the Under Secretary for Rural Development, and the head of any other appropriate Federal agency, the Administrator shall conduct outreach and provide technical assistance to farmers and other rural businesses with regard to programs of the Administration for which the farmers and rural businesses may be eligible.

''(2) AGREEMENT.—The coordination under this subsection shall include evaluating whether the Administrator should enter an agreement under which—

''(A) offices of the Department of Agriculture may assist in completing and accept applications for programs of the Administration; or

''(B) employees of the Administration periodically have office hours at offices of the Department of Agriculture.''.

SA 4361. Mr. NELSON of Florida submitted an amendment intended to be proposed to amendment SA 4301 proposed by Mr. BAUCUS to the bill H.R. 4213 to amend the Internal Revenue Code of 1986 to extend certain expiring provisions, and for other purposes, which was ordered to lie on the table; as follows:

On page 363, between lines 3 and 4, insert the following:

SEC. 621. EXCLUSIVITY PERIOD.

(a) FIRST APPLICANT.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is amended—

(1) in subparagraph (B)(iv)—

(A) in subclause (II), by striking item (bb) and inserting the following:

''(bb) FIRST APPLICANT.—As used in this subsection, the term 'first applicant' means—

''(AA) an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug; or

''(BB) an applicant for the drug not described in item (AA) that satisfies the requirements of subclause (III).''; and

(B) by adding at the end the following:

''(III) An applicant described in subclause (II)(bb)(BB) shall—

''(aa) submit and lawfully maintain a certification described in paragraph (2)(A)(vii)(IV) or a statement described in paragraph (2)(A)(viii) for each unexpired patent for which a first applicant described in item (AA) had submitted a certification described in paragraph (2)(A)(vii)(IV) on the first day on which a substantially complete application containing such a certification was submitted;

''(bb) with regard to each such unexpired patent for which the applicant submitted a certification described in paragraph (2)(A)(vii)(IV), no action for patent infringement was brought against the applicant within the 45-day period specified in paragraph (5)(B)(iii), or if an action was brought within such time period, the applicant has obtained the decision of a court (including a district court) that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity, and including a settlement order or consent decree signed and entered by the court stating that the patent is invalid or not infringed); and

''(cc) but for the effective date of approval provisions in subparagraphs (B) and (F) and sections 505A and 527, be eligible to receive immediately effective approval at a time before any other applicant has begun commercial marketing.''; and

(2) in subparagraph (D)—

(A) in clause (i)(IV), by striking ''The first applicant'' and inserting ''The first applicant, as defined in subparagraph (B)(iv)(II)(bb)(AA),''; and

(B) in clause (iii), in the matter preceding subclause (I)—

(i) by striking ''If all first applicants forfeit the 180-day exclusivity period under clause (ii)''; and

(ii) by inserting ''If all first applicants, as defined in subparagraph (B)(iv)(II)(bb)(AA), forfeit the 180-day exclusivity period under clause (ii) at a time at which no applicant has begun commercial marketing''.

(b) EFFECTIVE DATE AND TRANSITIONAL PROVISION.—

(1) EFFECTIVE DATE.—The amendments made by subsection (a) shall be effective only with respect to an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) to which the amendments made by section 1102(a) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (Public Law 108–173) apply.

(2) TRANSITIONAL PROVISION.—An application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), to which the 180-day exclusivity period described in paragraph (5)(iv) of such section does not apply, and that contains a certification under paragraph (2)(A)(vii)(IV) of such Act, shall be regarded as a previous application containing such a certification within the meaning of section 505(j)(5)(B)(iv) of such Act (as in effect before the amendments made by Medicare Prescription Drug Improvement and Modernization Act of 2003 (Public Law 108–173)) if—

(A) no action for infringement of the patent that is the subject of such certification was brought against the applicant within the 45-day period specified in section 505(j)(5)(B)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iii)), or if an action was brought within such time period, the applicant has obtained the decision of a court (including a district court) that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity, and including a settlement order or consent decree signed and entered by the court stating that the patent is invalid or not infringed);

(B) the application is eligible to receive immediately effective approval, but for the effective date of approval provisions in sections 505(j)(5)(B) (as in effect before the amendment made by Public Law 108–173), 505(j)(5)(F), 505A, and 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B), 355(j)(5)(F), 355a, 360cc); and

(C) no other applicant has begun commercial marketing.

