

# Union Calendar No. 208

109TH CONGRESS  
2D SESSION

# H. R. 4167

[Report No. 109-379]

To amend the Federal Food, Drug, and Cosmetic Act to provide for uniform food safety warning notification requirements, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

OCTOBER 27, 2005

Mr. ROGERS of Michigan (for himself, Mr. TOWNS, Mr. ADERHOLT, Mr. ALEXANDER, Mr. ANDREWS, Mr. BARROW, Mr. BASS, Mr. BEAUPREZ, Mr. BERRY, Mrs. BIGGERT, Mr. BISHOP of Georgia, Mrs. BLACKBURN, Mr. BLUNT, Mr. BOEHLERT, Mr. BOEHNER, Mr. BONILLA, Mr. BONNER, Mr. BOREN, Mr. BOUCHER, Mr. BOUSTANY, Mr. BOYD, Mr. BRADLEY of New Hampshire, Mr. BURGESS, Mr. CALVERT, Mr. CAMP, Mr. CANNON, Mr. CANTOR, Mrs. CAPITO, Mr. CARDOZA, Mr. CARTER, Mr. CHANDLER, Mr. CHOCOLA, Mr. COBLE, Mr. CONAWAY, Mr. CRAMER, Mr. CRENSHAW, Mr. CROWLEY, Mrs. CUBIN, Mr. DAVIS of Illinois, Mr. DAVIS of Kentucky, Mrs. JO ANN DAVIS of Virginia, Mr. DAVIS of Tennessee, Mr. TOM DAVIS of Virginia, Mr. LINCOLN DIAZ-BALART of Florida, Mr. DOOLITTLE, Mr. DOYLE, Mrs. DRAKE, Mr. DUNCAN, Mr. EHLERS, Mr. EMANUEL, Mrs. EMERSON, Mr. ENGLISH of Pennsylvania, Mr. ETHERIDGE, Mr. FERGUSON, Mr. FOLEY, Mr. GALLEGLY, Mr. GERLACH, Mr. GILLMOR, Mr. GINGREY, Mr. GOODE, Mr. GOODLATTE, Mr. GORDON, Ms. GRANGER, Mr. GRAVES, Mr. GREEN of Wisconsin, Mr. HALL, Ms. HART, Mr. HAYES, Mr. HENSARLING, Mr. HERGER, Mr. HIGGINS, Mr. HOEKSTRA, Mr. HULSHOF, Ms. JACKSON-LEE of Texas, Ms. EDDIE BERNICE JOHNSON of Texas, Mr. SAM JOHNSON of Texas, Mr. JOHNSON of Illinois, Mr. JONES of North Carolina, Mrs. KELLY, Mr. KENNEDY of Minnesota, Mr. KINGSTON, Mr. KIRK, Mr. KLINE, Mr. KOLBE, Mr. KUHL of New York, Mr. LAHOOD, Mr. LATHAM, Mr. LATOURETTE, Mr. LEWIS of Georgia, Mr. LEWIS of Kentucky, Mr. LINDER, Mr. LUCAS, Mr. MARCHANT, Mr. MARSHALL, Mr. MATHESON, Mr. McCOTTER, Mr. MCINTYRE, Miss McMORRIS, Mr. MEEKS of New York, Mr. MICHAUD, Ms. MILLENDER-McDONALD, Mr. MOORE of Kansas, Mr. MORAN of Kansas, Mr. MORAN of Virginia, Mrs. MUSGRAVE, Mrs. NORTHUP, Mr. NORWOOD, Mr. NUNES, Mr. ORTIZ, Mr. OSBORNE, Mr. OTTER, Mr.

OXLEY, Mr. PEARCE, Mr. PENCE, Mr. PETERSON of Minnesota, Mr. PICKERING, Mr. PITTS, Mr. POMBO, Mr. PORTER, Mr. PRICE of Georgia, Ms. PRYCE of Ohio, Mr. RADANOVICH, Mr. RAMSTAD, Mr. REGULA, Mr. REHBERG, Mr. ROHRABACHER, Mr. ROSS, Mr. ROYCE, Mr. RUPPERSBERGER, Mr. RUSH, Mr. SCHWARZ of Michigan, Mr. SESSIONS, Mr. SHADEGG, Mr. SHIMKUS, Mr. SHUSTER, Mr. SIMPSON, Mr. SKELTON, Mr. SODREL, Mr. SOUDER, Mr. STRICKLAND, Mr. SULLIVAN, Mr. SWEENEY, Mr. TERRY, Mr. THOMPSON of Mississippi, Mr. TIAHRT, Mr. TIBERI, Mr. UPTON, Mr. WAMP, Mr. WELLER, Mr. WESTMORELAND, Mr. WICKER, Mrs. WILSON of New Mexico, Mr. WILSON of South Carolina, Mr. WYNN, Mr. WHITFIELD, Mr. SHERWOOD, Mr. JEFFERSON, Mr. DAVIS of Alabama, and Mr. MANZULLO) introduced the following bill; which was referred to the Committee on Energy and Commerce

