

**FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY**

**REGULATORY - BIOLOGICS**

**FUNCTIONS PERTAINING TO SAFER VACCINES**

Effective Date: 04/02/2001

**1. AUTHORITIES DELEGATED AND TO WHOM DELEGATED.**

The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER) are authorized to perform the functions of the Commissioner of Food and Drugs (Commissioner) under part C, subtitle 2 of title XXI of the PHS Act (42 U.S.C. 300aa-25 et seq.), as amended, and the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 300aa-1 note), as amended hereafter, as follows:

1. Section 2125 of the PHS Act (42 U.S.C. 300aa-25)-Recording and reporting of information.
2. Section 2127 of the PHS Act (42 U.S.C. 300aa-27)-Mandate for safer childhood vaccines.
3. Section 2128 of the PHS Act (42 U.S.C. 300aa-28)-Manufacturer recordkeeping and reporting.
4. Section 312 of the National Childhood Vaccine Injury Act of 1986-Related studies (42 U.S.C. 300aa-1 note), except that the authority to provide for notice and opportunity for public hearing on the review of vaccines and related illnesses and conditions under sections 312(a) and (d) of the National Childhood Vaccine Injury Act of 1986 is not redelegated by the Commissioner.
5. Section 313 of the National Childhood Vaccine Injury Act of 1986- Study of other vaccine risks (42 U.S.C. 300aa-1 note), except that the authority to provide for notice and opportunity for public hearing on the establishment of guidelines regarding the risks to children of certain vaccines under section 313(a)(1)(B) and (b) of the National Childhood Vaccine Injury Act of 1986 is not redelegated by the Commissioner.
6. Section 314 of the National Childhood Vaccine Injury Act of 1986- Review of warnings, use instructions, and precautionary information (42 U.S.C. 300aa-1 note).

## **2. REDELEGATION.**

These officials may not further redelegate this authority.

## **3. EFFECTIVE DATE.**

The Acting Principal Deputy Commissioner approved this delegation on April 2, 2001 (Via Memorandum from the Acting Senior Associate Commissioner for Management and Services to the Acting Principal Deputy Commissioner, Subject: Comprehensive Update to 21 CFR Part 5, Delegations of Authority and Organization - ACTION, dated April 2, 2001, and Tab C - Delegations of Authority Statement signed by the Acting Principal Deputy Commissioner, dated April 2, 2001). This information was previously published in the June 8, 2001, Final Rule, 66 Federal Register 30992-31025.