

protocols, and Phase 3 protocols for clinical trials that will form the primary basis of an efficacy claim. (For such Phase 3 protocols to qualify for this comprehensive protocol assessment, the sponsor must have had an end of Phase 2/pre-Phase 3 meeting with the review division so that the division is aware of the developmental context in which the protocol is being reviewed and the questions being answered.)

4. N.B. For products that will be using Subpart E or Subpart H development schemes, the Phase 3 protocols mentioned in this paragraph should be construed to mean those protocols for trials that will form the primary basis of an efficacy claim no matter what phase of drug development in which they happen to be conducted.

5. If a protocol is reviewed under the process outlined above and agreement with the Agency is reached on design, execution, and analyses and if the results of the trial conducted under the protocol substantiate the hypothesis of the protocol, the Agency agrees that the data from the protocol can be used as part of the primary basis for approval of the product. The fundamental agreement here is that having agreed to the design, execution, and analyses proposed in protocols reviewed under this process, the Agency will not later alter its perspective on the issues of design, execution, or analyses unless public health concerns unrecognized at the time of protocol assessment under this process are evident.

#### B. Performance goals

60 percent of special protocols assessments and agreement requests completed and returned to sponsor within time frames (based on cohort year of request) starting in FY 1999; 70 percent in FY 2000; 80 percent in FY 2001; and 90 percent FY 2002.

### VII. ELECTRONIC APPLICATIONS AND SUBMISSIONS

The Agency shall develop and update its information management infrastructure to allow, by fiscal year 2002, the paperless receipt and processing of INDs and human drug applications, as defined in PDUFA, and related submissions.

### VIII. ADDITIONAL PROCEDURES

#### A. Simplification of action letters

To simplify regulatory procedures, the CBER and the CDER intend to amend their regulations and processes to provide for the issuance of either an "approval" (AP) or a "complete response" (CR) action letter at the completion of a review cycle for a marketing application.

#### B. Timing of sponsor notification of deficiencies in applications

To help expedite the development of drug and biologic products, CBER and CDER intend to submit deficiencies to sponsors in the form of an "information request" (IR) letter when each discipline has finished its initial review of its section of the pending application.

### IX. DEFINITIONS AND EXPLANATION OF TERMS

A. The term "review and act on" is understood to mean the issuance of a complete action letter after the complete review of a filed complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval.

B. A major amendment to an original application submitted within three months of the goal date extends the goal date by three months.

C. A resubmitted original application is a complete response to an action letter addressing all identified deficiencies.

D. Class 1 resubmitted applications are applications resubmitted after a complete re-

sponse letter (or a not approvable or approvable letter) that include the following items only (or combinations of these items):

1. Final printed labeling;
2. Draft labeling;
3. Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and changes highlighted (except when large amounts of new information including important new adverse experiences not previously reported with the product are presented in the resubmission);
4. Stability updates to support provisional or final dating periods;
5. Commitments to perform Phase 4 studies, including proposals for such studies;
6. Assay validation data;
7. Final release testing on the last 1-2 lots used to support approval;
8. A minor reanalysis of data previously submitted to the application (determined by the agency as fitting the Class 1 category);
9. Other minor clarifying information (determined by the Agency as fitting the Class 1 category); and
10. Other specific items may be added later as the Agency gains experience with the scheme and will be communicated via guidance documents to industry.

E. Class 2 resubmissions are resubmissions that include any other items, including any item but would require presentation to an advisory committee.

F. A Type A Meeting is a meeting which is necessary for an otherwise stalled drug development program to proceed (a "critical path" meeting).

G. Type B Meeting is a (1) pre-IND, (2) end of Phase 1 (for Subpart E or Subpart H or similar products) or end of Phase 2/pre-Phase 3, or (3) a pre-NDA/PLA/BLA meeting. Each requestor should usually only request 1 each of these Type B meetings for each potential application (NDA/PLA/BLA) (or combination of closely related products, i.e., same active ingredient but different dosage forms being developed concurrently).

H. A Type C Meeting is any other type of meeting.

I. The performance goals and procedures also apply to original applications and supplements for human drugs initially marketed on an over-the-counter (OTC) basis through an NDA or switched from prescription to OTC status through an NDA or supplement.

