Attachment 1

Applicable Laws or Regulations (Excerpts)

Attachment 1 - Applicable Laws or Regulations (Excerpts)

A. Excerpts from the Public Health Service Act

National Center for Health Statistics

Sec. 306 [242k]
(a) There is established in the Department of Health and Human Services the National Center for Health Statistics (hereinafter in this section referred to as the "Center") which shall be under the direction of a Director who shall be appointed by the Secretary. The Secretary, acting through the Center, shall conduct and support statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States.

(b) In carrying out subsection (a), the Secretary, acting through the Center-

(1) shall collect statistics on-
(A) the extent and nature of illness and disability of the population of the United States (or of any groupings of the people included in the population), including life expectancy, the incidence of various acute and chronic illnesses, and infant and maternal morbidity and mortality,
(B) the impact of illness and disability of the population on the economy of the United States and on other aspects of the well-being of its population (or of such groupings),
(C) environmental, social, and other health hazards,
(D) determinants of health,
(E) health resources, including physicians, dentists, nurses, and other health professionals by specialty and type of practice and the supply of services by hospitals, extended care facilities, home health agencies, and other health institutions,
(F) utilization of health care, including utilization of (i) ambulatory health services by specialties and types of practice of the health professionals providing such services, and (ii) services of hospitals, extended care facilities, home health agencies, and other institutions,
(G) health care costs and financing, including the trends in health care prices and cost, the sources of payments for health care services, and Federal, State, and local governmental expenditures for health care services, and
(H) family formation, growth, and dissolution;

B. Excerpts from the Food, Conservation, and Energy Act of 2008 (P.L. 110-234)

SEC. 4403. JOINT NUTRITION MONITORING AND RELATED RESEARCH ACTIVITIES.
The Secretary and the Secretary of Health and Human Services shall continue to provide jointly for national nutrition monitoring and related research activities carried out as of the date of enactment of this Act—
(1) to collect continuous dietary, health, physical activity, and diet and health knowledge data on a nationally representative sample;
(2) to periodically collect data on special at-risk populations, as identified by the Secretaries;
(3) to distribute information on health, nutrition, the environment, and physical activity to the public in a timely fashion;
(4) to analyze new data that becomes available;
(5) to continuously update food composition tables; and
(6) to research and develop data collection methods and standards.

C. Excerpts from the Food Quality Protection Act of 1996 (P.L. 104-170)

TITLE III--DATA COLLECTION ACTIVITIES TO ASSURE THE HEALTH OF INFANTS AND CHILDREN AND OTHER MEASURES

SEC. 301. DATA COLLECTION ACTIVITIES TO ASSURE THE HEALTH OF INFANTS AND CHILDREN.

(a) In General.--The Secretary of Agriculture, in consultation with the Administrator of the Environmental Protection Agency and the Secretary of Health and Human Services, shall coordinate the development and implementation of survey procedures to ensure that adequate data on food consumption patterns of infants and children are collected.

(b) Procedures.--To the extent practicable, the procedures referred to in subsection (a) shall include the collection of data on food consumption patterns of a statistically valid sample of infants and children.

(c) Residue Data Collection.--The Secretary of Agriculture shall ensure that the residue data collection activities conducted by the Department of Agriculture in cooperation with the Environmental Protection Agency and the Department of Health and Human Services, provide for the improved data collection of pesticide residues, including guidelines for the use of comparable analytical and standardized reporting methods, and the increased sampling of foods most likely consumed by infants and children.

D. Excerpts from the Federal Food, Drug, and Cosmetic Act (21 USC 393)

TITLE 21 - FOOD AND DRUGS, CHAPTER 9 - FEDERAL FOOD, DRUG, AND COSMETIC ACT - SUBCHAPTER IX – MISCELLANEOUS - SEC. 393. FOOD AND DRUG ADMINISTRATION (21 USC 393)

US Code as of: 01/23/00

Sec. 393. Food and Drug Administration

- (a) In general

There is established in the Department of Health and Human Services the Food and Drug Administration (hereinafter in this section referred to as the "Administration").

- (b) Mission

The Administration shall -

- (1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;
- (2) with respect to such products, protect the public health by ensuring that -
- (A) foods are safe, wholesome, sanitary, and properly labeled;
- (B) human and veterinary drugs are safe and effective;
- (C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;
- (D) cosmetics are safe and properly labeled; and (E) public health and safety are protected from electronic product radiation;

- (3) participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and
  (4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.
- (c) Interagency collaboration

The Secretary shall implement programs and policies that will foster collaboration between the Administration, the National Institutes of Health, and other science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and advances in nutrition and food science.

- (d) Commissioner
- (1) Appointment
  There shall be in the Administration a Commissioner of Food and Drugs (hereinafter in this section referred to as the "Commissioner") who shall be appointed by the President by and with the advice and consent of the Senate.
- (2) General powers
  The Secretary, through the Commissioner, shall be responsible for executing this chapter and for -
- (A) providing overall direction to the Food and Drug Administration and establishing and implementing general policies respecting the management and operation of programs and activities of the Food and Drug Administration;
- (B) coordinating and overseeing the operation of all administrative entities within the Administration;
- (C) research relating to foods, drugs, cosmetics, and devices in carrying out this chapter;
- (D) conducting educational and public information programs relating to the responsibilities of the Food and Drug Administration; and
  (E) performing such other functions as the Secretary may prescribe.
- (e) Technical and scientific review groups
  The Secretary through the Commissioner of Food and Drugs may, without regard to the provisions of title 5 governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific review groups as are needed to carry out the functions of the Administration, including functions under this chapter, and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups.
- (f) Agency plan for statutory compliance
- (1) In general
  Not later than 1 year after November 21, 1997, the Secretary, after consultation with appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry, shall develop and publish in the Federal Register a plan bringing the Secretary into compliance with each of the obligations of the Secretary under this chapter. The Secretary shall review the plan biannually and shall revise the plan as necessary, in consultation with such persons.
- (2) Objectives of agency plan

The plan required by paragraph (1) shall establish objectives and mechanisms to achieve such objectives, including objectives related to -

- (A) maximizing the availability and clarity of information about the process for review of applications and submissions (including petitions, notifications, and any other similar forms of request) made under this chapter;
- (B) maximizing the availability and clarity of information for consumers and patients concerning new products;
- (C) implementing inspection and postmarket monitoring provisions of this chapter;
- (D) ensuring access to the scientific and technical expertise needed by the Secretary to meet obligations described in paragraph (1);
- (E) establishing mechanisms, by July 1, 1999, for meeting the time periods specified in this chapter for the review of all applications and submissions described in subparagraph (A) and submitted after November 21, 1997; and

  (F) eliminating backlogs in the review of applications and submissions described in subparagraph (A), by January 1, 2000.
- (g) Annual report

The Secretary shall annually prepare and publish in the Federal Register and solicit public comment on a report that -

- (1) provides detailed statistical information on the performance of the Secretary under the plan described in subsection (f) of this section;
- (2) compares such performance of the Secretary with the objectives of the plan and with the statutory obligations of the Secretary; and

  (3) identifies any regulatory policy that has a significant negative impact on compliance with any objective of the plan or any statutory obligation and sets forth any proposed revision to any such regulatory policy.