when that bomb went off and tore the whole facade off our Embassy in Beirut and killed two marines who were up front, in their position, guarding the security of the Embassy and who comes in the front door, who is barred entrance.

The bombings in London. I have a photograph back in the Cloakroom. I would have brought it out, but it would just look brown to the gallery or to the C–SPAN audience. It is of a car bomb set off in the financial district of London. And that only one human being died is a miracle when you look at this photograph: Skyscrapers and buildings going back 100, 200 years; roofs torn off; every single window for a quarter of a mile on both sides of the street wiped out.

We know about these car bombs. Is it the bureaucracy in the House that has no corporate memory? In the Senate? About 30 percent of us were here when the 1983 bombings took place in Beirut killing so many Americans and so many servicemen.

In the military, though, general officers were around during these bombings. They do not have this rollover problem and this loss of institutional memory.

I do not want to see people pay the price of having their careers destroyed, some of them with combat missions in Southeast Asia or in the gulf region of the Middle East, but we simply cannot forget the past. The past is prolog to the future. Study the past, and implement the security needed.

Mr. SCARBOROUGH. Mr. Speaker, I reserve the balance of my time.

Mr. DELLUMS. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I have tried to listen diligently to all of the remarks of my distinguished colleagues as they have marched into the well to address themselves to House Concurrent Resolution 200.

First with respect to the general issue of terrorism, yes, Mr. Speaker, it is here, it is real, it is alive, it is expanding, it is evolving, and it will be a threat that America and the world will have to deal with on an increasing basis as we move into the 21st century. That is a matter that we must come to grips with and address in significant terms. It will require the highest and the best in us. It will require our best thinking, our best judgment and our best thoughts.

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That is not the moment that we are in at this point. There will also be recriminations about who did what and who was responsible. That also is an integral part of the process. But that is not why we are here today.

We are here today for a very simple, thoughtful, and compassionate reason; not to politicize, not to demagogue, not to point fingers, but simply to pause as human beings and to attempt to put our emotional arms around people who have experienced great tragedy. First, 19 human beings who paid the ultimate and supreme price of dying in a terrorist tragedy, Khobar Towers in Saudi Arabia.

Something we have not focused upon is the 200 people, many of whom severely and significantly were injured, who also paid a very heavy price. The families that my distinguished colleague from Florida spoke about, the young child speaking in those kinds of real and powerful human terms, bring the reality of the risk of serving abroad in dangerous places as we carry out the foreign policy and national security policy of this country. It comes to us all too real.

But I just want to rise, along with the distinguished gentleman from Florida, the author of this concurrent resolution, and join with all of my colleagues on the Committee on National Security, for we passed this resolution unanimously, in acknowledging the personal sacrifices the 19 American military personnel to which I alluded earlier gave, killed, and the more than 200 wounded, on June 25 of this year.

I know that I join with the rest of the country when I say to their families and fellow service members that they can be assured that this Nation will long remember their bravery and sacrifices that they have made for their country.

So I am simply saying, Mr. Speaker, all of the other comments notwithstanding what this resolution is about, is to ask this body to pause for a moment, to embrace human life in a compassionate way, to embrace the families of this country that have grieved and paid an incredible price; people dying, and mothers and fathers crying, and children not quite understanding what is going on.

So I urge all of my colleagues to come to the floor at the appropriate point in these proceedings, to join with the gentleman from the State of Florida, this gentleman, and all of my colleagues on the House Committee on National Security, and unanimously pass this resolution as some modest way of saying to people we feel, we understand, we care, and we pay tribute.

Mr. DELLUMS. Mr. Speaker, I yield back the balance of my time.

Mr. SCARBOROUGH. Mr. Speaker, I thank the distinguished gentleman from California for his kind words.

Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore (Mr. GUNDERSON). The question is on the motion offered by the gentleman from South Carolina [Mr. SPENCE] that the House suspend the rules and agree to the concurrent resolution, House Concurrent Resolution 200, as amended.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the concurrent resolution, as amended, was agreed to.

The title of the concurrent resolution was amended so as to read: ''Concurrent resolution honoring the victims of the June 25, 1996, terrorist bombing in Dhahran, Saudi Arabia.''

A motion to reconsider was laid on the table.

MAKING IN ORDER AT ANY TIME CONSIDERATION OF CONFERENCE REPORT ON H.R. 3666, DEPARTMENTS OF VETERANS AFFAIRS AND HOUSING AND URBAN DEVELOPMENT, AND INDEPENDENT AGENCIES APPROPRIATIONS ACT, 1997

Mr. LIVINGSTON. Mr. Speaker, I ask unanimous consent that it be in order at any time to consider a conference report to accompany the bill, H.R. 3666, that all points of order against the conference report and against its consideration be waived, and that the conference report be considered as read when called up. This request has been cleared with the minority.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Louisiana?

There was no objection.

ANIMAL DRUG AVAILABILITY ACT OF 1996

Mr. BILIRAKIS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 2508) to amend the Federal Food, Drug, and Cosmetic Act to provide for improvements in the process of approving and using animal drugs, and for other purposes, as amended.

The Clerk read as follows:

H.R. 2508

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

SECTION 1. SHORT TITLE; REFERENCE.

(a) SHORT TITLE.—This Act may be cited as the ''Animal Drug Availability Act of 1996''.

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

SEC. 2. EVIDENCE OF EFFECTIVENESS.

(a) ORIGINAL APPLICATIONS.—Paragraph (3) of section 512(d) (21 U.S.C. 360b(d)) is amended to read as follows:

''(3) As used in this section, the term 'substantial evidence' means evidence consisting of one or more adequate and well controlled investigations, such as—

''(A) a study in a target species;

''(B) a study in laboratory animals;

''(C) any field investigation that may be required under this section and that meets the requirements of subsection (b)(3) if a presubmission conference is requested by the applicant;

''(D) a bioequivalence study; or

''(E) an in vitro study;

by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts 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 labeling or proposed labeling thereof.''.

