

(ii) in the second sentence—

(I) by striking “inspections” and inserting “inspectional findings”; and

(II) by inserting “relevant” after “together with all other”;

(D) in paragraph (6)(C)(ii), by striking “in accordance with section 510(h), or has not during such period been inspected pursuant to section 510(i), as applicable”;

(E) in paragraph (10)(B)(iii), by striking “a reporting” and inserting “a report”; and

(F) in paragraph (12)—

(i) by striking subparagraph (A) and inserting the following:

“(A) the number of inspections conducted by accredited persons pursuant to this subsection and the number of inspections conducted by Federal employees pursuant to section 510(h) and of device establishments required to register under section 510(i);” and

(ii) in subparagraph (E), by striking “obtained by the Secretary” and all that follows and inserting “obtained by the Secretary pursuant to inspections conducted by Federal employees.”

(2) OTHER CORRECTIONS.—

(A) PROHIBITED ACTS.—Section 301(gg) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(gg)), as amended by section 201(d) of Public Law 107-250 (116 Stat. 1609), is amended to read as follows:

“(gg) The knowing failure to comply with paragraph (7)(E) of section 704(g); the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.”

(B) ELECTRONIC LABELING.—Section 502(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)), as amended by section 206 of Public Law 107-250 (116 Stat. 1613), is amended, in the last sentence—

(i) by inserting “or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments” after “in health care facilities”;

(ii) by inserting a comma after “means”;

(iii) by striking “requirements of law and, that” and inserting “requirements of law, and that”;

(iv) by striking “the manufacturer affords health care facilities the opportunity” and inserting “the manufacturer affords such users the opportunity”; and

(v) by striking “the health care facility”.

(c) TITLE III; ADDITIONAL AMENDMENTS.—

(1) EFFECTIVE DATE.—Section 301(b) of Public Law 107-250 (116 Stat. 1616), is amended by striking “18 months” and inserting “36 months”.

(2) PREMARKET NOTIFICATION.—Section 510(o) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(o)), as added by section 302(b) of Public Law 107-250 (116 Stat. 1616), is amended—

(A) in paragraph (1)(B), by striking “, adulterated” and inserting “or adulterated”; and

(B) in paragraph (2)—

(i) in subparagraph (B), by striking “, adulterated” and inserting “or adulterated”; and

(ii) in subparagraph (E), by striking “semicritical” and inserting “semi-critical”.

(d) MISCELLANEOUS CORRECTIONS.—

(1) CERTAIN AMENDMENTS TO SECTION 515.—

(A) IN GENERAL.—

(i) TECHNICAL CORRECTION.—Section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)), as amended by sections 209 and 302(c)(2)(A) of Public Law 107-250 (116 Stat. 1613, 1618), is amended by redesignating paragraph (3) (as added by section 209 of such Public Law) as paragraph (4).

(ii) MODULAR REVIEW.—Section 515(c)(4)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)(4)(B)) is amended by striking

“unless an issue of safety” and inserting “unless a significant issue of safety”.

(B) CONFORMING AMENDMENT.—Section 210 of Public Law 107-250 (116 Stat. 1614) is amended by striking “, as amended” and all that follows through “by adding” and inserting “is amended in paragraph (3), as redesignated by section 302(c)(2)(A) of this Act, by adding”.

(2) CERTAIN AMENDMENTS TO SECTION 738.—

(A) IN GENERAL.—Section 738(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(a)), as amended by subsection (a), is amended—

(i) in the matter preceding paragraph (1)—

(I) by striking “(a) TYPES OF FEES.—Beginning on” and inserting the following:

“(a) TYPES OF FEES.—

“(1) IN GENERAL.—Beginning on”; and

(II) by striking “this section as follows:” and inserting “this section.”; and

(ii) by striking “(1) PREMARKET APPLICATION,” and inserting the following: “(2) PREMARKET APPLICATION.”.