FEBRUARY 28, 2006

Additional sponsors: Mr. BARRETT of South Carolina, Mr. OWENS, Mr. SCOTT of Georgia, Mr. SIMMONS, Mr. HEFLEY, Mr. FORD, Mr. COOPER, Mrs. JOHNSON of Connecticut, Mr. HASTINGS of Washington, Ms. GINNY BROWN-WAITE of Florida, Mr. BISHOP of Utah, Mr. LOBIONDO, Mr. SHAW, Mr. MURPHY, Mr. WALDEN of Oregon, Mr. MCHENRY, Mr. PLATTS, Mr. RYAN of Wisconsin, Mrs. MYRICK, Mr. COLE of Oklahoma, Ms. BEAN, Ms. ROS-LEHTINEN, Mr. PETRI, Ms. FOXX, Mr. JINDAL, Mr. AKIN, Mr. MCCAUL of Texas, Mr. PETERSON of Pennsylvania, Mr. INGLES of South Carolina, Mr. MILLER of Florida, Mr. GUTKNECHT, Mr. TANCREDO, Mr. SALAZAR, Mr. MACK, Mr. HOBSON, Ms. HARRIS, Mr. KELLER, Mr. SHAYS, Mr. BOOZMAN, Mr. MELANCON, Mr. TAYLOR of Mississippi, Mr. LIPINSKI, Mr. CLAY, Mrs. JONES of Ohio, Mr. REYNOLDS, Mr. KANJORSKI, Mr. STEARNS, Mr. SAXTON, Mr. REICHERT, Mr. MCHUGH, Mrs. MILLER of Michigan, Mr. KING of Iowa, Mr. RYUN of Kansas, Mr. NUSSLE, Mr. JENKINS, Mr. ISRAEL, Mr. COSTELLO, Mr. WELDON of Pennsylvania, Mr. POE, Ms. HERSETH, Mr. MCCRERY, Mr. FORBES, Mrs. SCHMIDT, Mr. COSTA, Mr. HOLDEN, Mr. BUTTERFIELD, Mr. BROWN of South Carolina, and Mr. DEAL of Georgia

FEBRUARY 28, 2006

Committed to the Committee of the Whole House on the State of the Union  
and ordered to be printed

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for uniform food safety warning notification requirements, 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. SHORT TITLE.**

4 This Act may be cited as the “National Uniformity  
5 for Food Act of 2005”.

6 **SEC. 2. NATIONAL UNIFORMITY FOR FOOD.**

7 (a) NATIONAL UNIFORMITY.—Section 403A(a) of the  
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–  
9 1(a)) is amended—

10 (1) in paragraph (4), by striking “or” at the  
11 end;

12 (2) in paragraph (5), by striking the period and  
13 inserting “, or”;

14 (3) by inserting after paragraph (5) the fol-  
15 lowing:

16 “(6) any requirement for a food described in  
17 section 402(a)(1), 402(a)(2), 402(a)(6), 402(a)(7),  
18 402(c), 404, 406, 409, 512, or 721(a), that is not  
19 identical to the requirement of such section.”; and

20 (4) by adding at the end the following: “For  
21 purposes of paragraph (6) and section 403B, the  
22 term ‘identical’ means that the language under the  
23 laws of a State or a political subdivision of a State  
24 is substantially the same language as the comparable  
25 provision under this Act and that any differences in

1 language do not result in the imposition of materi-  
2 ally different requirements. For purposes of para-  
3 graph (6), the term ‘any requirement for a food’  
4 does not refer to provisions of this Act that relate  
5 to procedures for Federal action under this Act.”.

