

July 1, 2003, and shall be allocated to each manufacturer on the bases of the dollar value (excluding duty, shipping, and related costs) of imported woven cotton shirting fabric of 80s or higher count and 2-ply in warp purchased by the manufacturer during calendar year 2002 (as evidenced by an affidavit from the manufacturer) used in the manufacturing of men's and boys' cotton shirts, compared to the dollar value (excluding duty, shipping, and related costs) of such fabric for all manufacturers who qualify under this subparagraph.

(4) **AFFIDAVIT OF SHIRTING MANUFACTURERS.**—For purposes of paragraph (3)(C), an officer of the manufacturer of men's and boys' shirts shall provide a notarized affidavit affirming—

(A) that the manufacturer used imported cotton fabric during the period January 1, 1998, through July 1, 2003, to cut and sew men's and boys' woven cotton shirts in the United States;

(B) the dollar value of imported woven cotton shirting fabric of 80s or higher count and 2-ply in warp purchased during calendar year 2002;

(C) that the manufacturer maintains invoices along with other supporting documentation (such as price lists and other technical descriptions of the fabric qualities) showing the dollar value of such fabric purchased, the date of purchase, and evidencing the fabric as woven cotton fabric of 80s or higher count and 2-ply in warp; and

(D) that the fabric was suitable for use in the manufacturing of men's and boys' cotton shirts.

(5) **DATE OF PURCHASE.**—For purposes of the affidavit required by paragraph (4), the date of purchase shall be the invoice date, and the dollar value shall be determined excluding duty, shipping, and related costs.

(6) **AFFIDAVIT OF YARN SPINNERS.**—For purposes of paragraph (3)(B), an officer of a company that produces ring spun yarns shall provide a notarized affidavit affirming—

(A) that the manufacturer used pima cotton grown in the United States during the period January 1, 2002, through December 31, 2002, to produce ring spun cotton yarns, measuring less than 83.33 decitex (exceeding 120 metric number), in single and plied form during 2002;

(B) the quantity, measured in pounds, of ring spun cotton yarns, measuring less than 83.33 decitex (exceeding 120 metric number), in single and plied form during calendar year 2002; and

(C) that the manufacturer maintains supporting documentation showing the quantity of such yarns produced, and evidencing the yarns as ring spun cotton yarns, measuring less than 83.33 decitex (exceeding 120 metric number), in single and plied form during calendar year 2002.

(7) **NO APPEAL.**—Any grant awarded by the Secretary under this section shall be final and not subject to appeal or protest.

(c) **AUTHORIZATION.**—There is authorized to be appropriated such sums as are necessary to carry out the provisions of this section, including funds necessary for the administration and oversight of the grants provided for in this section.

TITLE VI—TECHNICAL AMENDMENTS RELATING TO ENTRY AND PROTEST

SEC. 6001. ENTRY OF MERCHANDISE.

(a) **IN GENERAL.**—Section 484(a) of the Tariff Act of 1930 (19 U.S.C. 1484) is amended—

(1) by amending paragraph (1)(A) to read as follows:

“(A) make entry therefor by filing with the Customs Service—

“(i) such documentation; or

“(ii) pursuant to an electronic data interchange system, such information as is necessary to enable the Customs Service to determine whether the merchandise may be released from customs custody; and”;

(2) in paragraph (1)(B), by inserting after “entry” the following: “, or substitute 1 or more reconfigured entries on an import activity summary statement,”; and

(3) in paragraph (2)(A)—

(A) by inserting after “statements” the following: “and permit the filing of reconfigured entries,”; and

(B) by adding at the end the following: “Entries filed under paragraph (1)(A) shall not be liquidated if covered by an import activity summary statement, but instead each reconfigured entry in the import activity summary statement shall be subject to liquidation or reliquidation pursuant to section 500, 501, or 504.”.

(b) **RECONCILIATION.**—Section 484(b)(1) of the Tariff Act of 1930 (19 U.S.C. 1484(b)(1)) is amended by striking “15 months” and inserting “21 months”.

SEC. 6002. LIMITATION ON LIQUIDATIONS.