(b) CONFORMING AMENDMENTS.—

(1) Clauses (ii) and (iii) of section 512(c)(2)(F) (21 U.S.C. 360b(c)(2)(F)) are each amended—

(A) by striking ''reports of new clinical or field investigations (other than bioequivalence or residue studies) and,'' and inserting ''substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or,''; and

(B) by striking ''essential to'' and inserting ''required for''.

(2) Section 512(c)(2)(F)(v) (21 U.S.C. 360b(c)(2)(F)(v)) is amended—

(A) by striking ''subparagraph (B)(iv)'' each place it appears and inserting ''clause (iv)'';

(B) by striking ''reports of clinical or field investigations'' and inserting ''substantial evidence of the effectiveness of the drug involved, any studies of animal safety,''; and

(C) by striking ''essential to'' and inserting ''required for''.

(c) COMBINATION DRUGS.—Section 512(d) (21 U.S.C. 360b(d)), as amended by subsection (a) is amended by adding at the end the following:

''(4) In a case in which an animal drug contains more than one active ingredient, or the labeling of the drug prescribes, recommends, or suggests use of the drug in combination with one or more other animal drugs, and the active ingredients or drugs intended for use in the combination have previously been separately approved for particular uses and conditions of use for which they are intended for use in the combination—

''(A) the Secretary shall not issue an order under paragraph (1)(A), (1)(B), or (1)(D) refusing to approve the application for such combination on human food safety grounds unless the Secretary finds that the application fails to establish that—

''(i) none of the active ingredients or drugs intended for use in the combination, respectively, at the longest withdrawal time of any of the active ingredients or drugs in the combination, respectively, exceeds its established tolerance; or

''(ii) none of the active ingredients or drugs in the combination interferes with the methods of analysis for another of the active ingredients or drugs in the combination, respectively;

''(B) the Secretary shall not issue an order under paragraph (1)(A), (1)(B), or (1)(D) refusing to approve the application for such combination on target animal safety grounds unless the Secretary finds that—

''(i)(I) there is a substantiated scientific issue, specific to one or more of the active ingredients or animal drugs in the combination, that cannot adequately be evaluated based on information contained in the application for the combination (including any investigations, studies, or tests for which the applicant has a right of reference or use from the person by or for whom the investigations, studies, or tests were conducted); or

''(II) there is a scientific issue raised by target animal observations contained in studies submitted to the Secretary as part of the application; and

''(ii) based on the Secretary's evaluation of the information contained in the application with respect to the issues identified in clauses (i)(I) and (II), paragraph (1)(A), (B), or (D) apply;

''(C) except in the case of a combination that contains a nontopical antibacterial ingredient or animal drug, the Secretary shall not issue an order under paragraph (1)(E) refusing to approve an application for a combination animal drug intended for use other than in animal feed or drinking water unless the Secretary finds that the application fails to demonstrate that—

''(i) there is substantial evidence that any active ingredient or animal drug intended only for the same use as another active ingredient or animal drug in the combination makes a contribution to labeled effectiveness;

''(ii) each active ingredient or animal drug intended for at least one use that is different from all other active ingredients or animal drugs used in the combination provides appropriate concurrent use for the intended target population; or

''(iii) where based on scientific information the Secretary has reason to believe the active ingredients or animal drugs may be physically incompatible or have disparate dosing regimens, such active ingredients or animal drugs are physically compatible or do not have disparate dosing regimens; and

''(D) the Secretary shall not issue an order under paragraph (1)(E) refusing to approve an application for a combination animal drug intended for use in animal feed or drinking water unless the Secretary finds that the application fails to demonstrate that—

''(i) there is substantial evidence that any active ingredient or animal drug intended only for the same use as another active ingredient or animal drug in the combination makes a contribution to the labeled effectiveness;

''(ii) each of the active ingredients or animal drugs intended for at least one use that is different from all other active ingredients or animal drugs used in the combination provides appropriate concurrent use for the intended target population;

''(iii) where a combination contains more than one nontopical antibacterial ingredient or animal drug, there is substantial evidence that each of the nontopical antibacterial ingredients or animal drugs makes a contribution to the labeled effectiveness; or

''(iv) where based on scientific information the Secretary has reason to believe the active ingredients or animal drugs intended for use in drinking water may be physically incompatible, such active ingredients or animal drugs intended for use in drinking water are physically compatible.''.

(d) PRESUBMISSION CONFERENCE.—Section 512(b) (21 U.S.C. 360b(b)) is amended by adding at the end the following:

''(3) Any person intending to file an application under paragraph (1) or a request for an investigational exemption under subsection (j) shall be entitled to one or more conferences prior to such submission to reach an agreement acceptable to the Secretary establishing a submission or an investigational requirement, which may include a requirement for a field investigation. A decision establishing a submission or an investigational requirement shall bind the Secretary and the applicant or requestor unless (A) the Secretary and the applicant or requestor mutually agree to modify the requirement, or (B) the Secretary by written order determines that a substantiated scientific requirement essential to the determination of safety or effectiveness of the animal drug involved has appeared after the conference. No later than 25 calendar days after each such conference, the Secretary shall provide a written order setting forth a scientific justification specific to the animal drug and intended uses under consideration if the agreement referred to in the first sentence requires more than one field investigation as being essential to provide substantial evidence of effectiveness for the intended uses of the drug. Nothing in this paragraph shall be construed as compelling the Secretary to require a field investigation.''.

(e) IMPLEMENTATION.—

(1) IN GENERAL.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue proposed regulations implementing the amendments made by this Act as described in paragraph (2)(A) of this subsection, and not later than 18 months after the date of enactment of this Act, the Secretary shall issue final regulations implementing such amendments. Not later than 12 months after the date of enactment of this Act, the Secretary shall issue proposed regulations implementing the other amendments made by this Act as described in paragraphs (2)(B) and (2)(C) of this subsection, and not later than 24 months after the date of enactment of this Act, the Secretary shall issue final regulations implementing such amendments.