6 (b) UNIFORMITY IN FOOD SAFETY WARNING NOTI-  
7 FICATION REQUIREMENTS.—Chapter IV of such Act (21  
8 U.S.C. 341 et seq.) is amended—

9 (1) by redesignating sections 403B and 403C  
10 as sections 403C and 403D, respectively; and

11 (2) by inserting after section 403A the fol-  
12 lowing new section:

13 **“SEC. 403B. UNIFORMITY IN FOOD SAFETY WARNING NOTI-  
14 FICATION REQUIREMENTS.**

15 **“(a) UNIFORMITY REQUIREMENT.—**

16 **“(1) IN GENERAL.—**Except as provided in sub-  
17 sections (c) and (d), no State or political subdivision  
18 of a State may, directly or indirectly, establish or  
19 continue in effect under any authority any notifica-  
20 tion requirement for a food that provides for a warn-  
21 ing concerning the safety of the food, or any compo-  
22 nent or package of the food, unless such a notifica-  
23 tion requirement has been prescribed under the au-  
24 thority of this Act and the State or political subdivi-  
25 sion notification requirement is identical to the noti-

1       fication requirement prescribed under the authority  
2       of this Act.

3               “(2) DEFINITIONS.—For purposes of paragraph  
4       (1)—

5                       “(A) the term ‘notification requirement’ in-  
6       cludes any mandatory disclosure requirement  
7       relating to the dissemination of information  
8       about a food by a manufacturer or distributor  
9       of a food in any manner, such as through a  
10      label, labeling, poster, public notice, advertising,  
11      or any other means of communication, except  
12      as provided in paragraph (3);

13                      “(B) the term ‘warning’, used with respect  
14      to a food, means any statement, vignette, or  
15      other representation that indicates, directly or  
16      by implication, that the food presents or may  
17      present a hazard to health or safety; and

18                      “(C) a reference to a notification require-  
19      ment that provides for a warning shall not be  
20      construed to refer to any requirement or prohi-  
21      bition relating to food safety that does not in-  
22      volve a notification requirement.

23               “(3) CONSTRUCTION.—Nothing in this section  
24      shall be construed to prohibit a State from con-  
25      ducting the State’s notification, disclosure, or other

1 dissemination of information, or to prohibit any ac-  
2 tion taken relating to a mandatory recall, civil ad-  
3 ministrative order, embargo, detention order, or  
4 court proceeding involving food adulteration under a  
5 State statutory requirement identical to a food adul-  
6 teration requirement under this Act.

7 “(b) REVIEW OF EXISTING STATE REQUIRE-  
8 MENTS.—

9 “(1) EXISTING STATE REQUIREMENTS; DEFER-  
10 RAL.—Any requirement that—

11 “(A)(i) is a State notification requirement  
12 that expressly applies to a specified food or food  
13 component and that provides for a warning de-  
14 scribed in subsection (a) that does not meet the  
15 uniformity requirement specified in subsection  
16 (a); or

17 “(ii) is a State food safety requirement de-  
18 scribed in section 403A(6) that does not meet  
19 the uniformity requirement specified in that  
20 paragraph; and

21 “(B) is in effect on the date of enactment  
22 of the National Uniformity for Food Act of  
23 2005, shall remain in effect for 180 days after  
24 that date of enactment.

1           “(2) STATE PETITIONS.—With respect to a  
2 State notification or food safety requirement that is  
3 described in paragraph (1), the State may petition  
4 the Secretary for an exemption or a national stand-  
5 ard under subsection (c). If a State submits such a  
6 petition within 180 days after the date of enactment  
7 of the National Uniformity for Food Act of 2005,  
8 the notification or food safety requirement shall re-  
9 main in effect in accordance with subparagraph (C)  
10 of paragraph (3), and the time periods and provi-  
11 sions specified in subparagraphs (A) and (B) of such  
12 paragraph shall apply in lieu of the time periods and  
13 provisions specified in subsection (c)(3) (but not the  
14 time periods and provisions specified in subsection  
15 (d)(2)).

16           “(3) ACTION ON PETITIONS.—

17           “(A) PUBLICATION.—Not later than 270  
18 days after the date of enactment of the Na-  
19 tional Uniformity for Food Act of 2005, the  
20 Secretary shall publish a notice in the Federal  
21 Register concerning any petition submitted  
22 under paragraph (2) and shall provide 180 days  
23 for public comment on the petition.

24           “(B) TIME PERIODS.—Not later than 360  
25 days after the end of the period for public com-

1           ment, the Secretary shall take final agency ac-  
2           tion on the petition.