Mr. BURR of North Carolina. Mr. Speaker, I reserve the balance of my time.

Mr. BROWN of Ohio. Mr. Speaker, I yield myself such time as I may consume. This is primarily a technical corrections bill to correct some provisions of the FDA reform bill that this House passed by voice on Sunday. This correction resolution does not change any of the underlying policies of the FDA legislation, nor does it make any new substantive policy changes.

Mr. Speaker, I ask for House support.

Mr. RUSH. Mr. Speaker, I am proud to speak today in support of the conference report to pass FDA reform legislation.

During the markup in the Commerce Committee of H.R. 1411, the Drug and Biological Products Modernization Act of 1997, I offered an amendment to the bill to ensure that women and members of minority and ethnic groups would be adequately represented in clinical trials of new drugs that are submitted to the Food and Drug Administration [FDA] for approval.

This amendment specifically directs the Secretary of Health and Human Services to

consult with the National Institute of Health [NIH] to review and develop guidelines on the inclusion of women and minorities in clinical trials.

This important amendment was unanimously adopted by the committee by voice vote.

In passing H.R. 1411, the Committee engaged in a vigorous debate about the respective roles of government and the industry. We have heard a lot about how we must not sacrifice the public health and consumer safety by allowing faster approval of new drugs. In the same spirit, we must not lose sight of equity issues.

I congratulate Members on both sides of the aisle for working hundreds of hours to craft this bill. And staff, on both sides, are to be commended for their dedication to fine-tuning this landmark legislation.

I look forward to working with Members of Congress, the administration, and medical and consumer groups to help expand the inclusion of women and minorities in clinical trials.

I rise in strong support of the conference report and urge all Members to vote "yes" on this bill.

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

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

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from North Carolina [Mr. BURR] that the House suspend the rules and agree to the concurrent resolution, House Concurrent Resolution 196.

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

A motion to reconsider was laid on the table.

### AMENDING CONSOLIDATED OMNIBUS BUDGET RECONCILIATION ACT OF 1985 RELATING TO CUSTOMS USER FEES

Mr. SHAW. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3034) to amend section 13031 of the Consolidated Omnibus Budget Reconciliation Act of 1985, relating to customs user fees, to allow the use of such fees to provide for customs inspectional personnel in connection with the arrival of passengers in Florida, and for other purposes.

The Clerk read as follows:

H.R. 3034

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

#### SECTION 1. FUNDS FOR CUSTOMS INSPECTION PERSONNEL.

(a) ACCESS TO CUSTOMS USER FEE ACCOUNT.—Section 13031(f)(3)(A) of the Consolidated Omnibus Budget Reconciliation Act of 1985 (19 U.S.C. 58c(f)(3)(A)), is amended—

(1) in clause (i)(V), by striking "and" at the end;

(2) in clause (ii)—

(A) by striking "to make reimbursements" and inserting "after making reimbursements"; and

(B) by striking the period at the end and inserting ", and", and

(3) by inserting after clause (ii) the following:

“(iii) to the extent funds remain available after making reimbursements under clause (ii), in providing salaries for up to 50 full-time equivalent inspectional positions through September 30, 1998, that enhance customs services in connection with the arrival in Florida of passengers aboard commercial vessels, regardless of whether those passengers are required to pay fees under paragraphs (1) through (8) of subsection (a).”.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Florida [Mr. SHAW] and the gentlewoman from Florida [Mrs. THURMAN] each will control 20 minutes.

The Chair recognizes the gentleman from Florida [Mr. SHAW].

GENERAL LEAVE

Mr. SHAW. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and include extraneous material on H.R. 3034.

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

There was no objection.

Mr. SHAW. Mr. Speaker, I yield myself such time as I may consume. I rise today in support of H.R. 3034, a bill to preserve current funding for Customs inspections positions throughout the State of Florida. I am pleased that the bipartisan leadership of the Committee on Ways and Means has agreed to allow this time sensitive bill to come to the floor under suspension of the rules.