(B) CONFORMING AMENDMENTS.—Section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j), as amended by subparagraph (A), is amended—

(i) in subsection (d)(1), in the last sentence, by striking “subsection (a)(1)(A)” and inserting “subsection (a)(2)(A)”;

(ii) in subsection (e)(1), by striking “subsection (a)(1)(A)(vii)” and inserting “subsection (a)(2)(A)(vii)”;

(iii) in subsection (e)(2)(C)—

(I) in each of clauses (i) and (ii), by striking “subsection (a)(1)(A)(vii)” and inserting “subsection (a)(2)(A)(vii)”;

(II) in clause (ii), by striking “subsection (a)(1)(A)(i)” and inserting “subsection (a)(2)(A)(i)”;

(iv) in subsection (j), by striking “subsection (a)(1)(D),” and inserting “subsection (a)(2)(D),”.

(C) ADDITIONAL CONFORMING AMENDMENT.—Section 102(b)(1) of Public Law 107-250 (116 Stat. 1600) is amended, in the matter preceding subparagraph (A), by striking “section 738(a)(1)(A)(ii)” and inserting “section 738(a)(2)(A)(ii)”.

(3) PUBLIC LAW 107-250.—Public Law 107-250 is amended—

(A) in section 102(a) (116 Stat. 1589), by striking “(21 U.S.C. 379f et seq.)” and inserting “(21 U.S.C. 379f et seq.)”;

(B) in section 102(b) (116 Stat. 1600)—

(i) by striking paragraph (2);

(ii) in paragraph (1), by redesignating subparagraphs (A) and (B) as paragraphs (1) and (2), respectively; and

(iii) by striking:

“(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUBMITTING PREMARKET REPORTS.—

“(1) IN GENERAL.—A person submitting a premarket report” and inserting:

“(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUBMITTING PREMARKET REPORTS.—A person submitting a premarket report”;

(C) in section 212(b)(2) (116 Stat. 1614), by striking “, such as phase IV trials.”.

**SEC. 3. REPORT ON BARRIERS TO AVAILABILITY OF DEVICES INTENDED FOR CHILDREN.**

Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the barriers to the availability of devices intended for the treatment or diagnosis of diseases and conditions that affect children. The report shall include any recommendations of the Secretary of Health and Human Services for changes to existing statutory authority, regulations, or agency policy or practice to encourage the invention and development of such devices.

Mr. McCONNELL. Mr. President, I ask unanimous consent that the com-

mittee substitute amendment be agreed to, the bill, as amended, be read a third time and passed, the motion to reconsider be laid upon the table, and that any statements relating to the bill be printed in the RECORD.

The PRESIDING OFFICER. Without objection, it is so ordered.

The committee amendment in the nature of a substitute was agreed to.

The bill (S. 1881), as amended, was read the third time and passed.

**COMMEMORATING THE 25TH ANNIVERSARY OF VIETNAM VETERANS OF AMERICA**

Mr. McCONNELL. Mr. President, I ask unanimous consent that the Judiciary Committee be discharged from further consideration of S. Res. 120 and that the Senate proceed to its immediate consideration.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will report the resolution by title.

The assistant legislative clerk read as follows:

A resolution (S. Res. 120) commemorating the 25th anniversary of Vietnam Veterans of America.

There being no objection, the Senate proceeded to consider the resolution.

Mr. McCONNELL. Mr. President, I ask unanimous consent that the resolution be agreed to, the preamble be agreed to, and the motion to reconsider be laid upon the table, with no intervening action or debate, and that any statements relating to the measure be printed in the RECORD.

The PRESIDING OFFICER. Without objection, it is so ordered.

The resolution (S. Res. 120) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, reads as follows:

**S. RES. 120**

Whereas the year 2003 marks the 25th anniversary of the founding of Vietnam Veterans of America;

Whereas the history of Vietnam Veterans of America is a story of the United States' gradual recognition of the tremendous sacrifices of its Vietnam-era veterans and their families;

Whereas Vietnam Veterans of America is dedicated to advocating on behalf of its members;

Whereas Vietnam Veterans of America raises public and member awareness of critical issues affecting Vietnam-era veterans and their families;

Whereas the local grassroots efforts of Vietnam Veterans of America chapters, such as Chapter One in Rutland, Vermont, which was founded 23 years ago in April of 1980, have greatly contributed to the quality of the lives of veterans in our Nation's communities;

Whereas Vietnam Veterans of America promotes its principles through volunteerism, professional advocacy, and claims work; and

Whereas the future of Vietnam Veterans of America will rely not only on its past accomplishments, but also on the future accomplishments of its members, and these will ensure that Vietnam Veterans of America remains a leader among veterans advocacy organizations: Now, therefore, be it

*Resolved*, That the Senate—

(1) commemorates the 25th anniversary of the founding of Vietnam Veterans of America, and commends it for its efforts in the advancement of veterans rights, which set the standard for all other veterans organizations around the country;

(2) asks all Americans to join in the celebration of the 25th anniversary of Vietnam Veterans of America, and its 25 years of advocacy on behalf of Vietnam veterans; and

(3) encourages Vietnam Veterans of America to continue to represent and promote its goals in the veterans' community and on Capitol Hill, and to continue to keep its national membership—consisting of 45,000 members and 600 chapters—strong.