3           “(C) ACTION.—

4                   “(i) IN GENERAL.—With respect to a  
5           State that submits to the Secretary a peti-  
6           tion in accordance with paragraph (2), the  
7           notification or food safety requirement in-  
8           volved shall remain in effect during the pe-  
9           riod beginning on the date of enactment of  
10          the National Uniformity for Food Act of  
11          2005 and ending on the applicable date  
12          under subclause (I) or (II), as follows:

13                           “(I) If the petition is denied by  
14                           the Secretary, the date of such denial.

15                           “(II) If the petition is approved  
16                           by the Secretary, the effective date of  
17                           the final rule that is promulgated  
18                           under subsection (c) to provide an ex-  
19                           emption or national standard pursu-  
20                           ant to the petition, except that there  
21                           is no applicable ending date under  
22                           this subparagraph for a provision of  
23                           State law that is part of such State  
24                           requirement in any case in which the



1 final rule does not establish any con-  
2 dition regarding such provision of law.

3 “(ii) NONCOMPLIANCE OF SECRETARY  
4 REGARDING TIMEFRAMES.—

5 “(I) JUDICIAL REVIEW.—The  
6 failure of the Secretary to comply  
7 with any requirement of subparagraph  
8 (A) or (B) shall constitute final agen-  
9 cy action for purposes of judicial re-  
10 view. If the court conducting the re-  
11 view determines that the Secretary  
12 has failed to comply with the require-  
13 ment, the court shall order the Sec-  
14 retary to comply within a period de-  
15 termined to be appropriate by the  
16 court.

17 “(II) STATUS OF STATE RE-  
18 QUIREMENT.—With respect to a State  
19 that submits to the Secretary a peti-  
20 tion in accordance with paragraph (2),  
21 if the Secretary fails to take final  
22 agency action on the petition within  
23 the period that applies under subpara-  
24 graph (B), the notification or food

1 safety requirement involved remains  
2 in effect in accordance with clause (i).

3 “(c) EXEMPTIONS AND NATIONAL STANDARDS.—

4 “(1) EXEMPTIONS.—Any State may petition  
5 the Secretary to provide by regulation an exemption  
6 from section 403A(a)(6) or subsection (a), for a re-  
7 quirement of the State or a political subdivision of  
8 the State. The Secretary may provide such an ex-  
9 emption, under such conditions as the Secretary may  
10 impose, for such a requirement that—

11 “(A) protects an important public interest  
12 that would otherwise be unprotected, in the ab-  
13 sence of the exemption;

14 “(B) would not cause any food to be in  
15 violation of any applicable requirement or prohi-  
16 bition under Federal law; and

17 “(C) would not unduly burden interstate  
18 commerce, balancing the importance of the pub-  
19 lic interest of the State or political subdivision  
20 against the impact on interstate commerce.

21 “(2) NATIONAL STANDARDS.—Any State may  
22 petition the Secretary to establish by regulation a  
23 national standard respecting any requirement under  
24 this Act or the Fair Packaging and Labeling Act

1 (15 U.S.C. 1451 et seq.) relating to the regulation  
2 of a food.

3 “(3) ACTION ON PETITIONS.—

4 “(A) PUBLICATION.—Not later than 30  
5 days after receipt of any petition under para-  
6 graph (1) or (2), the Secretary shall publish  
7 such petition in the Federal Register for public  
8 comment during a period specified by the Sec-  
9 retary.

10 “(B) TIME PERIODS FOR ACTION.—Not  
11 later than 60 days after the end of the period  
12 for public comment, the Secretary shall take  
13 final agency action on the petition or shall in-  
14 form the petitioner, in writing, the reasons that  
15 taking the final agency action is not possible,  
16 the date by which the final agency action will  
17 be taken, and the final agency action that will  
18 be taken or is likely to be taken. In every case,  
19 the Secretary shall take final agency action on  
20 the petition not later than 120 days after the  
21 end of the period for public comment.

22 “(4) JUDICIAL REVIEW.—The failure of the  
23 Secretary to comply with any requirement of this  
24 subsection shall constitute final agency action for  
25 purposes of judicial review. If the court conducting

1 the review determines that the Secretary has failed  
2 to comply with the requirement, the court shall  
3 order the Secretary to comply within a period deter-  
4 mined to be appropriate by the court.

