VIII. ADDITIONAL PROCEDURES

A. Simplification of action letters

To simplify regulatory procedures, the CBER and 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 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 response 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 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 that 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. A 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.●

TRIBUTE TO WILLIAM D. MOORE

● Mr. DODD. Mr. President, I want to take a moment to recognize the work of one of my constituents—William D. Moore of Old Saybrook, Connecticut. Bill left his post as Executive Director of the Southeastern Connecticut Chamber of Commerce this month and his work in that post deserves special recognition.

Bill has been at the helm of so many economic and development initiatives in the Southern portion of our state that it is hard to list all of them in this brief statement. But without a doubt, it is Bill's leadership through some of the most difficult economic times in our state that really stand out in my mind.

When the very first round of base closures were being proposed in the Pentagon in 1989, it was Bill Moore who literally marshaled the forces in Southern Connecticut. He recruited some of the most dynamic and brilliant minds in our state to come together and review every single document, every single calculation, and even the very computer model used to analyze the various Groton-New London regional facilities under the Defense Department's review. Bill created one of the most cohesive and effective team strategies ever presented to address the economic impact issues which clearly were not being assessed by the Pentagon.

Although not all of our efforts were successful, it was Bill's foresight and commanding presence that eventually led our team to victory in the fight to remove the New London Submarine Base from the Base Closure list in 1993. As a measure of credit, the Base Closure Commission belatedly admitted that the Navy's assumptions used to evaluate New London were flawed. Bill Moore was the man who first presented that information to the commission.

However, Bill's efforts have gone far beyond that monumental task. He has been the usher at the door of an entire new economic era for Southeastern Connecticut. Just as the defense downsizing efforts were taking their ravenous toll on our state and New London County in particular, Bill encouraged and fostered new development for our state and helped bring about a more level-headed transition for our heavily defense weighted economy. For example, he assisted in the appropriation of funds to rebuild the Connecticut State Pier and helped with the private-public partnerships that have rebuilt downtown New London. That was no small task.

During Bill's tenure, the membership of the Southeastern Chamber has more than doubled. Clearly, the contributions of those members have made New London County what it is today.

Finally, I would be remiss if I did not mention Bill's contributions during the creation and expansion of two of the most successful Indian gaming facilities in the hemisphere. Bill's unique skills and perseverence made this transition for our region a positive and inclusive process.

In closing, let me just add my personal thanks and congratulations to Bill and his family. I wish Bill and Maureen every success in their new endeavors.●

NATIONAL ACADEMY OF SCIENCES STUDY ON IMMIGRATION

● Mr. ABRAHAM. Mr. President, I rise today to discuss the National Academy of Sciences study on immigration that has received so much attention in the past year. This is a study the Senate Immigration Subcommittee held a hearing on this September featuring two of the principal authors of the report.

In releasing the study, the Academy stated quite clearly that ''Immigration benefits the U.S. economy overall and has little negative effect on the income and job opportunities of most native-born Americans.'' Moreover, the recent hearing showed that the study's findings were actually more positive than the initial press reports indicated.

Ronald Lee, a professor of demography and economics at the University of California at Berkeley who performed the key fiscal analysis for the Academy study, testified at the hearing that ''[The NAS] Panel asked how the arrival of an additional immigrant today would affect U.S. taxpayers. According to the report, over the long run an additional immigrant and all descendants would actually save the taxpayers $80,000.'' Lee notes that immigrant taxes ''help pay for government activities such as defense for which they impose no additional costs.'' Immigrants also ''contribute to servicing the national debt'' and are big net contributors to Social Security.

Critics of immigration cite only the study's figures on the annual costs immigrant households are said to impose on natives. However, Lee testified that ''These numbers do not best represent the Panel's findings, and should not be used for assessing the consequences of immigration policies.'' This is a pretty clear statement that citing the household cost figures to urge cuts in legal immigration is an improper use of the study's data.

The problem, Lee found, was that calculating annual numbers requires using an older model that counts the native-born children of immigrants as ''costs'' created by immigrant households when those children are in school, but fails to include the taxes paid by those children of immigrants once they complete their schooling, enter the work force, and become big tax contributors. The key fiscal analysis in the report, performed in Chapter

7, corrects the flaws in the annual figures by using a dynamic model that factors in the descendants of immigrants.

In response to a question from the subcommittee, Ronald Lee noted that, with the necessary assumptions, a dynamic analysis would likely show at least 49 of the 50 States come out ahead fiscally from legal immigration, with California a close call.

Jim Smith, chairman of the NAS study, testified that ''Due to the immigrants who arrived since 1980, total Gross National Product is about $200 billion higher each year.'' In other words, recent immigrants will add approximately $2 trillion to the nation's GNP over the course of the 1990s.

I ask to have printed in the RECORD a recent Wall Street Journal article that goes into greater detail on the Academy study.

The article follows:

[The Wall Street Journal, Tuesday, Nov. 11, 1997]

IMMIGRANTS BRING PROSPERITY

(By Spencer Abraham)

Critics of America's immigration policy are attempting to reignite the heated debate that almost produced laws severely restricting legal immigration. Ironically, they are using as their vehicle a National Academy of Sciences study, released earlier this year, that was highly favorable toward immigration. Anti-immigrant writers and advocacy groups have engaged in a concerted effort to put a negative spin on the report. ''The study highlights significant problems with regard to immigration,'' crows the Center for Immigration Studies.

That just won't wash. A recent hearing before the Senate Subcommittee on Immigration found that the study's findings were even more positive than initial press reports indicated.