Mr. Speaker, this bill is needed to preserve Customs inspectional positions in Florida ports due to the fact that Customs' authority to access the Customs COBRA User Fee Account expired on September 30, 1997. The User Fee Account has a substantial surplus, and my bill would allow Customs limited access to pay the salary of Customs inspectors who process cruise-ship passengers returning to Florida from the Caribbean Basin. My bill will allow Customs more than enough time to develop a long-term plan to continue processing the current level of cruise-ship passengers, as well as expected future increases. As a longtime champion of the Customs Service and their fine work in south Florida, I am confident of their commitment to provide full service to the cruise ship industry which is so vital to the economy of my home State of Florida. Let me acknowledge that the Committee on Ways and Means will have to consider any extension or expansion of this temporary provision beyond September 30, 1998.

Mr. Speaker, enactment of the temporary measure in H.R. 3034 will ensure that the smooth flow of passengers at Florida's ports continue and that our State's vibrant cruise ship industry will not be damaged while a long-term solution is found. I urge my colleagues to support H.R. 3034.

Mr. Speaker, I yield such time as he may consume to the gentleman from Kentucky [Mr. ROGERS].

[Conference Report submitted by Mr. ROGERS is in Part I.]

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

Mr. Speaker, this bill is going to address a critical situation for Florida's tourist industry. On September 30, the Customs Service lost authority to collect fees used to inspect cruise vessels traveling to the Caribbean island community. Customs has advised cruise ship companies in Florida that Customs will be unable to provide inspection service to vessels that will be starting cruises from Florida on or after December 1, 1997. Customs claims that the expiration of the user fee authority will require the reduction of inspectional positions in Florida. This bill prevents the loss of these positions and will ensure that tourists seeking to enjoy cruises in Florida this winter are not disappointed. Specifically the bill allows Customs to access the Customs user fee account to provide for up to 50 full-time inspectors. The account contains about \$120 million, far more than the \$1 million or so needed to maintain these positions.

I understand because of the expiration of the user fee authority, Customs intends to remove an additional 27 inspectors who provide similar services for cruise ships arriving at Long Beach, CA, and for the preclearance of aircraft passengers in Canada. I believe that the Committee on Ways and Means should work with the Customs Service to develop a long-term solution that ensures the continuation of inspection services for air and sea passengers and for all affected ports of entry.

I will work with the gentleman from Florida [Mr. SHAW] to correct this situation in 1998, but Congress must approve this legislation before we adjourn. If we do not, the cruise industry in Florida will be decimated this winter.

Finally, I want to thank the gentleman from Texas [Mr. ARCHER], the chairman of the Committee on Ways and Means; the gentleman from New York [Mr. RANGEL], the ranking member; the gentleman from Illinois [Mr. CRANE] the chairman of the Subcommittee on Trade; and the gentleman from California [Mr. MATSUI] for their assistance, and certainly the gentleman from Florida [Mr. SHAW] for his advancement of this piece of legislation.

Mr. Speaker, I yield such time as he may consume to the gentleman from Florida [Mr. DEUTSCH] who has many of these ports in his district.

Mr. DEUTSCH. Mr. Speaker, south Florida really is known as the cruise capital literally of the entire world. Because of the situation that we are in, unless we pass this legislation at this point in time, several ships that would be sailing from south Florida, or have plans to be sailing from south Florida during the winter season when we are in our break potentially would not be able to sail.

□ 1600

These are ships, multi-million-dollar ships. Probably more importantly,

these are ships that have already advertised and collected money from hundreds of people, if not thousands of people, who are planning their vacations to go on these ships and, in fact, would have to cancel without this legislation.

It is a fair, appropriate piece of legislation in terms of funds that we need to use to have several, as was mentioned, a very few, customs officials because of the way the law is being interpreted. I talked with the customs commissioner himself about this, and again I want to thank the staff and the members of the committee for their help in this matter.

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

Mr. SHAW. Mr. Speaker, I yield such time as he may consume to the gentleman from New York [Mr. GILMAN].

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

Mr. GILMAN. Mr. Speaker, I thank the gentleman for yielding this time to me.

Mr. Speaker, I am pleased to rise in support of H.R. 3034 introduced by both the gentleman from Florida [Mr. SHAW] and the gentleman from Illinois [Mr. CRANE], a measure that would allow the user fee account to be used for the Customs Service in the Florida area.

