

117TH CONGRESS
1ST SESSION

S. 3395

To amend the Federal Food, Drug, and Cosmetic Act with respect to records and other information inspections.

IN THE SENATE OF THE UNITED STATES

DECEMBER 14, 2021

Ms. BALDWIN (for herself and Mr. CASSIDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to records and other information inspections.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medical Device Integ-
5 rity Act”.

6 **SEC. 2. RECORDS AND OTHER INFORMATION INSPECTION.**

7 (a) IN GENERAL.—Section 704(a)(4)(A) of the Fed-
8 eral Food, Drug, and Cosmetic Act (21 U.S.C.
9 374(a)(4)(A)) is amended—

1 (1) in the first sentence, by inserting “or de-
2 vice” after “processing of a drug”; and

3 (2) in the second sentence, by striking “shall
4 include” and all that follows through the period at
5 the end and inserting the following: “shall include—

6 “(A) a sufficient description of the records
7 requested; and

8 “(B) a rationale for requesting such infor-
9 mation in advance of, or in lieu of, an inspec-
10 tion.”.

11 (b) GUIDANCE.—Not later than 1 year after the date
12 of enactment of this Act, the Secretary shall issue draft
13 guidance describing the circumstances in which the Sec-
14 retary intends to issue requests for records or other infor-
15 mation in advance of, or in lieu of, an inspection, processes
16 for responding to such requests electronically or in phys-
17 ical form, and factors the Secretary intends to consider
18 in evaluating whether such records are provided within a
19 reasonable timeframe, within reasonable limits, and in a
20 reasonable manner, accounting for resource and other lim-
21 itations that may exist, including for small businesses. The
22 Secretary shall issue final guidance not later than 1 year
23 after the close of the comment period for the draft guid-
24 ance.

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