The most important finding of the NAS report is that an additional immigrant to the U.S. and all his descendants would actually save taxpayers $80,000 over the long run. Ronald Lee of the University of California, who was the report's key fiscal analyst, notes that immigrant taxes ''help pay for government activities such as defense for which they impose no additional costs.'' Immigrants also ''contribute to servicing the national debt'' and are big net contributors to Social Security.

Critics of immigration cite only the study's figures on the annual costs immigrant households are said to impose on natives. However, Mr. Lee testified that ''these numbers do not best represent the panel's findings, and should not be used for assessing the consequences of immigration policies.'' The problem, Mr. Lee found, was that calculating annual numbers requires using an older model that counts the native-born children of immigrants as ''costs'' created by immigrant households when those children are in school, but fails to include the taxes those children pay once they enter the work force. The $80,000 figure was arrived at using a dynamic model that factors in the descendants of immigrants. As for the fiscal impact on states of legal immigration. Mr. Lee said, with the necessary assumptions, a dynamic analysis would likely show 49 of them coming out ahead, with California a close call.

The benefits of legal immigration don't end there. Mr. Lee said that the net present value to the nation of the immigrants who will enter the U.S. during the 1990s is over $500 billion. Jim Smith, chairman of the NAS study and a RAND economist, testified that ''due to the immigrants who arrived since 1980, total gross national product is about $200 billion higher each year.'' In other words, recent immigrants will add approximately $2 trillion to the nation's GNP over the course of the 1990s.

Opponents of immigration also would like Americans to believe that nearly everyone's wages are significantly lower because of competition from immigrants. That is far from the truth. The NAS study estimates that only two groups have seen their wages affected by immigration: those who immigrated a few years earlier, and native-born Americans who did not finish high school. Wages for these groups are about 5% lower than they would have been without immigration—a figure that drops to 3% if only legal immigrants are counted, according to Mr. Smith. Cutting legal immigration would have a ''quite limited'' effect even on this group's wages, he said. ''Fortunately,'' he noted, ''90% of Americans are not high school dropouts, an the percent of high school dropouts has been declining rapidly.'' Indeed, Mr. Smith added that competition from immigrants sends wage signals that encourage native-born Americans to stay in school.

''The competition from immigration for even some native-born workers can be easily exaggerated,'' testified Mr. Smith. ''To the extent immigrants do work different than that of native-born workers, immigration benefits all native-Americans who gain in their other role as consumers of these now less-expensive goods and services.''

In short, the NAS study confirms what most Americans have known all along: Our tradition of welcoming immigrants pays off—for the immigrants and for the rest of us.●

EXTENDING CERTAIN PROGRAMS UNDER THE ENERGY POLICY AND CONSERVATION ACT

● Mr. BINGAMAN. Mr. President, the situation in which we find ourselves on this bill is a disgrace. The daily newspapers have been filled recently with stories of our developing political confrontation with Saddam Hussein. Just today, Saddam Hussein has ordered all American arms inspectors to leave Iraq immediately, escalating Iraq's crisis with the United Nations and heightening the possibility of a military confrontation. We may well see military action in the Persian Gulf before Congress convenes next year. We all know what that could do to oil markets. Prices might well spike up, right in the middle of the winter heating season. The most effective antidote to such damaging price fluctuations is close communication among the major oil consumption nations, and joint action to calm oil markets through the International Energy Agency [IEA]. Yet the bill before us, once again, fails to make the legal changes that are needed for the United States to continue to participate meaningfully in the IEA.

The United States took the lead in forming the IEA after the Arab oil embargo of 1973, so that we would never again have to experience the market chaos that reigned at that time. At that time, it seemed that the best way to avoid a repeat of gas lines around the world was through mandatory allocations of world oil supplies. This was basically a command-and-control approach to the problem. This mandatory allocation mechanism was enshrined in our basic law on oil emergencies, the Energy Policy and Conservation Act of 1975 [EPCA], which also authorized the Strategic Petroleum Reserve, and which this bill would extend. But the world has changed since the 1970's. Oil markets have changed dramatically since then. And the mandatory allocation scheme contained in the original EPCA is a dinosaur.

The United States has taken the lead in designing a flexible international response mechanism to oil supply disruptions that respects market forces. Our domestic oil industry played a key role in the planning process and has endorsed it. We convinced all of the other countries in the IEA to adopt it. But without statutory changes to EPCA, the United States is placed in the absurd position of not being able to participate in the international oil emergency response system that it designed. And all indications from the Persian Gulf are that we could have another emergency sometime soon.

Why are we in such a predicament? It is not the fault of the administration. They have been pressing for the adoption of the needed legal changes for 3 years now. It is not the fault of this Body. We have passed the requisite legal changes in both the last Congress and in this Congress, and have forwarded them to the other Body. There is no good answer to the question of why the other Body continues to refuse to act on such clearly needed changes. These necessary changes have apparently been made a hostage to other, non-related issues. So we must pass the bill before us today, which is inadequate to our national security needs, or the President will also be without clear legal authorities to operate the Strategic Petroleum Reserve in case of an oil supply emergency.

I will vote for this bill, Mr. President, with extreme reluctance. But I hope that no one is under the illusion that it advances our energy security. Quite the opposite. The bill sent to us by the other Body will likely reduce our energy security, by inflicting long-term damage on the International Energy Agency. This is because failure of the bill to allow IEA to work with U.S. oil companies threatens the future of the Agency. When there are severe supply shortages or market instability, the IEA requires real-time information about the movement and location of oil stocks that only these oil companies can provide. In such a case, this information is shared at the express request of the U.S. Government. But the sharing of this information is normally forbidden under our antitrust laws, so an antitrust exemption of cover information-sharing undertaken at the U.S. Government's request is both needed and justified.

What is U.S. industry to make of our refusal, for a third time now, to make