(2) CONTENTS.—In issuing regulations implementing the amendments made by this Act, and in taking an action to review an application for approval of a new animal drug under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b), or a request for an investigational exemption for a new animal drug under subsection (j) of such section, that is pending or has been submitted prior to the effective date of the regulations, the Secretary shall—

(A) further define the term ''adequate and well controlled'', as used in subsection (d)(3) of section 512 of such Act, to require that field investigations be designed and conducted in a scientifically sound manner, taking into account practical conditions in the field and differences between field conditions and laboratory conditions;

(B) further define the term ''substantial evidence'', as defined in subsection (d)(3) of such section, in a manner that encourages the submission of applications and supplemental applications; and

(C) take into account the proposals contained in the citizen petition (FDA Docket No. 91P–0434/CP) jointly submitted by the American Veterinary Medical Association and the Animal Health Institute, dated October 21, 1991.

Until the regulations required by subparagraph (A) are issued, nothing in the regulations published at 21 C.F.R. 514.111(a)(5) (April 1, 1996) shall be construed to compel the Secretary of Health and Human Services to require a field investigation under section 512(d)(1)(E) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(d)(1)(E)) or to apply any of its provisions in a manner inconsistent with the considerations for scientifically sound field investigations set forth in subparagraph (A).

(f) MINOR SPECIES AND USES.—The Secretary of Health and Human Services shall consider legislative and regulatory options for facilitating the approval under section 512 of the Federal Food, Drug, and Cosmetic Act of animal drugs intended for minor species and for minor uses and, within 18 months after the date of enactment of this Act, announce proposals for legislative or regulatory change to the approval process under such section for animal drugs intended for use in minor species or for minor uses.

SEC. 3. LIMITATION ON RESIDUES.

Section 512(d)(1)(F) (21 U.S.C. 360b(d)(1)(F)) is amended to read as follows:

''(F) upon the basis of information submitted to the Secretary as part of the application or any other information before the Secretary with respect to such drug, any use prescribed, recommended, or suggested in labeling proposed for such drug will result in a residue of such drug in excess of a tolerance found by the Secretary to be safe for such drug;''.

SEC. 4. IMPORT TOLERANCES.

Section 512(a) (21 U.S.C. 360b(a)) is amended by adding the following new paragraph at the end:

''(6) For purposes of section 402(a)(2)(D), a use or intended use of a new animal drug

shall not be deemed unsafe under this section if the Secretary establishes a tolerance for such drug and any edible portion of any animal imported into the United States does not contain residues exceeding such tolerance. In establishing such tolerance, the Secretary shall rely on data sufficient to demonstrate that a proposed tolerance is safe based on similar food safety criteria used by the Secretary to establish tolerances for applications for new animal drugs filed under subsection (b)(1). The Secretary may consider and rely on data submitted by the drug manufacturer, including data submitted to appropriate regulatory authorities in any country where the new animal drug is lawfully used or data available from a relevant international organization, to the extent such data are not inconsistent with the criteria used by the Secretary to establish a tolerance for applications for new animal drugs filed under subsection (b)(1). For purposes of this paragraph, 'relevant international organization' means the Codex Alimenterius Commission or other international organization deemed appropriate by the Secretary. The Secretary may, under procedures specified by regulation, revoke a tolerance established under this paragraph if information demonstrates that the use of the new animal drug under actual use conditions results in food being imported into the United States with residues exceeding the tolerance or if scientific evidence shows the tolerance to be unsafe.''.

SEC. 5. VETERINARY FEED DIRECTIVES.

(a) SECTION 503.—Section 503(f)(1)(A) (21 U.S.C. 353(f)(1)(A)) is amended by inserting after ''other than man'' the following: '', other than a veterinary feed directive drug intended for use in animal feed or an animal feed bearing or containing a veterinary feed directive drug,''.

(b) SECTION 504.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 503 the following:

''VETERINARY FEED DIRECTIVE DRUGS

''SEC. 504. (a)(1) A drug intended for use in or on animal feed which is limited by an approved application filed pursuant to section 512(b) to use under the professional supervision of a licensed veterinarian is a veterinary feed directive drug. Any animal feed bearing or containing a veterinary feed directive drug shall be fed to animals only by or upon a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice. When labeled, distributed, held, and used in accordance with this section, a veterinary feed directive drug and any animal feed bearing or containing a veterinary feed directive drug shall be exempt from section 502(f).

''(2) A veterinary feed directive is lawful if it—

''(A) contains such information as the Secretary may by general regulation or by order require; and

''(B) is in compliance with the conditions and indications for use of the drug set forth in the notice published pursuant to section 512(i).

''(3)(A) Any persons involved in the distribution or use of animal feed bearing or containing a veterinary feed directive drug and the licensed veterinarian issuing the veterinary feed directive shall maintain a copy of the veterinary feed directive applicable to each such feed, except in the case of a person distributing such feed to another person for further distribution. Such person distributing the feed shall maintain a written acknowledgment from the person to whom the feed is shipped stating that that person shall not ship or move such feed to an animal production facility without a veterinary feed directive or ship such feed to another person for further distribution unless that person has provided the same written acknowledgment to its immediate supplier.

''(B) Every person required under subparagraph (A) to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

''(C) Any person who distributes animal feed bearing or containing a veterinary feed directive drug shall upon first engaging in such distribution notify the Secretary of that person's name and place of business. The failure to provide such notification shall be deemed to be an act which results in the drug being misbranded.

''(b) A veterinary feed directive drug and any feed bearing or containing a veterinary feed directive drug shall be deemed to be misbranded if their labeling fails to bear such cautionary statement and such other information as the Secretary may by general regulation or by order prescribe, or their advertising fails to conform to the conditions and indications for use published pursuant to section 512(i) or fails to contain the general cautionary statement prescribed by the Secretary.

''(c) Neither a drug subject to this section, nor animal feed bearing or containing such a drug, shall be deemed to be a prescription article under any Federal or State law.''.

(c) CONFORMING AMENDMENT.—Section 512 (21 U.S.C. 360b) is amended in subsection (i) by inserting after ''(including special labeling requirements'' the following: ''and any requirement that an animal feed bearing or containing the new animal drug be limited to use under the professional supervision of a licensed veterinarian''.

(d) SECTION 301(e).—Section 301(e) (21 U.S.C. 331(e)) is amended by inserting after ''by section 412'' the following: '', 504,''; and by inserting after ''under section 412,'' the following: ''504,''.

