalent level of safety, to the extent such strategy is relevant to such testing activities; and

(IV) such other information as the Secretary may require for purposes of making an authorization under clause (ii).

Beginning on page 16, line 18, strike ''the court shall'' and all that follows through page 19, line 3, and insert ''the sole remedies shall be—

(i) an injunction requiring the sale of sufficient quantities of the covered product by the license holder to the eligible product developer without delay on commercially reasonable, market-based terms; and

(ii) in the court's discretion, an award to the prevailing party of costs incurred by such party in the litigation, which award

may include reasonable attorney fees and expenses.

On page 19, line 5, insert ''that has provided testing supplies to an eligible product developer, and the agents, contractors, affiliates, collaborators, assignees, transferees, and successors in interest of such license holder,'' after ''A license holder for a covered product''.

Strike section 4.