Section 504 of the Tariff Act of 1930 (19 U.S.C. 1504) is amended—

(1) in subsection (a)—

(A) by striking “or” at the end of paragraph (3);

(B) in paragraph (4), by striking “filed,” and inserting “filed, whichever is earlier; or”;

(C) by inserting after paragraph (4) the following:

“(5) if a reconfigured entry is filed under an import activity summary statement, the date the import activity summary statement is filed or should have been filed, whichever is earlier;”; and

(2) by striking “at the time of entry” each place it appears.

SEC. 6003. PROTESTS.

Section 514 of the Tariff Act of 1930 (19 U.S.C. 1514) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking “(relating to refunds and errors) of this Act” and inserting “(relating to refunds), any clerical error, mistake of fact, or other inadvertence, whether or not resulting from or contained in an electronic transmission, adverse to the importer, in any entry, liquidation, or reliquidation, and”;

(B) in paragraph (5), by inserting “, including the liquidation of an entry, pursuant to either section 500 or section 504;” after “thereof”; and

(C) in paragraph (7), by striking “(c) or”; and

(2) in subsection (c)—

(A) in paragraph (1), in the sixth sentence, by striking “A protest may be amended,” and inserting “Unless a request for accelerated disposition is filed under section 515(b), a protest may be amended,”;

(B) in paragraph (3)(A), by striking “notice of” and inserting “date of”; and

(C) in paragraph (3)—

(i) by striking “ninety days” and inserting “180 days”; and

(ii) by striking “90 days” and inserting “180 days”.

SEC. 6004. REVIEW OF PROTESTS.

Section 515(b) of the Tariff Act of 1930 (19 U.S.C. 1515(b)) is amended by striking “after ninety days” and inserting “concurrent with or”.

SEC. 6005. REFUNDS AND ERRORS.

Section 520(c) of the Tariff Act of 1930 (19 U.S.C. 1520(c)) is repealed.

SEC. 6006. DEFINITIONS AND MISCELLANEOUS PROVISIONS.

Section 401 of the Tariff Act of 1930 (19 U.S.C. 1401) is amended by adding at the end the following:

“(t) **RECONFIGURED ENTRY.**—The term ‘reconfigured entry’ means an entry filed on an import activity summary statement which substitutes for all or part of 1 or more entries filed under section 484(a)(1)(A) or filed on a reconciliation entry that aggregates the entry elements to be reconciled under section 484(b) for purposes of liquidation, reliquidation, or protest.”.

SEC. 6007. VOLUNTARY RELIQUIDATIONS.

Section 501 of the Tariff Act of 1930 (19 U.S.C. 1501) is amended by inserting “or 504” after “section 500”.

SEC. 6008. EFFECTIVE DATE.

The amendments made by this title shall apply to merchandise entered, or withdrawn from

warehouse for consumption, on or after the 15th day after the date of the enactment of this Act.

TITLE VII—EXTENSION OF SUSPENSIONS

SEC. 7001. EXTENSION OF DUTY SUSPENSIONS.

Except as provided in sections 1303, 1309, 1380, 1388, 1389, 1392, 1393, 1394, 1419, and 1420, each of the headings of the Harmonized Tariff Schedule added by chapter 1 of subtitle A of title I is amended by striking the date in the effective period column and inserting “12/31/2006”.

MORNING BUSINESS

Mr. NICKLES. Mr. President, I ask unanimous consent that the Senate now proceed to a period of morning business, with Senators permitted to speak for up to 10 minutes each.

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

EXECUTIVE SESSION

EXECUTIVE CALENDAR

Mr. NICKLES. Mr. President, I ask unanimous consent that the Senate immediately proceed to Executive session to consider the follow nominations on the Executive Calendar, Calendar Nos. 568, 569, 570, and 571. I further ask unanimous consent that the nominations be confirmed en bloc, the motions to reconsider be laid on the table, the President be immediately notified of the Senate's action, and the Senate then return to legislative session.

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

The nominations considered and confirmed are as follows:

DEPARTMENT OF JUSTICE

Michele M. Leonhart, of California, to be Deputy Administrator of Drug Enforcement.