SEC. 6. FEED MILL LICENSES.

(a) SECTION 512(a).—Paragraphs (1) and (2) of section 512(a) (21 U.S.C. 360b(a)) are amended to read as follows:

''(a)(1) A new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for the purposes of section 501(a)(5) and section 402(a)(2)(D) unless —

''(A) there is in effect an approval of an application filed pursuant to subsection (b) with respect to such use or intended use of such drug, and

''(B) such drug, its labeling, and such use conform to such approved application.

A new animal drug shall also be deemed unsafe for such purposes in the event of removal from the establishment of a manufacturer, packer, or distributor of such drug for use in the manufacture of animal feed in any State unless at the time of such removal such manufacturer, packer, or distributor has an unrevoked written statement from the consignee of such drug, or notice from the Secretary, to the effect that, with respect to the use of such drug in animal feed, such consignee (i) holds a license issued under subsection (m) and has in its possession current approved labeling for such drug in animal feed; or (ii) will, if the consignee is not a user of the drug, ship such drug only to a holder of a license issued under subsection (m).

''(2) An animal feed bearing or containing a new animal drug shall, with respect to any particular use or intended use of such animal feed be deemed unsafe for the purposes of section 501(a)(6) unless—

''(A) there is in effect an approval of an application filed pursuant to subsection (b) with respect to such drug, as used in such animal feed,

''(B) such animal feed is manufactured at a site for which there is in effect a license issued pursuant to subsection (m)(1) to manufacture such animal feed, and

''(C) such animal feed and its labeling, distribution, holding, and use conform to the conditions and indications of use published pursuant to subsection (i) .''.

(b) SECTION 512(m).—Section 512(m) (21 U.S.C. 360b(m)) is amended to read as follows:

''(m)(1) Any person may file with the Secretary an application for a license to manufacture animal feeds bearing or containing new animal drugs. Such person shall submit to the Secretary as part of the application (A) a full statement of the business name and address of the specific facility at which the manufacturing is to take place and the facility's registration number, (B) the name and signature of the responsible individual or individuals for that facility, (C) a certification that the animal feeds bearing or containing new animal drugs are manufactured and labeled in accordance with the applicable regulations published pursuant to subsection (i), and (D) a certification that the methods used in, and the facilities and controls used for, manufacturing, processing, packaging, and holding such animal feeds are in conformity with current good manufacturing practice as described in section 501(a)(2)(B).

''(2) Within 90 days after the filing of an application pursuant to paragraph (1), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall (A) issue an order approving the application if the Secretary then finds that none of the grounds for denying approval specified in paragraph (3) applies, or (B) give the applicant notice of an opportunity for a hearing before the Secretary under paragraph (3) on the question whether such application is approvable. The procedure governing such a hearing shall be the procedure set forth in the last two sentences of subsection (c)(1).

''(3) If the Secretary, after due notice to the applicant in accordance with paragraph (2) and giving the applicant an opportunity for a hearing in accordance with such paragraph, finds, on the basis of information submitted to the Secretary as part of the application, on the basis of a preapproval inspection, or on the basis of any other information before the Secretary—

''(A) that the application is incomplete, false, or misleading in any particular;

''(B) that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such animal feed are inadequate to preserve the identity, strength, quality, and purity of the new animal drug therein; or

''(C) that the facility manufactures animal feeds bearing or containing new animal drugs in a manner that does not accord with the specifications for manufacture or labels animal feeds bearing or containing new animal drugs in a manner that does not accord with the conditions or indications of use that are published pursuant to subsection (i),

the Secretary shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that subparagraphs (A) through (C) do not apply, the Secretary shall issue an order approving the application. An order under this subsection approving an application for a license to manufacture animal feeds bearing or containing new animal drugs shall permit a facility to manufacture only those animal feeds bearing or containing new animal drugs for which there are in effect regulations pursuant to subsection (i) relating to

the use of such drugs in or on such animal feed.

''(4)(A) The Secretary shall, after due notice and opportunity for hearing to the applicant, revoke a license to manufacture animal feeds bearing or containing new animal drugs under this subsection if the Secretary finds—

''(i) that the application for such license contains any untrue statement of a material fact; or

''(ii) that the applicant has made changes that would cause the application to contain any untrue statements of material fact or that would affect the safety or effectiveness of the animal feeds manufactured at the facility unless the applicant has supplemented the application by filing with the Secretary adequate information respecting all such changes and unless there is in effect an approval of the supplemental application.

If the Secretary (or in the Secretary's absence the officer acting as the Secretary) finds that there is an imminent hazard to the health of humans or of the animals for which such animal feed is intended, the Secretary may suspend the license immediately, and give the applicant prompt notice of the action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this sentence shall not be delegated.

''(B) The Secretary may also, after due notice and opportunity for hearing to the applicant, revoke a license to manufacture animal feed under this subsection if the Secretary finds—

''(i) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under paragraph (5)(A) of this subsection or section 504(a)(3)(A), or the applicant has refused to permit access to, or copying or verification of, such records as required by subparagraph (B) of such paragraph or section 504(a)(3)(B);

''(ii) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such license was issued, the methods used in, or the facilities and controls used for, the manufacture, processing, packing, and holding of such animal feed are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drug therein, and were not made adequate within a reasonable time after receipt of written notice from the Secretary, specifying the matter complained of;

''(iii) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such license was issued, the labeling of any animal feeds, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or

''(iv) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such license was issued, the facility has manufactured, processed, packed, or held animal feed bearing or containing a new animal drug adulterated under section 501(a)(6) and the facility did not discontinue the manufacture, processing, packing, or holding of such animal feed within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

''(C) The Secretary may also revoke a license to manufacture animal feeds under this subsection if an applicant gives notice to the Secretary of intention to discontinue the manufacture of all animal feed covered under this subsection and waives an opportunity for a hearing on the matter.

''(D) Any order under this paragraph shall state the findings upon which it is based.

