Commission members expressed the view that the starting point for revisions to the Table should be the original Table in the statute. The other commissioners agreed that the Secretary should further refine the Table, but that the starting point for additional revisions should be the modified Table as published in the NPRM on August 14, 1992.

The Department has listened carefully to the Commissioners' concerns. After weighing all the varied opinions expressed at the June meeting, as well as the written comments received from two commission members, the Department has decided that a final rule which is a revised and refined version of the proposed rule published in 1992 will reflect best the scientific evidence. However, in drafting the final rule, the Department made many of the changes suggested by members of the Commission. These changes will be explained below. In this regard, the Department recognizes that one of the objectives of the National Vaccine Plan, which was released recently by the National Vaccine Program Office/OASH, is to ensure that the Vaccine Injury Table is updated periodicall to reflect the latest scientific knowledge. The final rule is consistent with this goal, as well as the statutory directive that the Secretary revise the Table.

Although by law the regulation will only affect those petitions filed after the effective date specified above, the Department encourages the Special Masters of the U.S. Court of Federal Claims to apply the scientific findings which form the basis of the revised Table where appropriate. For instance, in cases where petitioners are intending to prove causation in fact, the IOM's conclusions regarding causation may be relevant for consideration by the Special Master. In addition, the Special Master could find, based on the conclusions of the IOM, that a particular injury was due to a factor unrelated to vaccine administration. Prior to promulgation of this rule, several Special Masters viewed the IOM report as instructive regarding certain illnesses and conditions and their relationship to vaccine administration. The Department hopes that the use of the IOM report continues, and that the findings and conclusions made by the Secretary in promulgating this rule will be applied by the Masters where the facts of the case make it appropriate to do so. In some cases, as explained below, the Secretary's findings as set forth in the NPRM at 57 FR 36879 were not incorporated into the final rule. This decision does not affect the Secretary's findings and should not deter the

Special Masters from applying the findings where appropriate.

The Department received 41 written comments and five oral comments on the NPRM, and five comments in response to the **Federal Register** Notice to Extend the Public Comment Period (March 24, 1994). Comments were received from health professional organizations, parent organizations, medical professionals, attorneys, and the general public. All comments were carefully considered. The Department's responses to the comments are discussed below in two separate sections. Section I discusses the comments addressing legal issues, and Section II discusses those comments addressing medical issues. The discussion does not address comments that either generally supported or generally criticized the proposed Table changes without making a specific point. In preparing this final rule, the Department also made a number of changes, both editorial and substantive in nature. The substantive changes are discussed where appropriate as follows:

## I. Legal Issues

The Secretary's Authority To Promulgate the Regulation

Several commenters suggested that the Department had exceeded its authority in promulgating the regulation. First, commenters argued that this is a function which belongs to the legislative branch and which cannot be delegated to the Department based on the Separation of Powers doctrine. The Department disagrees with this legal argument for several reasons. In enacting a particular statutory scheme, Congress will often leave particular gaps with instructions to the Department charged with executing the statute to promulgate regulations to fill the gaps and interpret the statutory language. See Chevron v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). In promulgating regulations, the Department is limited to the authority delegated by Congress, and is obligated to act consistent with Congressional intent. See Bowen v. Georgetown University Hospital, 488 U.S. 204 (1988). Pursuant to these basic principles of administrative law, the Secretary is promulgating this regulation to amend the Vaccine Injury

The statute explicitly authorizes the Secretary in section 2114(c) of the Act to modify the Table and states that the "Secretary may promulgate regulations to modify \* \* \* the Vaccine Injury Table." See 42 U.S.C. 300aa–14(c)(1). The statute further provides that "a

modification of the Vaccine Injury Table under paragraph (1) may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided, or may change the time periods for the first symptom or manifestation of the onset of the significant aggravation of any such injury, disability, illness, condition, or death." See 42 U.S.C. 300aa–14(c)(3). Under section 312 of Pub. L. 99–660, Congress mandated that the Secretary review the scientific literature and other information on specific adverse consequences of pertussis and rubella vaccines. As mandated by the statute, after completion of this study (undertaken by the Institute of Medicine), and the consultation required by section 2114(c) of the Act, the Department proposed the revisions to the Table. In so doing, the Department was acting exactly within the authority delegated to it by the Congress.

Further, as stated in the preamble to the Notice of Proposed Rulemaking, the legislative history explains that Congress intended the Secretary to modify the Table. The Conference Report states as follows:

The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of vaccinerelatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related. The Committee anticipates that the research on vaccine injury and vaccine safety now ongoing and mandated by this legislation will soon provide more definitive information about the incidence of vaccine injury and that, when such information is available, the Secretary or the Advisory Commission on Childhood Vaccines \* \* may propose to revise the Table, as provided below in section 2114 [Initial Table]. Until such time, however, the Committee has chosen to provide compensation to all persons whose injuries meet the requirements of the petition and the Table and whose injuries cannot be demonstrated to be caused by other factors.

See H.R. Rept. 99–908, Part 1, September 26, 1986, page 18 (reprinted in 1986 U.S. Code Cong. and Admin. News, Vol. 6, page 6359). This passage indicates that the Department is acting consistent with Congressional intent.

At least two commenters argued that the Department exceeded its authority in modifying the "Qualifications and Aids to Interpretation" (Qualifications) found in section 2114(b) of the Act. This argument, too, is misplaced. First, section 312 requires that the Secretary make findings regarding which illnesses