I just visited that region in Miami and was appalled to learn that 50 inspectional positions would help arriving vessels, cruise ships, in Florida which would inure some \$1 million in revenue to the port, and because there is some shortsightedness here we have a limitation on customs inspectors, and I would hope that the Congress can join in this measure that would help alleviate that problem for the Florida ports so that ships could come in, so that the region could obtain that kind of revenue at a time when we are trying to enhance the economy throughout the Nation.

I think that this is an important measure, and I urge my colleagues to support it.

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

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

Very briefly, I would like to thank the gentleman from Texas [Mr. ARCHER] and the gentleman from Illinois [Mr. CRANE] as well as the ranking Democrat Members, the gentleman from California [Mr. MATSUI] and the gentleman from New York [Mr. RANGEL], for allowing this to come to the floor in this expedited procedure. This is a very important bill for Florida. I would also like to commend the gentlewoman from Florida [Mrs. THURMAN] and the gentleman from Florida [Mr. DEUTSCH] for their involvement in moving this bill along.

Mr. CRANE. Mr. Speaker, yesterday Mr. SHAW introduced H.R. 3034, a bill to allow the U.S. Customs Service limited and temporary access to the Customs COBRA User Fee Account to fund, through September 30, 1998, up to 50 inspectional positions for processing

passengers arriving on commercial vessels—cruise ships—in Florida. As of September 30, 1997, Customs no longer collects user fees from passengers arriving from Canada, Mexico, and the Caribbean. Current law states that the funds can only be used to enhance inspectional service at ports if Customs COBRA User fees are collected. Thus, Customs may not use any money from the Customs COBRA User Fee Account to fund positions in those ports to enhance the inspection of passengers who arrive from Canada, Mexico, and the Caribbean.

As of September 30, 1997, fees are no longer collected from cruise ship passengers arriving in Florida from Caribbean countries. Therefore, Customs no longer has the authority to access the user fee account to pay for inspectional positions previously acquired in these Florida ports. Forty-three of these positions have been added in Florida ports where user fees had previously been collected from cruise ship passengers. Mr. SHAW's bill would give Customs limited access to the user fee account to fund these 43 positions, plus an additional 7 positions to account for any growth in the cruise ship industry in fiscal year 1998.

The bill has no pay-go impact because revenues to fund these inspectors would come from the Customs COBRA User Fee Account, under the current permanent, indefinite appropriation.

Mr. Speaker, I must emphasize three important points with regard to the decision of the Committee on Ways and Means to allow this bill to come to the floor under suspension of the rules. First, this is being done with the understanding that the committee will be treated without prejudice in the future as to its jurisdictional prerogatives on this or similar provisions. This bill should not be considered as precedent for consideration of matters of jurisdictional interest to the committee in the future. Second, the bill provides limited relief for the processing of cruise ship passengers in Florida only. The bill sets no precedent for providing Customs access to the Customs COBRA User Fee Account to fund inspectional positions for the processing of passengers arriving on commercial vessels arriving at any port of entry outside of Florida. Third, the committee's decision to allow the provision to be considered under suspension of the rules shall set no precedent for allowing additional access to the user fee account after fiscal year 1998. The Subcommittee on Trade intends to review several issues involving Customs user fees next year, including H.R. 2262, my bill to reform the overtime and nighttime pay reform system for Customs inspectors.

I would finally like to add that the Customs Service could fund these and other positions through its salaries and expenses account. The bill will therefore provide Customs additional time to develop a plan by which current and future cruise ship passengers can be processed as part of Customs ongoing commitment to process passengers as efficiently as possible. The bill will provide short-term relief for the cruise ship industry in Florida, the group most immediately impacted by Customs' failure to develop such a plan.

Mr. GILMAN. Mr. Speaker, I rise in support of H.R. 3034, a bill to allow the U.S. Customs Service limited and temporary access to the Customs COBRA User Fee Account to fund, through September 30, 1998, up to 50

inspectional positions for processing passengers arriving on commercial vessels in Florida.

Cutbacks in the U.S. Customs Service have threatened the voyages of numerous cruise ships in Florida, due to the fact that the Customs Service no longer has authority to access the user fee account to pay for inspectional positions.