''(5) When a license to manufacture animal feeds bearing or containing new animal drugs has been issued—

''(A) the applicant shall establish and maintain such records, and make such reports to the Secretary, or (at the option of the Secretary) to the appropriate person or persons holding an approved application filed under subsection (b), as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or paragraph (4); and

''(B) every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

''(6) To the extent consistent with the public health, the Secretary may promulgate regulations for exempting from the operation of this subsection facilities that manufacture, process, pack, or hold animal feeds bearing or containing new animal drugs.''.

(c) TRANSITIONAL PROVISION.—A person engaged in the manufacture of animal feeds bearing or containing new animal drugs who holds at least one approved medicated feed application for an animal feed bearing or containing new animal drugs, the manufacture of which was not otherwise exempt from the requirement for an approved medicated feed application on the date of the enactment of this Act, shall be deemed to hold a license for the manufacturing site identified in the approved medicated feed application. The revocation of license provisions of section 512(m)(4) of the Federal Food, Drug, and Cosmetic Act, as amended by this Act, shall apply to such licenses. Such license shall expire within 18 months from the date of enactment of this Act unless the person submits to the Secretary a completed license application for the manufacturing site accompanied by a copy of an approved medicated feed application for such site, which license application shall be deemed to be approved upon receipt by the Secretary.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Florida [Mr. BILIRAKIS] and the gentleman from New York [Mr. MANTON] each will control 20 minutes.

The Chair recognizes the gentleman from California [Mr. BILIRAKIS].

Mr. BILIRAKIS. Mr. Speaker, I yield myself such time as I may consume.

(Mr. BILIRAKIS asked and was given permission to revise and extend his remarks.)

Mr. BILIRAKIS. Mr. Speaker, I rise in strong support of H.R. 2508, The Animal Drug Availability Act of 1996. The bill will better protect our animals by streamlining the approval and marketing of new animal drugs and medicated feeds.

A broad bipartisan consensus has enabled us to develop this important legislation which will bring needed flexibility to the FDA animal drug review processes.

Among its improvements, the legislation redefines ''substantial evidence'' to provide FDA with greater flexibility to determine what types of studies, including field investigations, are necessary and appropriate for demonstrating the effectiveness of any specific animal drug product. The bill requires FDA to issue regulations defining substantial evidence and adequate and well-controlled field investigations taking into account the practical conditions that exist in the field.

To improve cooperation between FDA and industry, the bill requires FDA to hold a presubmission conference at the request of a sponsor submitting a new animal drug application or a request for an investigational exemption.

The legislation also streamlines the process for the approval of combination animal drug products when the individual active ingredients or animal drugs used in combination have been approved previously. In addition it authorizes FDA to establish a scientifically based safe tolerance for new animal drugs.

The bill creates a new class of animal drugs, veterinary feed directive drugs, intended for use in feed under the professional supervision of a licensed veterinarian. The bill streamlines the requirements for feed mills that make medicated feeds. Finally, the bill authorizes FDA to establish import tolerances for new animal drugs not approved in the United States.

In conclusion, I want to thank Members on both sides of the aisle who support the Animal Drug Availability Act of 1996.

Mr. Speaker, I reserve the balance of my time.

Mr. MANTON. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, the Animal Drug Availability Act makes important changes to the process by which the Food and Drug Administration reviews applications for new animal drugs.

We have heard a great deal in this Congress about reforming Government and streamlining regulation. This legislation demonstrates that these goals can be accomplished if all of the interested parties are willing to negotiate. This amendment to H.R. 2508 is the result of compromise between the FDA and the animal drug coalition. It is bipartisan, and it achieves reforms responsibly and carefully.

We are pleased that this legislation incorporates FDA proposals included in the Vice President's reinventing Government initiatives, one that will reduce unnecessary requirements and paperwork associated with feed mill licensing and another that will authorize FDA to establish import tolerances for animal drugs not approved for use in the United States.

The provisions of this bill complete a task begun with enactment in 1994 of the Animal Medicinal Drug Use Clarification Act. When the House passed that important legislation, we knew that expanding drug availability would require addressing the underlying issue

that there are not enough new animal drugs available for veterinarians to treat all the diseases and conditions that affect animals. That is the issue dealt with by H.R. 2508.

The legislation does this through simplifying the process if determining an animal drug's effectiveness; establishing a process by which FDA and the animal drug sponsor can agree in advance about what the sponsor must provide FDA to facilitate the approval of the new product; providing a streamlined process for FDA to review combination drugs; and establishing a new category of animal drugs, called Veterinary Feed Directive drugs.

Mr. Speaker, this is good legislation. It will help FDA work more efficiently, and it will help get safe and effective new animal drugs on the market more quickly. It illustrates that a cooperative effort between a regulatory agency, its regulated community, and Congress can produce results that all parties find acceptable. This is how regulatory reform can and should work.

I support this legislation, and I urge my colleagues to support it.

Mr. Speaker, I reserve the balance of my time.

Mr. BILIRAKIS. Mr. Speaker, I yield 2 minutes to the gentleman from Wisconsin [Mr. KLUG] who will speak on behalf of himself and a few hundred thousand cattle in Wisconsin.

The SPEAKER pro tempore. Including the dairy farmers of the Chair.

Mr. KLUG. Mr. Speaker, 319,000 dairy cows, to be more specific.

Mr. Speaker, I would like to thank my colleague, the gentleman from Florida [Mr. BILIRAKIS], for his terrific work on behalf of this legislation, and also the full chairman of committee, the gentleman from Virginia [Mr. BLILEY], and my colleague, the gentleman from Colorado [Mr. ALLARD], one of the few veterinarians in Congress, who has been such a strong advocate for this piece of legislation.

Mr. Speaker, as you know, for the last year the Committee on Commerce has been struggling with the ways to modernize the Food and Drug Administration, which now regulates a quarter of this Nation's economy. We have high hopes in the next session of Congress we will be able to streamline the process to approve prescription drugs and also medical devices.

Part of what we have been able to accomplish this session of Congress are two major changes in terms of the FDA's responsibility in food content. One of them is the modernization of the Delaney clause, and then this piece of legislation we have in front of us today.

As we know, the current law requires animal drugs to be approved in 6 months, but it actually takes an average of 58 months. Only 1 in 7,500 chemicals ever makes it through the current approval process. In the past 5 years the FDA has approved only four new drugs for food-producing animals.