#### MEASURES DISCHARGED

Mr. McCONNELL. Mr. President, I ask unanimous consent that the Judiciary Committee be discharged from further consideration of the following: S. 99, S. 1130, S. 103, S. 848, and S. 541, and that the Senate proceed to their immediate consideration en bloc.

The PRESIDING OFFICER. Without objection, it is so ordered.

The Senate will proceed to the consideration of the measures en bloc.

Mr. McCONNELL. Mr. President, I further ask unanimous consent that the bills be read three times and passed en bloc, and the motion to reconsider be laid upon the table, with no intervening action or debate, and that any statements relating to these measures be printed in the RECORD.

The PRESIDING OFFICER. Without objection, it is so ordered.

#### FOR THE RELIEF OF JAYA GULAB TOLANI AND HITESH GULAB TOLANI

The bill (S. 99) for the relief of Jaya Gulab Tolani and Hitesh Gulab Tolani, was considered, ordered to be engrossed for a third reading, read the third time, and passed, as follows:

S. 99

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

##### SECTION 1. PERMANENT RESIDENCE.

Notwithstanding any other provision of law, for purposes of the Immigration and Nationality Act (8 U.S.C. 1101 et seq.), Jaya Gulab Tolani and Hitesh Gulab Tolani shall be held and considered to have been lawfully admitted to the United States for permanent residence as of the date of enactment of this Act upon payment of the required visa fees.

##### SEC. 2. REDUCTION OF NUMBER OF AVAILABLE VISAS.

Upon the granting of permanent residence to Jaya Gulab Tolani and Hitesh Gulab Tolani, as provided in section 1, the Secretary of State shall instruct the proper officer to reduce by the appropriate number during the current fiscal year the total number of immigrant visas available to natives of the country of the aliens' birth under section 203(a) of the Immigration and Nationality Act (8 U.S.C. 1153(a)).

#### FOR THE RELIEF OF ESIDRONIO ARREOLA-SAUCEDO, MARIA ELANA COBIAN ARREOLA, NAYELY BIBIANA ARREOLA, AND CINDY JAEL ARREOLA

The bill (S. 1130) for the relief of Esidronio Arreola-Saucedo, Maria Elana Cobian Arreola, Nayely Bibiana Arreola, and Cindy Jael Arreola, was considered, ordered to be engrossed for a third reading, read the third time, and passed, as follows:

S. 1130

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

##### SECTION 1. PERMANENT RESIDENT STATUS FOR ESIDRONIO ARREOLA-SAUCEDO, MARIA ELENA COBIAN ARREOLA, NAYELY BIBIANA ARREOLA, AND CINDY JAEL ARREOLA.

(a) IN GENERAL.—Notwithstanding subsections (a) and (b) of section 201 of the Immigration and Nationality Act, Esidronio Arreola-Saucedo, Maria Elena Cobian Arreola, Nayely Bibiana Arreola, and Cindy Jael Arreola shall be eligible for the issuance of immigrant visas or for adjustment of status to that of aliens lawfully admitted for permanent residence upon filing an application for issuance of immigrant visas under section 204 of that Act or for adjustment of status to lawful permanent resident.

(b) ADJUSTMENT OF STATUS.—If Esidronio Arreola-Saucedo, Maria Elena Cobian Arreola, Nayely Bibiana Arreola, and Cindy Jael Arreola enter the United States before the filing deadline specified in subsection (c), Esidronio Arreola-Saucedo, Maria Elena Cobian Arreola, Nayely Bibiana Arreola, and Cindy Jael Arreola shall be considered to have entered and remained lawfully and shall be eligible for adjustment of status under section 245 of the Immigration and Nationality Act as of the date of enactment of this Act.

