117TH CONGRESS 1ST SESSION

H. R. 1186

To amend the Federal Food, Drug, and Cosmetic Act to reduce the threat of counterfeit drugs to the pharmaceutical supply chain, and to make the pharmaceutical supply chain more robust, while ensuring the authenticity, content, purity, and manufacturing location and batch number of drugs (including COVID–19 therapeutics and vaccines) and allowing patient verification of authenticity, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

February 18, 2021

Mr. VAN DREW (for himself and Mr. BAIRD) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to reduce the threat of counterfeit drugs to the pharmaceutical supply chain, and to make the pharmaceutical supply chain more robust, while ensuring the authenticity, content, purity, and manufacturing location and batch number of drugs (including COVID–19 therapeutics and vaccines) and allowing patient verification of authenticity, and for other purposes.

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

1 SECTION 1. SHORT TITLE.

2	This Act may be cited as the "Supply Chain Security
3	and Pharmaceutical Authentication Act of 2021".
4	SEC. 2. PACKAGES SUBJECT TO PHARMACEUTICAL DIS-
5	TRIBUTION SUPPLY CHAIN REQUIREMENTS.
6	Subparagraph (B) of section 581(11) of the Federal
7	Food, Drug, and Cosmetic Act (21 U.S.C. 360eee(11)) is
8	amended to read as follows:
9	"(B) Individual saleable unit.—For
10	purposes of this paragraph, an 'individual sale-
11	able unit' is the smallest solid oral dosage form
12	of product, or other individual solid oral dosage
13	form of product, introduced into commerce by
14	the manufacturer or repackager.".
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