.....

(Original Signature of Member)

114TH CONGRESS
2D SESSION

H. R. _____

To establish requirements for reusable medical devices relating to cleaning instructions and validation data, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. LIEU of California introduced the following bill; which was referred to the Committee on _____

A BILL

To establish requirements for reusable medical devices relating to cleaning instructions and validation data, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Preventing Superbugs and Protecting Patients Act''.

SEC. 2. CLEANING INSTRUCTIONS AND VALIDATION DATA REQUIREMENT.

Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended by adding at the end the following:

''(q) REUSABLE MEDICAL DEVICES.—(1) Not later than 6 months after the date of enactment of this subsection, the Secretary shall identify and publish a list of reusable device types for which reports under subsection (k) must include instructions for use, which have been validated in a manner specified by the Secretary, and validation data, the types of which shall be specified by the Secretary, regarding cleaning, disinfection, and sterilization, and for which a substantial equivalence determination may be based.

''(2) The Secretary shall revise such list as necessary with notice in the Federal Register.

''(3) Reports under subsection (k) that are submitted after the publication of the list described in paragraph (1), for devices or types of devices included on such list, are required to include such instructions for use and validation data.''.

SEC. 3. DEVICE MODIFICATIONS.

The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue final guidance regarding when a premarket notification

under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) is required to be submitted for a modification or change to a legally marketed device not later than 1 year after the date on which the comment period closes for the draft guidance on such subject.