Realistically, without this bill minor use products would never be brought to market, and the time and expense of bringing a new animal drug to market is already discouraging drug companies from pursuing approval for important medications.

This legislation today will establish a procedure by which the agency and company can sit down ahead of time to discuss the approval requirements for a new drug. It would create a new category of drugs that can be prescribed by a veterinarian and administered by a farmer in the animal's feed and it would refocus the regulation of the use of two or more drugs simultaneously on the need to prove the safety to humans.

This piece of legislation has the support of 160 cosponsors in the House, the Clinton administration supports it, FDA Commissioner Kessler supports it, industry supports the bill, and I strongly support this bill and encourage my fellow committee members, as well as my colleagues in the House, to approve it as well.

Mr. BILIRAKIS. Mr. Speaker, I yield 3 minutes to the gentleman from Colorado [Mr. ALLARD], a sponsor of this very much needed legislation.

Mr. ALLARD. Mr. Speaker, I thank the gentleman for yielding me time.

Mr. Speaker, first of all, I would like to extend my thanks to other members of the committee, the gentleman from Florida [Mr. BILIRAKIS], the gentleman from Virginia [Mr. BLILEY], the gentleman from Iowa [Mr. GANSKE], the gentleman from Wisconsin [Mr. KLUG], who we just heard on the floor, and then the gentleman from Michigan [Mr. DINGELL]. I appreciate all of their efforts in making sure that this legislation came out of committee in good shape. I know they worked very hard to make sure that we ended up with a good piece of legislation.

Mr. Speaker, this has been a bipartisan effort, both Democrats and Republicans working together with the administration to reform the Food and Drug Administration as they apply the laws as they apply to animal drugs.

This is the second major reform of the Food and Drug Administration. The first was the Delaney reform, and then this is the second step, which is the animal Food and Drug Administration reform. Both of these provisions are going to be a great help to the agricultural community.

We are looking at a crisis as far as approval of animal drugs is concerned. The drugs are being approved at a very slow rate, and it is having an impact on the type of quality and care, not only to the livestock, but also to pets.

To further compound this problem, over the past several years, the Food and Drug Administration has taken a number of drugs off of the market, and the research has not been moving along at an adequate enough rate to replace the loss of these particular products. As a consequence of that, we have lost animals to disease and also had an increased mortality rate on animals, which also cuts down on production.

When a drug has finally been approved after some time, and I would say, again, an internal audit by the FDA shows it takes an average of 58 months to approve a new drug, this law will take it down to where it actually will take only 6 months.

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Because of this, the number of drugs that have been approved over the last 23 years have dwindled. We used to have about 60 drugs approved in 1 year, about two decades ago, in 1973; and now, this last year, we have only had 10 approved. This certainly is not keeping up with science.

This is a tremendous disincentive for drug companies to create new products when it takes this long extended length of period for approval. And now, in order to develop a new product, we are looking at a cost of anywhere from $15 to $200 million, and yet most of these animal drugs have a very limited market and will generate sales of only a million dollars or less.

I think this legislation is going to help solve this problem. It will help make these drugs available for animals, both pets and in the livestock industry, and it is going to move forward many of the advances that should be moved forward and made available to the public.

In conclusion, I want to thank again the members of the committee for all their hard work on this issue and I hope that we will continue to move forward in our efforts to reform the Food and Drug Administration.

Mr. MANTON. Mr. Speaker, I yield 3 minutes to the gentleman from Florida [Mr. DEUTSCH].

Mr. DEUTSCH. Mr. Speaker, I too rise today in support of the Animal Drug Availability Act. This is Congress at its best, a bipartisan effort which is going to really streamline the efforts at the FDA, that is going to help really major livestock, poultry producers, commercial feed industry, veterinarians, some animal owners, and pharmaceutical companies as well.

Currently it takes the FDA an average of 58 months to a new animal drug, and the cost of bringing a drug to the approval stage in some instances can approach $200 million.

If the consensus bill becomes law, it will give the FDA greater flexibility in determining the type and number of studies it can accept as proof of an animal drug's efficacy.

It will reduce efficacy testing when a drug company seeks approval to use in combination two drugs that are already approved individually.

It will eliminate the requirement that a time-consuming field investigation be used in all instances to prove efficacy.

It will create a presubmission conference at which the FDA drug companies will agree before an application is submitted on the types of tests needed to approve a drug's effectiveness.

And it will increase veterinary oversight in dispensing of certain feed drugs.

In addition, the bill implements two items from the National Performance Review. It would allow FDA to set tolerance for drugs used on farm animals whose meat ultimately is imported into the United States. It also would reduce significantly the paperwork involved in licensing of a feed mill to mix animal drugs with feed.

The consensus bill maintains all human and animal health protections in current law.

Having spoken to individual veterinarians and pet owners, who have unfortunately been denied access to some of the drugs that hopefully will be readily accessible as soon as this bill is adopted, I can again speak from their personal experiences of how valuable I believe this bill will be once it is adopted into law.

Mr. BILIRAKIS. Mr. Speaker, I yield such time as he may consume to the gentleman from Nebraska [Mr. BEREUTER], who, if he does not have the largest animal drug manufacturer in his district, I understand he certainly has one of the largest.

(Mr. BEREUTER asked and was given permission to revise and extend his remarks.)

Mr. BEREUTER. Mr. Speaker, I thank the distinguished gentleman from Florida for yielding me this time.

I rise in support of H.R. 2508, the Animal Drug Availability Act. As original cosponsor of this important legislation, I would like to commend the distinguished gentlemen from Florida and New York, and the gentleman from Virginia, Mr. BLILEY, and the gentleman from Michigan, Mr. DINGELL, the ranking member, for bringing this work to the floor today. Certainly I also commend my distinguished colleague from Colorado, Mr. ALLARD, for his initiative in introducing the bill.

Mr. Speaker, this legislation is clearly needed to streamline the bureaucracy and improve the current, outdated process of approving new animal health products. Our Nation's livestock producers deserve to have the best new products available in a timely and efficient manner. This is commonsense legislation which has strong, bipartisan support in Congress and broad support in the agricultural and veterinary science communities.

