

107<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 5488

To amend the Federal Food, Drug, and Cosmetic Act to provide the Food and Drug Administration with authority to recall food when there is a reasonable basis for believing that the food is adulterated and presents a risk to human health, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 26, 2002

Mr. PALLONE introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide the Food and Drug Administration with authority to recall food when there is a reasonable basis for believing that the food is adulterated and presents a risk to human health, 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,*

3       **SECTION 1. FOOD RECALL AUTHORITY FOR FOOD AND**  
4       **DRUG ADMINISTRATION.**

5       (a) IN GENERAL.—Chapter IV of the Federal Food,  
6       Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-  
7       ed by adding at the end the following section:

1 “RECALL AUTHORITY

2 “SEC. 416. (a) ORDER TO CEASE DISTRIBUTION.—

3 “(1) IN GENERAL.—If the Secretary determines  
4 that there is a reasonable basis for believing that  
5 food is adulterated and presents a risk to human  
6 health, the Secretary shall issue an order requiring  
7 the appropriate persons (including manufacturers,  
8 importers, distributors, or retailers) to immediately  
9 cease distribution of the food.

10 “(2) INFORMAL HEARING.—An order under  
11 paragraph (1) shall provide the person subject to the  
12 order with an opportunity for an informal hearing,  
13 to be held not later than 10 days after the date of  
14 the issuance of the order, on the actions required by  
15 the order and on whether the order should be  
16 amended to require a recall of the food involved. If,  
17 after providing an opportunity for such a hearing,  
18 the Secretary determines that inadequate grounds  
19 exist to support the actions required by the order,  
20 the Secretary shall vacate the order.

21 “(b) RECALL ORDER.—If, after providing an oppor-  
22 tunity for an informal hearing under subsection (a)(2), the  
23 Secretary determines that the order involved should be  
24 amended to include a recall of the food with respect to  
25 which the order was issued, the Secretary shall amend the

1 order to require a recall. The Secretary shall specify a  
2 timetable in which the food recall will occur and shall re-  
3 quire periodic reports to the Secretary describing the  
4 progress of the recall.

5 “(c) INFANT FORMULA.—With respect to the recall  
6 of infant formula, section 412(e) applies in lieu of sub-  
7 sections (a) and (b).”.

8 (b) PROHIBITED ACT.—Section 301 of the Federal  
9 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-  
10 ed by adding at the end the following:

11 “(gg) The failure to comply with an order under sec-  
12 tion 416.”.

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