Domingo S. Herraiz, of Ohio, to be Director of the Bureau of Justice Assistance.

LaFayette Collins, of Texas, to be United States Marshal for the Western District of Texas for the term of four years.

Ronald J. Tenpas, of Illinois, to be United States Attorney for the Southern District of Illinois for a term of four years.

LEGISLATIVE SESSION

The PRESIDING OFFICER. Under the previous order, the Senate will return to legislative session.

COMMEMORATION OF THE 150TH ANNIVERSARY OF THE FIRST MEETING OF THE REPUBLICAN PARTY

Mr. NICKLES. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of S. Con. Res. 96 submitted earlier today by Senator FEINGOLD and Senator KOHL.

The PRESIDING OFFICER. The clerk will report the concurrent resolution by title.

The legislative clerk read as follows:

A concurrent resolution (S. Con. Res. 96) commemorating the 150th anniversary of the first meeting of the Republican Party in Ripon, WI.

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

Mr. NICKLES. Mr. President, I ask unanimous consent that the concurrent resolution and preamble be agreed to en bloc, the motion to reconsider be laid upon the table, and that any statements related thereto be printed in the RECORD without intervening action or debate.

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

The concurrent resolution (S. Con. Res. 96) was agreed to.

The preamble was agreed to.

The concurrent resolution, with its preamble, reads as follows:

S. CON. RES. 96

Whereas on March 20, 1854, 50 men, 3 women, and 1 child assembled in a simple frame schoolhouse, now known as the Little White Schoolhouse, in Ripon, Wisconsin, to advocate the creation of a new political party under the name "Republican";

Whereas this March 20, 1854, meeting in Ripon, Wisconsin was the first of many grassroots meetings that led to the formal founding of the Republican Party;

Whereas the city of Ripon is commemorating the 150th anniversary of the first meeting of the Republican Party with a celebration entitled "From Schoolhouse to White House: a Celebration of Active Citizenship," which includes a series of civic and educational events;

Whereas the Little White Schoolhouse is listed on the National Registry of Historic Places, was designated by the Department of the Interior as a National Historic Landmark on May 30, 1974, and attracts visitors from around the world; and

Whereas the Little White Schoolhouse serves as a symbol of civic responsibility and grassroots political activism: Now, therefore, be it

Resolved by the Senate (the House of Representatives concurring), That Congress commemorates the 150th anniversary of the first meeting of the Republican Party in Ripon, Wisconsin.

MINOR USE AND MINOR SPECIES ANIMAL HEALTH ACT OF 2003

Mr. NICKLES. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 431, S. 741.

The PRESIDING OFFICER. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 741) to amend the Federal Food, Drug and Cosmetic Act with regard to new animal drugs, and for other purposes.

There being no objection, the Senate proceeded to consider the bill which had been reported from the Committee on Health, Education, Labor and Pensions, with an amendment to strike all after the enacting clause and inserting in lieu thereof the following:

(Strike the part shown in black brackets and insert the part shown in italic.)

S. 741

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

[SECTION 1. SHORT TITLE.

[This Act may be cited as the "Minor Use and Minor Species Animal Health Act of 2003".

[SEC. 2. FINDINGS.

[Congress makes the following findings:

[(1) There is a severe shortage of approved new animal drugs for use in minor species.

[(2) There is a severe shortage of approved new animal drugs for treating animal diseases and conditions that occur infrequently or in limited geographic areas.

[(3) Because of the small market shares, low-profit margins involved, and capital investment required, it is generally not economically feasible for new animal drug applicants to pursue approvals for these species, diseases, and conditions.

[(4) Because the populations for which such new animal drugs are intended may be small and conditions of animal management may vary widely, it is often difficult to design and conduct studies to establish drug safety and effectiveness under traditional new animal drug approval processes.

[(5) It is in the public interest and in the interest of animal welfare to provide for special procedures to allow the lawful use and marketing of certain new animal drugs for minor species and minor uses that take into account these special circumstances and that ensure that such drugs do not endanger animal or public health.