The need for change is obvious. Although research and development costs have increased dramatically in recent decades, the number of new animal health products being approved by the Food and Drug Administration's Center for Veterinary Medicine has declined. The Animal Drug Availability Act modifies requirements for proving efficacy, streamlines the bureaucracy involved in approving new claims for products used in the treatment of minor species, simplifies requirements for combination drugs, and makes other improvements in the current process. Mr. Speaker, quite simply, this legislation will improve the ability of manufacturers to provide the animal health products needed by our Nation's farmers and pet owners, among others. Therefore, this Member strongly urges his colleagues to support H.R. 2508, the Animal Drug Availability Act.

Mr. BILIRAKIS. Mr. Speaker, I yield 3 minutes to the gentleman from Iowa [Mr. GANSKE], who, as we know, performed a humanitarian act in South America during the break and has come back with a fairly serious sickness.

As I understand it, he came back specifically today to speak on this particular piece of legislation because he feels very strongly about it.

The SPEAKER pro tempore (Mr. GUNDERSON). If the gentleman from Iowa would suspend for just a moment, I know the Chair speaks for all Members in welcoming him back.

The gentleman from Iowa is now recognized.

Mr. GANSKE. Mr. Speaker, first let me thank Members of both sides of the aisle for their get-well wishes. I appreciate it very much.

Earlier this month I was seriously ill and so I want to speak about this bill in a little different vein, so to speak.

There will be a lot of talk about how this bill will economically be beneficial to farmers, and that is true, and this will help our country, I think, compete internationally in terms of livestock production.

But I want to speak about something else. We have not had new drugs to treat animals, have many of them, for a long time, and this bill will streamline the process and help us get new ones. There is a term called animal husbandry. It is an old term. It has been applied to farmers, but I think it is appropriate.

When a farmer has a herd or has a flock, and they come down with a respiratory infection and they are suffering and they are sick, that farmer is not thinking just about the economic impact. He is looking at his flock and he is looking at his herds and he knows they are sick and he knows they are suffering. And if you talk to a family that has had a pet and their pet dog or cat becomes sick, they see the suffering in that animal.

I have been the beneficiary recently of modern medicine and some good antibiotics and good medicines and I think it is time that we make the modern technology that we have had on the human side more available on the animal side as well.

I really think it is the only humanitarian thing to do. It will be beneficial economically, but even more importantly, I think it will help prevent animals from suffering when they are sick. I urge all of my colleagues to vote for this bipartisan bill.

Mr. MILLER of California. Mr. Speaker, I am pleased to be an original cosponsor of H.R. 3217, the National Invasive Species Act, which we consider today. This legislation embodies a reasonable approach to addressing economic and environmental concerns while maintaining sensitivity to the maritime industry. It will establish a national voluntary ballast management program for vessels visiting U.S. ports. In addition to ballast management, this legislation will provide for research, education, and new technology to investigate and prevent species introduction in coastal and inland waters. In short, it is a major step toward protecting our natural resources.

Prevention of further species introductions can occur to a great extent by ballast exchange as provided in this legislation. I only caution that the ballast exchange provisions in this bill are based on a large part on a good faith agreement with industry to take appropriate responsibility for the consequences of ballast transport. Based on industry's support of this bill, I believe that agreement is sound. However, I would encourage the Coast Guard to be diligent in monitoring compliance and assessing the effectiveness of those voluntary guidelines, and, where necessary, make mandatory regulations to ensure protection for regions that are critically impacted by nonindigenous species.

Some regions of our country such as the San Francisco Bay-Delta Estuary are especially susceptible to species introduction from ballast water. There are greater than 200 nonindegenous species identified so far in the bay-delta with one new species established every 12 weeks. In fact, the bay-delta is recognized as the most invaded aquatic ecosystem in North America. These nonindigenous species are having serious consequences on California's aquatic ecosystem, water supplies, fisheries, and agricultural industry. This legislation will address those consequences through prevention as well as research efforts in the bay-delta. Understanding the patterns of species introductions and reducing the occurrence of those introductions is imperative in promoting the economic and ecological health of the bay-delta as well as the rest of our coastal regions.

I thank Mr. LATOURETTE for his leadership on this bill. I would also thank my colleague from California, Mr. FILNER, as well as Chairman SHUSTER and Mr. OBERSTAR, for working with me to include provisions which address critical concerns in California.

Mr. HASTERT. Mr. Speaker, I rise in strong support of H.R. 2508, the Animal Drug Availability Act of 1995. I'd like to commend the gentleman from Colorado [Mr. ALLARD] for crafting a bill that enjoys such broad, bipartisan support. I know of no opposition to this bill.

This bill is critical to animal agriculture and is sorely needed to improve the animal drug approval process. Currently, it takes the FDA an average of 58 months to approve a new animal drug, and the cost of bringing a drug to approval in some instances can be as high as $200 million. This bill will streamline the approval process for animal drugs, making safe drugs available more quickly and less expensively.

Clearly, the pork, cattle, poultry, and wool producers in my district in Illinois will benefit tremendously from this legislation, as will every pet owner in the country. But the benefits of this bill go far beyond making life a little easier for our farmers and for our animals. Ultimately, the real benefactors of this legislation will be every consumer across America, as safe, cheaper animal products are made more available.

The bill before us today represents a consensus that has been negotiated with the

FDA. It enjoys broad bipartisan congressional support, and the full support of the administration. I urge quick passage today of the Animal Drug Availability Act. Thank you; I yield back the balance of my time.

Mr. BLILEY. Mr. Speaker, we now take up a bill that is important to protect animal health at home and on the farm. The animal health industry keeps our pets healthy—including some 130 million dogs and cats—and agricultural animals that are vital to our food supply. The animal health industry protects human health by safeguarding the health of food and domestic animals.

I have heard repeated concern from Members on both sides of the aisle that our FDA system for reviewing animal drug products needs significant improvement. Their concern reflects the frustration of diverse groups including agricultural interests, the animal drug industry, veterinarians, and animal producer groups.

Our arsenal of drugs to fight animal disease is not growing.

The FDA review process for animal drugs is much too slow—instead of 6 months, the process has averaged up to 5 years.

