SMG 1212.5

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFI CE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

OFFICE OF COMPLIANCE AND BIOLOGICS QUALITY

DIVISION OF MANUFACTURING AND PRODUCT QUALITY

Effective Date: July 8, 2011

1. DIVISION OF MANUFACTURING AND PRODUCT QUALITY (DKKBCB).

A. Provides, direction, clarification, and interpretation on policy and technical issues for the Division.

B. Manages the overall program responsibilities for the Division, primarily lot release, review of submissions, and inspections.

C. Reviews, evaluates, and takes appropriate action on Investigational New Drug applications (INDs), marketing applications, supplements, and amendments submitted to the Center for Biologics Evaluation and Research (CBER), as part of the managed review process. Performs Chemistry, Manufacturing, and Controls (CMC) and Current Good Manufacturing Practice (CGMP) reviews for specific CBER-regulated products.

D. Performs quality assurance review of completed submissions for consistency in technical content as well as administrative process requirements.

E. Supports enforcement activities by evaluating inspection reports and corrective actions when inspections are performed by other CBER or field components.

2. PRODUCT RELEASE BRANCH (DKKBCB1).

A. Develops and administers the biological products lot release program, in coordination with other CBER components.

B. Reviews manufacturers' submissions for licensed biological product lots.

C. Receives, maintains, and distributes samples of biological products submitted for testing.

D. Provides the final quality review for lot release submissions and prepares release correspondence for company notifications

3. MANUFACTURING AND REVIEW BRANCH 1 (DKKBCB4).

A. Reviews, evaluates, and takes appropriate action on Investigational New Drug applications (INDs), marketing applications, supplements, and amendments submitted to the Center for Biologics Evaluation and Research (CBER), as part of the managed review process. Performs Chemistry, Manufacturing, and Controls (CMC) and Current Good Manufacturing Practice (CGMP) reviews.

B. Meets with manufacturers to review facility design/CGMP/new products and technologies.

C. Leads prelicense and preapproval inspections supporting Biologics License Application submissions and supplements, as part of the CBER managed review process. Prepares inspection reports as part of an inspection team and evaluates firms' corrective actions.

D. Supports enforcement activities by evaluating inspection reports and corrective actions when inspections are performed by other CBER or field components.

E. In coordination with the Office of Communication, Outreach and Development, provides expert technical and regulatory guidance and training to CBER and other agency components, government agencies, and representatives of domestic and foreign biological establishments regarding biological product manufacturing and quality.

4. MANUFACTURING AND REVIEW BRANCH 2 (DKKBCB5).

A. Reviews, evaluates, and takes appropriate action on Investigational New Drug applications (INDs), marketing applications, supplements, and amendments submitted to the Center for Biologics Evaluation and Research (CBER), as part of the managed review process. Performs Chemistry, Manufacturing, and Controls (CMC) and Current Good Manufacturing Practice (CGMP) reviews.

B. Meets with manufacturers to review facility design/CGMP/new products and technologies.

C. Leads prelicense and preapproval inspections supporting Biologics License Application submissions and supplements, as part of the CBER managed review process. Prepares inspection reports as part of an inspection team and evaluates firms' corrective actions.

D. Supports enforcement activities by evaluating inspection reports and corrective actions when inspections are performed by other CBER or field components.

E. In coordination with the Office of Communication, Outreach and Development, provides expert technical and regulatory guidance and training to CBER and other agency components, government agencies, and representatives of domestic and foreign biological establishments regarding biological product manufacturing and quality.

5. APPLICATIONS REVIEW BRANCH (DKKBCB6).

A. Performs administrative processing of all submissions chaired by the Office.

B. Prepares review packages and correspondence for final action on supplements.

C. Schedules and coordinates meetings with industry as well as finalizes meeting minutes for distribution.

D. Performs all data entry for assignment and tracking of submissions and also generates work load reports in order to maintain operations within the designated PDUFA and MDUFMA time frames.

E. Issues and reissues U.S. and biologics licenses.

6. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Secretary of the Department of Health and Human Services on July 8, 2011.

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OFFICE OF THE DIRECTOR

Product Release Branch
Manufacturing Review Branch 1
Manufacturing Review Branch 2
Applications Review Branch

Staff Manual Guide 1212.5
Organizations and Functions
Effective Date: July 8, 2011

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality, Division of Manufacturing and Product Quality organization structure depicting all the organizational structures reporting to the Office of the Director.

OFFICE OF THE DIRECTOR:

- Product Release Branch
- Manufacturing Review Branch 1
- Manufacturing Review Branch 2
- Applications Review Branch