5 “(d) IMMINENT HAZARD AUTHORITY.—

6 “(1) IN GENERAL.—A State may establish a re-  
7 quirement that would otherwise violate section  
8 403A(a)(6) or subsection (a), if—

9 “(A) the requirement is needed to address  
10 an imminent hazard to health that is likely to  
11 result in serious adverse health consequences or  
12 death;

13 “(B) the State has notified the Secretary  
14 about the matter involved and the Secretary  
15 has not initiated enforcement action with re-  
16 spect to the matter;

17 “(C) a petition is submitted by the State  
18 under subsection (c) for an exemption or na-  
19 tional standard relating to the requirement not  
20 later than 30 days after the date that the State  
21 establishes the requirement under this sub-  
22 section; and

23 “(D) the State institutes enforcement ac-  
24 tion with respect to the matter in compliance  
25 with State law within 30 days after the date

1           that the State establishes the requirement  
2           under this subsection.

3           “(2) ACTION ON PETITION.—

4                   “(A) IN GENERAL.—The Secretary shall  
5           take final agency action on any petition sub-  
6           mitted under paragraph (1)(C) not later than 7  
7           days after the petition is received, and the pro-  
8           visions of subsection (e) shall not apply to the  
9           petition.

10                   “(B) JUDICIAL REVIEW.—The failure of  
11           the Secretary to comply with the requirement  
12           described in subparagraph (A) shall constitute  
13           final agency action for purposes of judicial re-  
14           view. If the court conducting the review deter-  
15           mines that the Secretary has failed to comply  
16           with the requirement, the court shall order the  
17           Secretary to comply within a period determined  
18           to be appropriate by the court.

19                   “(3) DURATION.—If a State establishes a re-  
20           quirement in accordance with paragraph (1), the re-  
21           quirement may remain in effect until the Secretary  
22           takes final agency action on a petition submitted  
23           under paragraph (1)(C).

1       “(e) NO EFFECT ON PRODUCT LIABILITY LAW.—  
2 Nothing in this section shall be construed to modify or  
3 otherwise affect the product liability law of any State.

4       “(f) NO EFFECT ON IDENTICAL LAW.—Nothing in  
5 this section relating to a food shall be construed to prevent  
6 a State or political subdivision of a State from estab-  
7 lishing, enforcing, or continuing in effect a requirement  
8 that is identical to a requirement of this Act, whether or  
9 not the Secretary has promulgated a regulation or issued  
10 a policy statement relating to the requirement.

11       “(g) NO EFFECT ON CERTAIN STATE LAW.—Noth-  
12 ing in this section or section 403A relating to a food shall  
13 be construed to prevent a State or political subdivision of  
14 a State from establishing, enforcing, or continuing in ef-  
15 fect a requirement relating to—

16               “(1) freshness dating, open date labeling, grade  
17 labeling, a State inspection stamp, religious dietary  
18 labeling, organic or natural designation, returnable  
19 bottle labeling, unit pricing, or a statement of geo-  
20 graphic origin; or

21               “(2) a consumer advisory relating to food sani-  
22 tation that is imposed on a food establishment, or  
23 that is recommended by the Secretary, under part  
24 3–6 of the Food Code issued by the Food and Drug  
25 Administration and referred to in the notice pub-

1 lished at 64 Fed. Reg. 8576 (1999) (or any cor-  
2 responding similar provision of such a Code).

3 “(h) DEFINITIONS.—In section 403A and this sec-  
4 tion:

5 “(1) The term ‘requirement’, used with respect  
6 to a Federal action or prohibition, means a manda-  
7 tory action or prohibition established under this Act  
8 or the Fair Packaging and Labeling Act (15 U.S.C.  
9 1451 et seq.), as appropriate, or by a regulation  
10 issued under or by a court order relating to, this Act  
11 or the Fair Packaging and Labeling Act, as appro-  
12 priate.

13 “(2) The term ‘petition’ means a petition sub-  
14 mitted in accordance with the provisions of section  
15 10.30 of title 21, Code of Federal Regulations, con-  
16 taining all data and information relied upon by the  
17 petitioner to support an exemption or a national  
18 standard.”.

19 (c) CONFORMING AMENDMENT.—Section 403A(b) of  
20 such Act (21 U.S.C. 343–1(b)) is amended by adding after  
21 and below paragraph (3) the following:

22 “The requirements of paragraphs (3) and (4) of section  
23 403B(c) shall apply to any such petition, in the same man-  
24 ner and to the same extent as the requirements apply to  
25 a petition described in section 403B(c).”.

Union Calendar No. 208

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

**H. R. 4167**

[Report No. 109-379]

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**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to provide for uniform food safety warning notification requirements, and for other purposes.

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FEBRUARY 28, 2006

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