Some industry has become discouraged and divested animal drug development capability.

Mr. ALLARD, Mr. GANSKE, Mr. KLUG, have been among those who said that it's time to take action and make changes. I particularly want to thank Mr. GANSKE who has come from his hospital bed to be here today to demonstrate his support. Even the administration recognized the need to reform to streamline animal drug regulation and made its own proposals that were consistent with our views.

The committee considered animal drug regulations as part of a broader initiative to streamline FDA regulation. We have made significant progress and I am very pleased that today we take up the completed animal drug reforms in H.R. 2508.

The committee efforts have been helped by collaboration from the administration, the animal health coalition, veterinarians, and others interested in safeguarding our animals. I would like to thank each of them and their dedicated staff for their hard work.

H.R. 2508 will facilitate the approval and marketing of new animal drugs and medicated feeds. It builds needed flexibility into the FDA animal drug review processes to enable more efficient approval and more expeditious marketing of safe and effective animal drugs.

H.R. 2508 accomplishes streamlines without decreasing FDA's existing authority to ensure that animal drug products are safe for the animals that use them and for the humans who consume animal food products.

Our reforms are sensible, pragmatic, and above all else, protective of public health. Of this accomplishment, I believe we can rightly be proud.

Mr. STENHOLM. Mr. Speaker, H.R. 2508 is an example of how serious reform can and should occur. The Animal Drug Availability Act of 1995 enjoys broad support from camps that do not always see things from the same viewpoint, however, both the FDA and the regulated community agree on the reform embodied in H.R. 2508. Additionally, the users of animal drugs, the veterinarians, and the various animal agriculture groups representing farmers and ranchers that raise beef, pork, and poultry all support this bill. The Animal Drug Availability Act represents what can be accomplished when all involved, regulators, those regulated, and the end users sit down and sincerely listen to each other. Unfortunately, the larger issue of FDA reform has been slowed for a variety of reasons. Hopefully, this bill should serve as an example of how future Congresses can approach larger FDA reform and of the progress that can result from bipartisan discussion open to all stakeholders.

H.R. 2508, the Animal Drug Availability Act of 1995, represents common sense reform that reduces regulatory hurdles for efficacy testing and preserves safety testing. Let me say that again. The Animal Drug Availability Act does not reduce evaluation of products on the basis of human safety, nor does it reduce the FDA's ability to require target animal safety information. Essential safety standards for humans and animals would not be weakened in any way. The effect of the reform should be a speedier approval process without jeopardizing safety confidence.

Animal health products many times do not command lucrative markets and it is difficult to justify investment into research and development for a new product or an additional approved use on a label if markets are limited or absent. Currently a large commitment in time and money is required to prove a product's efficacy claims. This bill would give the FDA greater flexibility in determining the type and number of studies it can accept as proof of an animal drug's efficacy. Streamlining the process and eliminating unnecessary field trials should speed the time to an approval decision and hopefully reduce some negative economic pressures being applied by the regulatory system.

Small markets or limited economic incentives, do not mean that drugs for animals are not important. Take for instance the cattleman who has experienced difficult times with low cattle prices who may be trying to diversify and is starting to raise ostriches or pheasants, or a farmer who is involved in aquaculture, or even the wildlife or zoo veterinarian who deals with very unique patients. These are examples of animals that as a species represent few in number and generate very little economic incentive for a drug manufacturer to pursue R&D in that area . . .the so-called minor use/minor species problem of animal drugs. The legislation that legalized extra label drug use in animals by veterinarians was sponsored by this Member and others in the last Congress—the Animal Medicinal Drug Clarification Act of 1994. Extra label drug use will always be necessary, however, this bill will potentially help reduce the reliance on using drugs extra label. It can offer an opportunity for FDA to evaluate how the Animal Medicinal Drug Use Clarification Act and the Animal Drug Availability Act could efficiently work together.

It is with some pride, as sponsor of the legislation that dealt with extra label use of animal drugs and now as one of the original cosponsors of the Animal Drug Availability Act, that this House is here addressing this issue on the Suspension Calendar. I am proud that animal drug regulatory reform may very well become an example of how larger FDA regulatory reform can be accomplished. I ask my colleagues to support H.R. 2508 and encourage the Senate to act quickly so that the President can sign this appropriate reform into law.

Mr. ROBERTS. Mr. Speaker, I rise in strong support of this legislation which is vital to the future health of the Nation's livestock and poultry industry in rural districts throughout this country. H.R. 2508, the Animal Drug Availability Act, is a noncontroversial, bipartisan bill that streamlines and significantly improves the process by which animal drugs are approved. The bill expands the types of studies FDA can accept as proof of a drug's efficacy; requires FDA and drug companies to agree to test protocols before a company submits a drug application for approval; eliminates time-consuming field investigations, unless they are the only way to prove a drug's efficacy; eliminates some efficacy testing when a company seeks to use two individually approved drugs in combination; creates veterinary feed directive drugs which increase veterinarian involvement in dispensing animal drugs; and eliminates much of the licensing paperwork for feed mills that dispense animal drugs.

The bottom line: this bill is perhaps the most significant thing this Congress can do to help the livestock and poultry industry reduce their cost of production and become more competitive.

The cumbersome and lengthy process of getting animal drug approvals from FDA has led to several U.S. animal drug companies setting up plants overseas. Passage of this bill will also help stem the flow of jobs—well paying jobs—from this country.

I am pleased to finally get a chance to discuss and vote on this important piece of legislation and I would strongly urge my colleagues to vote in favor of its passage.

Mr. MANTON. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

Mr. BILIRAKIS. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Florida [Mr. BILIRAKIS] that the House suspend the rules and pass the bill, H.R. 2508, as amended.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

GENERAL LEAVE

Mr. BILIRAKIS. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks on H.R. 2508.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Florida?

There was no objection.

CONFERENCE REPORT ON H.R. 2202, ILLEGAL IMMIGRATION REFORM AND IMMIGRANT RESPONSIBILITY ACT OF 1996

Mr. SMITH of Texas submitted the following conference report and statement on the bill (H.R. 2202) to amend the Immigration and Nationality Act