

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 sup-

plements 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 perseverance 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