

AMENDMENT NO. 1

Calendar No. _____

Purpose: To establish a requirement for the prescribing of certain drugs.

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

Viz:

1 At the appropriate place in title V, insert the fol-
2 lowing:
3 **SEC. 5 _____. REQUIREMENT FOR PRESCRIPTION OF CER-**
4 **TAIN DRUGS.**

5 Notwithstanding any other provision of law, in the
6 case of a drug approved under section 505 of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 355) that is
8 subject to a risk evaluation and mitigation strategy under
9 section 505–1 of such Act (21 U.S.C. 355–1), and that
10 is offered as an alternative to a surgical or otherwise
11 invasive procedure, such drug may be prescribed to a pa-

- 1 tient only after such patient has been diagnosed using a
- 2 medical imaging device.