(c) DEADLINE FOR APPLICATION AND PAYMENT OF FEES.—Subsections (a) and (b) shall apply only if the application for issuance of immigrant visas or the application for adjustment of status are filed with appropriate fees within 2 years after the date of enactment of this Act.

(d) REDUCTION OF IMMIGRANT VISA NUMBERS.—Upon the granting of immigrant visas or permanent residence to Esidronio Arreola-Saucedo, Maria Elena Cobian Arreola, Nayely Bibiana Arreola, and Cindy Jael Arreola, the Secretary of State shall instruct the proper officer to reduce by 4, during the current or next following fiscal year, the total number of immigrant visas that are made available to natives of the country of the aliens' birth under section 203(a) of the Immigration and Nationality Act or, if applicable, the total number of immigrant visas that are made available to natives of the country of the aliens' birth under section 202(e) of that Act.

#### FOR THE RELIEF OF LINDITA IDRIZI HEATH

The bill (S. 103) for the relief of Lindita Idrizi Heath, was considered, ordered to be engrossed for a third reading, read the third time, and passed, as follows:

S. 103

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

##### SECTION 1. PERMANENT RESIDENT STATUS FOR LINDITA IDRIZI HEATH.

(a) IN GENERAL.—Notwithstanding section 101(b)(1) and subsections (a) and (b) of section

201 of the Immigration and Nationality Act, Lindita Idrizi Heath shall be eligible for issuance of an immigrant visa or for adjustment of status to that of an alien lawfully admitted for permanent residence upon filing an application for issuance of an immigrant visa under section 204 of that Act or for adjustment of status to lawful permanent resident.

(b) ADJUSTMENT OF STATUS.—If Lindita Idrizi Heath enters the United States before the filing deadline specified in subsection (c), Lindita Idrizi Heath shall be considered to have entered and remained lawfully and shall, if otherwise eligible, be eligible for adjustment of status under section 245 of the Immigration and Nationality Act as of the date of enactment of this Act.

(c) DEADLINE FOR APPLICATION AND PAYMENT OF FEES.—Subsections (a) and (b) shall apply only if the application for issuance of an immigrant visa or the application for adjustment of status is filed with appropriate fees within 2 years after the date of enactment of this Act.

(d) REDUCTION OF IMMIGRANT VISA NUMBERS.—Upon the granting of an immigrant visa or permanent residence to Lindita Idrizi Heath, the Secretary of State shall instruct the proper officer to reduce by one, during the current or next following fiscal year, the total number of immigrant visas that are made available to natives of the country of birth of Lindita Idrizi Heath under section 203(a) of the Immigration and Nationality Act or, if applicable, the total number of immigrant visas that are made available to natives of the country of birth of Lindita Idrizi Heath under section 202(e) of that Act.

##### SEC. 2. ELIGIBILITY FOR CITIZENSHIP.

For purposes of section 320 of the Immigration and Nationality Act (8 U.S.C. 1431; relating to the automatic acquisition of citizenship by certain children born outside the United States), Lindita Idrizi Heath shall be considered to have satisfied the requirements applicable to adopted children under section 101(b)(1) of that Act (8 U.S.C. 1101(b)(1)).

##### SEC. 3. LIMITATION.

No natural parent, brother, or sister, if any, of Lindita Idrizi Heath shall, by virtue of such relationship, be accorded any right, privilege, or status under the Immigration and Nationality Act.

#### FOR THE RELIEF OF DANIEL KING CAIRO

The bill (S. 848) for the relief of Daniel King Cairo, was considered, ordered to be engrossed for a third reading, read the third time, and passed, as follows:

S. 848

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

##### SECTION 1. PERMANENT RESIDENCE.

Notwithstanding any other provision of law, for purposes of the Immigration and Nationality Act (8 U.S.C. 1101 et seq.), Daniel King Cairo shall be held and considered to have been lawfully admitted to the United States for permanent residence as of the date of enactment of this Act upon payment of the required visa fees.

##### SEC. 2. REDUCTION OF NUMBER OF AVAILABLE VISAS.

Upon the granting of permanent residence to Daniel King Cairo, the Secretary of State shall instruct the proper officer to reduce by the appropriate number during the current fiscal year the total number of immigrant visas available to natives of the country of