Appendix 3.1
THE DEVELOPMENT OF THE FEDERAL GOVERNMENT'S STATUTORY AUTHORITY TO REGULATE VACCINE SAFETY AND EFFICACY (1902-73)

In **1902,** Congress enacted the Virus Serums and Toxins Act to "regulate the sale of vaccines, serums, toxins, and analogous products" (Hecht, 1977). This biologics control law, which gave the Secretary of the Treasury authority to license biological products and manufacturing establishments, marked the first attempt by the Federal Government to regulate products used for disease prevention or treatment.

Congress passed the 1902 law in response to a tragic event. The year before, 10 children had died from contaminated diphtheria antitoxin that had been prepared hurriedly and in the absence of manufacturing safety standards. The main intent of the Virus Serums and Toxins Act was to mandate assumption by Federal Government of responsibility for helping to ensure the safety of biological products intended for human use. Labeling regulations under the **1902** law required manufacturers to document claims they made about the efficacy of their products; these regulations, however, did not clearly establish product efficacy as a criterion for Federal licensing of new biological products.

The Virus Serums and Toxins Act of 1902 contained several key statutory provisions that still are enforced today (Timm, 1977):

1. Mandatory Federal licensing of all biological products to be sold in the United States
2. Mandatory Federal licensing of all manufacturing establishments engaged in the production of biological products to be sold in the United States
3. Mandatory inclusion of the following items on the label of each biological product sold in the United States:
   —Proper name of product content
   —Name, address, and establishment license number of the manufacturer
   –Product expiration date
4. Federal authority to inspect establishments licensed to manufacture biological products for sale in the United States
5. Federal authority to revoke or suspend biological product and manufacturing establishment licenses
6. Federal authority to punish by fine or imprisonment violators 'of the statute's provisions.

Regulations pursuant to the Virus Serums and Toxins Act, promulgated by a board consisting of the Surgeons General of the Army, Navy, and the Public Health and Marine-Hospital Service, were these:

1. Product and manufacturing licenses are to be issued and reissued on the basis of annual inspections. (1903)
2. Criteria for suspending or revoking licenses shall include faulty methods of preparation, faulty construction or administration of manufacturing establishments, and impurities or subpotency of products as demonstrated by laboratory examination. (1903)
3. Inspectors shall be commissioned medical officers of the Public Health and Marine-Hospital Service, and their visits to manufacturers shall be unannounced. (1903)
4. Samples of products shall be examined for purity and potency. (1903)

Additional regulations issued in 1909 and 1919 included these:

1. Licensable products are defined. (1909)
2. Product importation is prohibited except from licensed establishments. (1909)
3. Manufacturers are to establish requirements for personnel training and competence assessment. (1919)
4. Manufacturers are to establish permanent records regarding production and control for each lot of vaccines manufactured. (1919)
5. Manufacturers' product labeling requirements are expanded to include, among other things, a product expiration date. (1919)
6. The Federal Government is authorized to request manufacturers to submit for examination prior to distribution samples of all lots of particular products. (1919)
7. Product distributors' labels must include the name of the product manufacturer(s). (1919)

The Virus Serums and Toxins Act of 1902 and pursuant regulations were incorporated into section 351 of the Public Health Service Act of 1944 (42 USC 262). A requirement of the 1944 law, which remains in effect, is that biological products be safe, pure, and potent.

In **1962,** Congress amended the Food, Drug, and Cosmetic Act of 1938 (42 USC 216) to include efficacy, along with increased standards for safety, as a criterion for licensure of new prescription drug products. It also amended the act to authorize the Federal Government to require manufacturers to demon-