Calendar No. 417

114TH CONGRESS
2D SESSION

S. 2503

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

IN THE SENATE OF THE UNITED STATES

FEBRUARY 4, 2016

Mrs. MURRAY introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

APRIL 5, 2016

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

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)(1) REUSABLE MEDICAL DEVICES.—Not later than 6 months after the date of enactment of this subsection, the Secretary shall identify and publish a list of reusable devices or types of devices for which reports under subsection (k) must include proposed labeling, including 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 labeling and validation data.''.

SEC. 3. DEVICE MODIFICATIONS.

The Secretary 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or change to a legally marketed device not later than 1 year after the date on which the comment period closes for the draft guidance on such subject.~~

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)(1) REUSABLE MEDICAL DEVICES.—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.

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