[(6) Exclusive marketing rights and tax credits for clinical testing expenses have helped encourage the development of "orphan" drugs for human use, and comparable incentives should encourage the development of new animal drugs for minor species and minor uses.

[SEC. 3. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

[(a) DEFINITIONS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

["(kk) The term 'major species' means cattle, horses, swine, chickens, turkeys, dogs, and cats, except that the Secretary may revise this definition by regulation.

["(ll) The term 'minor species' means animals other than humans that are not major species.

["(mm) The term 'minor use' means the intended use of a drug in a major species for an indication that occurs infrequently or in limited geographical areas.".

[(b) THREE-YEAR EXCLUSIVITY FOR MINOR USE AND MINOR SPECIES APPROVALS.—Section 512(c)(2)(F) (ii), (iii), and (v) of the Federal Food, Drug, and Cosmetic Act is amended by striking "(other than bioequivalence or residue studies)" and inserting "(other than bioequivalence studies or residue depletion studies, except residue depletion studies for minor uses or minor species)" every place it appears.

[(c) SCOPE OF REVIEW FOR MINOR USE AND MINOR SPECIES APPLICATIONS.—Section 512(d) of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end the following new paragraph:

["(5) In reviewing an application that proposes a change to add an intended use for a minor use or a minor species to an approved new animal drug application, the Secretary shall reevaluate only the relevant information in the approved application to determine whether the application for the minor use or minor species can be approved. A decision to approve the application for the minor use or minor species is not, implicitly or explicitly, a reaffirmation of the approval of the original application.".

[(d) MINOR USE AND MINOR SPECIES NEW ANIMAL DRUGS.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

["Subchapter F—New Animal Drugs for Minor Use and Minor Species

["SEC. 571. CONDITIONAL APPROVAL OF NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES.

["(a)(1) Except as provided in paragraph (3) of this section, any person may file with the Secretary an application for conditional approval of a new animal drug intended for a minor use or a minor species. Such an application may not be a supplement to an application approved under section 512. Such application must comply in all respects with the provisions of section 512 of this Act except sections 512(a)(4), 512(b)(2), 512(c)(1), 512(c)(2), 512(c)(3), 512(d)(1), 512(e), 512(h), and 512(n) unless otherwise stated in this section, and any additional provisions of this section.

["(2) The applicant shall submit to the Secretary as part of an application for the conditional approval of a new animal drug—

["(A) all information necessary to meet the requirements of section 512(b)(1) except section 512(b)(1)(A);

["(B) full reports of investigations which have been made to show whether or not such drug is safe and there is a reasonable expectation of effectiveness for use;

["(C) data for establishing a conditional dose;

["(D) projections of expected need and the justification for that expectation based on the best information available;

["(E) information regarding the quantity of drug expected to be distributed on an annual basis to meet the expected need; and

["(F) a commitment that the applicant will conduct additional investigations to meet the requirements for the full demonstration of effectiveness under section 512(d)(1)(E) within 5 years.

["(3) A person may not file an application under paragraph (1) if—

["(A) the person has previously filed an application for conditional approval under paragraph (1) for the same drug in the same dosage form for the same intended use whether or not subsequently conditionally approved by the Secretary under subsection (b), or

["(B) the person obtained the application, or data or other information contained therein, directly or indirectly from the person who filed for conditional approval under paragraph (1) for the same drug in the same dosage form for the same intended use whether or not subsequently conditionally approved by the Secretary under subsection (b).

["(b) Within 180 days after the filing of an application pursuant to subsection (a), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

["(1) issue an order, effective for one year, conditionally approving the application if the Secretary finds that none of the grounds for denying conditional approval, specified in subsection (c) of this section applies, or

["(2) give the applicant notice of an opportunity for an informal hearing on the question whether such application can be conditionally approved.

["(c) If the Secretary finds, after giving the applicant notice and an opportunity for an informal hearing, that—

["(1) any of the provisions of section 512(d)(1) (A) through (D) or (F) through (I) are applicable;

["(2) the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such drug, is insufficient to show that there is a reasonable expectation that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or