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(Original Signature of Member)

119TH CONGRESS
1ST SESSION

H. R. _____

To improve the safety of pasteurized donor human milk and enhance regulation.

IN THE HOUSE OF REPRESENTATIVES

Ms. DELAURO introduced the following bill; which was referred to the Committee on _____

A BILL

To improve the safety of pasteurized donor human milk and enhance regulation.

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 “Developing Oversight
5 for Nutrition through the Official Regulation of Milk Act”
6 or the “DONOR Milk Act”.

1 **SEC. 2. REGULATION OF PASTEURIZED DONOR HUMAN**
2 **MILK.**

3 (a) DEFINITIONS.—Section 201 of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 321) is amended—

5 (1) in subsection (ss)—

6 (A) in paragraph (1), by striking “or” at
7 the end;

8 (B) in paragraph (2), by striking the pe-
9 riod at the end and inserting “; or”; and

10 (C) by adding at the end the following:

11 “(3) pasteurized donor human milk.”; and

12 (2) by adding at the end the following:

13 “(tt) The term ‘pasteurized donor human milk’
14 means human milk which—

15 “(1) is expressed by a mother and donated for
16 use by a recipient that is not the mother’s own in-
17 fant; and

18 “(2) has been collected, pasteurized, and dis-
19 pensed without additives.”.

20 (b) CLARIFICATION OF FOOD MANUFACTURER REG-
21 ISTRATION REQUIREMENT.—Section 415(c)(1) of the
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 350d(e)(1)) is amended by adding at the end the fol-
24 lowing: “Beginning on the date of the enactment of the
25 DONOR Milk Act, a food establishment that manufac-
26 tures, processes, packs, or holds critical foods shall not

1 be considered a nonprofit food establishments in which
2 food is prepared for or served directly to the consumer
3 and the exception in the preceding sentence shall no longer
4 apply to such a facility”.

5 (c) ANNUAL INSPECTIONS OF DONOR HUMAN MILK
6 MANUFACTURERS.—Section 412 of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 350a) is amended by
8 adding at the end the following:

9 “(n) ANNUAL INSPECTIONS OF DONOR HUMAN MILK
10 MANUFACTURERS.—Beginning not later than 1 year after
11 the date of the enactment of this subsection, and not less
12 frequently than once each year thereafter, the Secretary
13 shall conduct inspections, including unannounced inspec-
14 tions, of the facilities of each entity that manufactures,
15 processes, packs, or holds pasteurized donor human milk
16 in accordance with a risk-based approach to ensure com-
17 pliance with relevant food safety and food labeling require-
18 ments under this Act or any other provision of law admin-
19 istered by the Secretary.”.

20 (d) COMPLIANCE GRANTS FOR DONOR HUMAN MILK
21 MANUFACTURERS.—Section 412 of the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C. 350a), as amended
23 by subsection (c) of this section, is further amended by
24 adding at the end the following:

1 “(o) COMPLIANCE GRANTS FOR DONOR HUMAN
2 MILK MANUFACTURERS.—

3 “(1) IN GENERAL.—The Secretary shall make
4 grants to nonprofit entities that manufacture, proc-
5 ess, pack, or hold pasteurized donor human milk and
6 are registered under section 415(c) to assist such
7 entities in complying with this Act, including
8 through assisting such entities with respect to mak-
9 ing any upgrades in equipment, obtaining necessary
10 certifications, and entering into contracts with third
11 parties for food safety quality consultations.

12 “(2) AUTHORIZATION OF APPROPRIATIONS.—
13 There are authorized to be appropriated \$8,000,000,
14 to remain available until expended, to carry out
15 paragraph (1).”.