SMG 1283.12

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF THE COMMISSIONER

OFFICE OF THE CHIEF SCIENTIST

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

OFFICE OF RESEARCH

DIVISION OF BIOINFORMATICS AND BIOSTATISTICS

Effective Date: 08/01/2012

1. DIVISION OF BIOINFORMATICS AND BIOSTATISTICS (DAECCH).

A. Advises the Deputy Director for Research in the planning and implementation of strategies for achieving annual and long-range plans for research and research support in the area of biometry and risk assessment.

B. Develops statistical testing methods and predictive systems for identifying potential health hazards associated with toxic substances.

C. Develops biometrical methods for estimating risks associated with toxic substances to enable setting exposure levels that correctly reflect underlying uncertainties.

D. Develops mathematical models for better representation of internal exposure levels of biological mechanisms in order to reduce uncertainty in estimates of risk.

E. Provides expertise to NCTR scientists on design, conduct and analysis of research studies to evaluate the toxicity of regulated products.

F. Assists other FDA centers in conducting risk assessments for the regulation of specific products and in investigating generic risk assessment issues.

G. Participates in interagency risk assessment activities to maintain knowledge of the state of the art, and to promote the improvement and unification of risk assessment practices across agencies.

H. Conducts research in bioinformatics and chemoinformatics, and develops and coordinates informatics capabilities within NCTR, across FDA Centers, and in the larger toxicology community.

I. Develop methods for the analysis and integration of omics (genomic, transcriptomic, proteomic, and metabolomic) databases with the objective of knowledge discovery and the elucidation of mechanisms of toxicity.

J. Conduct of scientific computing which involves application of algorithms to extract knowledge, construct models, and make inferences from scientific data to support FDA regulatory need.

2. AUTHORITY AND EFFECTIVE DATE

The functional statements for this Division were approved by the Center Director on August 1, 2012.

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The following is the Food and Drug Administration, Office of the Commissioner,Office of Chief Scientist, National Center for Toxicological Research, Office of Research, Division of Genetic & Molecular Toxicology organization structure depicting all the organizational structures reporting to the Center Director.

OFFICE OF THE DIRECTOR