H.R. 3034 will give Customs limited access to the user fee account to fund 43 positions, plus an additional 7 positions to account for any growth in the cruise ship industry in fiscal year 1998.

I applaud my colleague, the distinguished gentleman from Florida, Mr. SHAW, and commend him for his efforts to ensure the success of the cruise ship industry.

Mr. SHAW. Mr. Speaker, 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. SHAW] that the House suspend the rules and pass the bill, H.R. 3034.

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

A motion to reconsider was laid on the table.

#### JUSTICE FOR VICTIMS OF COMMUNISM ACT OF 1997

Mr. CANADY of Florida. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3037) to clarify that unmarried children of Vietnamese reeducation camp internees are eligible for refugee status under the Orderly Departure Program.

The Clerk read as follows:

H.R. 3037

*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 "Justice for Victims of Communism Act of 1997".

#### SEC. 2. ELIGIBILITY FOR REFUGEE STATUS.

Section 584 of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1997 (Public Law 104-208; 110 Stat. 3009-171) is amended—

(1) in subsection (a)—

(A) by striking 'For purposes' and inserting "Notwithstanding any other provision of law, for purposes", and

(B) by striking "fiscal year 1997" and inserting "fiscal years 1997 and 1998"; and

(2) by amending subsection (b) to read as follows:

"(b) ALIENS COVERED—

"(1) IN GENERAL.—An alien described in this subsection is an alien who—

"(A) is the son or daughter of a qualified national;

"(B) is 21 years of age or older; and

"(C) was unmarried as of the date of acceptance of the alien's parent for resettlement under the Orderly Departure Program.

"(2) QUALIFIED NATIONAL.—For purposes of paragraph (1), the term 'qualified national' means a national of Vietnam who—

"(A)(i) was formerly interned in a reeducation camp in Vietnam by the Government of the Socialist Republic of Vietnam; or

"(ii) is the widow or widower of an individual described in clause (i); and

"(B)(i) qualified for refugee processing under the reeducation camp internees sub-

program of the Orderly Departure Program; and

"(ii) on or after April 1, 1995, is or has been accepted—

"(I) for resettlement as a refugee; or

"(II) for admission as an immigrant under the Orderly Departure Program."

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Florida [Mr. CANADY] and the gentleman from North Carolina [Mr. WATT] each will control 20 minutes.

The Chair recognizes the gentleman from Florida [Mr. CANADY].

Mr. CANADY of Florida. Mr. Speaker, I yield myself such time as I may consume.

Briefly, this is a bill which will extend and clarify an important State Department and Immigration and Naturalization Service authority that expired on September 30, 1997, which is necessary to help protect the victims of communism.

Mr. Speaker, I yield such time as he may consume to the gentleman from New Jersey [Mr. SMITH] for further explanation.

Mr. SMITH of New Jersey. Mr. Speaker, this authority was necessary for longtime reeducation camp victims who had been persecuted in Vietnam for their pro-U.S. associations to bring their unmarried children with them to the United States if these children have reached the age of 21 during their incarceration or the long wait for an exit visa from the Communist authorities. A member of these former prisoners of conscience have refused to leave Vietnam unless they can bring their children with them. These families are trapped in Vietnam until the provision is reauthorized.

I would just like to point out to the Members that extension of this authority has been endorsed by the administration, on the other side of the building Senators MCCAIN, ABRAHAM, and KENNEDY, and it has the bipartisan support of the gentleman from Illinois [Mr. HYDE], the gentleman from New York [Mr. GILMAN], and the gentleman from California [Mr. BERMAN], and I appreciate their cosponsorship of this legislation, and Mr. BERMAN and Mr. DAVIS, as a matter of fact, are additional cosponsors as well.

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

Mr. WATT of North Carolina. Mr. Speaker, I yield such time as she may consume to the gentleman from California [Ms. LOFGREN].

Ms. LOFGREN. Mr. Speaker, I rise in support of H.R. 3037. I do regret only that it has come up so quickly that many Members who would be here to speak in favor of it were not even aware that it was going to be brought up.

It is important that this country, who stood shoulder to shoulder, stood side by side and fighting communism in South Vietnam, stand yet again with those who have been the victims of torture and oppression subsequent to the fall of the South Vietnamese Government.