SA 4362. Mr. LEVIN (for himself, Mr. KAUFMAN, Mr. NELSON of Florida, Mrs. SHAHEEN, Mrs. MCCASKILL, Mr. WHITEHOUSE, and Mr. REED) submitted an amendment intended to be proposed to amendment SA 4301 proposed by Mr. BAUCUS to the bill H.R. 4213 to amend the Internal Revenue Code of 1986 to extend certain expiring provisions, and for other purposes, which was ordered to lie on the table; as follows:

At the end of the amendment, insert the following:

TITLE ____—AUTHORIZING SPECIAL MEASURES FOR JURISDICTIONS, FINANCIAL INSTITUTIONS, INTERNATIONAL TRANSACTIONS, OR TYPES OF ACCOUNTS THAT ARE OF PRIMARY MONEY LAUNDERING CONCERN OR IMPEDE UNITED STATES TAX ENFORCEMENT

SEC. ____. AUTHORIZING SPECIAL MEASURES FOR JURISDICTIONS, FINANCIAL INSTITUTIONS, INTERNATIONAL TRANSACTIONS, OR TYPES OF ACCOUNTS THAT ARE OF PRIMARY MONEY LAUNDERING CONCERN OR IMPEDE UNITED STATES TAX ENFORCEMENT.

Section 5318A of title 31, United States Code, is amended—

(1) by striking the section heading and inserting the following:

''§ 5318A. Special measures for jurisdictions, financial institutions, or international transactions that are of primary money laundering concern or impede United States tax enforcement'';

(2) in subsection (a), by striking the subsection heading and inserting the following:

''(a) SPECIAL MEASURES TO COUNTER MONEY LAUNDERING AND EFFORTS TO IMPEDE UNITED STATES TAX ENFORCEMENT.—'';

(3) in subsection (c), by striking the subsection heading and inserting the following:

''(c) CONSULTATIONS AND INFORMATION TO BE CONSIDERED IN FINDING JURISDICTIONS, INSTITUTIONS, TYPES OF ACCOUNTS, OR TRANSACTIONS TO BE OF PRIMARY MONEY LAUNDERING CONCERN OR TO BE IMPEDING UNITED STATES TAX ENFORCEMENT.—'';

(4) in subsection (a)(1), by inserting ''or is impeding United States tax enforcement'' after ''primary money laundering concern'';

(5) in subsection (a)(4)—

(A) in subparagraph (A)—

(i) by inserting ''in matters involving money laundering,'' before ''shall consult''; and

(ii) by striking ''and'' at the end;

(B) by redesignating subparagraph (B) as subparagraph (C); and

(C) by inserting after subparagraph (A) the following:

''(B) in matters involving United States tax enforcement, shall consult with the Commissioner of the Internal Revenue, the Secretary of State, the Attorney General of the United States, and in the sole discretion of the Secretary, such other agencies and interested parties as the Secretary may find to be appropriate; and'';

(6) in each of paragraphs (1)(A), (2), (3), and (4) of subsection (b), by inserting ''or to be impeding United States tax enforcement'' after ''primary money laundering concern'' each place that term appears;

(7) in subsection (b), by striking paragraph (5) and inserting the following:

''(5) PROHIBITIONS OR CONDITIONS ON OPENING OR MAINTAINING CERTAIN CORRESPONDENT OR PAYABLE-THROUGH ACCOUNTS OR AUTHORIZING CERTAIN PAYMENT CARDS.—If the Secretary finds a jurisdiction outside of the United States, 1 or more financial institutions operating outside of the United States, or 1 or more classes of transactions within or involving a jurisdiction outside of the United States to be of primary money laundering concern or to be impeding United States tax enforcement, the Secretary, in consultation with the Secretary of State, the Attorney General of the United States, and the Chairman of the Board of Governors of the Federal Reserve System, may prohibit, or impose conditions upon—

''(A) the opening or maintaining in the United States of a correspondent account or payable-through account; or

''(B) the authorization, approval, or use in the United States of a credit card, charge