FDA STAFF MANUAL GUIDES, VOLUME I – ORGANIZATIONS AND FUNCTIONS

Department of Health and Human Services

Food and Drug Administration

Center for Veterinary Medicine

Office of New Animal Product Evaluation

Division of Manufacturing Technologies

Effective Date: August 23, 2024

1. DIVISION OF MANUFACTURING TECHNOLOGIES (DCGCE).

A. Recommends raw material specifications to evaluate if the ingredients are adequate to ensure the identity, strength, quality, and purity of the generic new animal drugs; reviews the drug formulation for composition, characteristics, and accuracy.

B. Manages the evaluation of specifications and methods of analysis for the generic new animal drugs and its components in its dosage forms; recommends product expiration dates from stability data.

C. Manages the evaluation of the total manufacturing and control operations of generic new animal drugs as submitted in an application to determine adherence to the Good Manufacturing Practice Regulations; ascertains the current regulatory status of a drug firm prior to recommending approval of an abbreviated new animal drug application (ANADA).

D. Manages intramural and extramural research projects to gain further information on generic new animal drug manufacturing; manages the recommendation of regulatory methods and provides technical support when requested by Food and Drug Administration (FDA) field laboratories.

E. Manages the development and implementation of regulations, guidance, and policies pertaining to manufacturing issues for generic new animal drugs intended for animal use.

F. Manages the evaluation of and recommendations concerning changes in the manufacturing chemistry and controls section of approved generic new animal drugs.

G. Develops short and long-range work plans and staffing need proposals for the Division.

2. BIOTHERAPEUTICS BRANCH (DCGCE1).

For soluble powders, drug products for use in aquaculture or minor use/minor species, and biotechnology products:

A. Determines raw material specifications to evaluate if the ingredients are adequate to ensure the identity, strength, quality, and purity of new animal products; reviews the product formulation for composition, characteristics, and accuracy.

B. Evaluates specifications and methods of analysis for the new animal product and its components in its dosage forms; recommends product expiration dates from stability data.

C. Evaluates the total manufacturing and control operations of a new animal product as submitted in an application to determine adherence to the Good Manufacturing Practice Regulations; ascertains the current regulatory status of a product developer prior to recommending approval of an application.

D. Recommends, and may participate in, intramural and extramural research projects to gain further information on animal product manufacturing; recommends regulatory methods and provides technical support when requested by FDA field laboratories.

E. Participates in the development and implementation of regulations, guidance, and policies pertaining to manufacturing issues for new animal products.

F. Evaluates and makes recommendations concerning changes in the manufacturing chemistry and controls section of approved new animal products.

3. CHEMOTHERAPEUTICS BRANCH (DCGCE2).

For oral dosage forms:

A. Determines raw material specifications to evaluate if the ingredients are adequate to ensure the identity, strength, quality, and purity of new animal products; reviews the product formulation for composition, characteristics, and accuracy.

B. Evaluates specifications and methods of analysis for the new animal product and its components in its dosage forms; recommends product expiration dates from stability data.

C. Evaluates the total manufacturing and control operations of a new animal product as submitted in an application to determine adherence to the Good Manufacturing Practice Regulations; ascertains the current regulatory status of a product developer prior to recommending approval of an application.

D. Recommends, and may participate in, intramural and extramural research projects to gain further information on animal product manufacturing; recommends regulatory methods and provides technical support when requested by FDA field laboratories.

E. Participates in the development and implementation of regulations, guidance, and policies pertaining to manufacturing issues for new animal products.

F. Evaluates and makes recommendations concerning changes in the manufacturing chemistry and controls section of approved new animal products.

4. DRUG SUBSTANCE BRANCH (DCGCE3).

For drug substances:

A. Determines raw material specifications to evaluate if the ingredients are adequate to ensure the identity, strength, quality, and purity of new animal substances.

B. Evaluates specifications and methods of analysis for the new animal substance; recommends expiration dates from stability data.

C. Evaluates the total manufacturing and control operations of a drug substance as submitted in an application to determine adherence to the Good Manufacturing Practice Regulations; ascertains the current regulatory status of a product developer prior to recommending approval of an application.

D. Recommends, and may participate in, intramural and extramural research projects to gain further information on animal product manufacturing; recommends regulatory methods and provides technical support when requested by FDA field laboratories.

E. Participates in the development and implementation of regulations, guidance, and policies pertaining to manufacturing issues for new animal products.

F. Evaluates and makes recommendations concerning changes in the manufacturing chemistry and controls section of approved new animal drug substances.

5. FEED AND TOPICAL BRANCH (DCGCE4).

For Type A medicated articles, topical drug products, and biomass drug products:

A. Determines raw material specifications to evaluate if the ingredients are adequate to ensure the identity, strength, quality, and purity of new animal products; reviews the product formulation for composition, characteristics, and accuracy.

B. Evaluates specifications and methods of analysis for the new animal product and its components in its dosage forms; recommends product expiration dates from stability data.

C. Evaluates the total manufacturing and control operations of a new animal product as submitted in an application to determine adherence to the Good Manufacturing Practice Regulations; ascertains the current regulatory status of a product developer prior to recommending approval of an application.

D. Recommends, and may participate in, intramural and extramural research projects to gain further information on animal product manufacturing;

recommends regulatory methods and provides technical support when requested by FDA field laboratories.

E. Participates in the development and implementation of regulations, guidance, and policies pertaining to manufacturing issues for new animal products.

F. Evaluates and makes recommendations concerning changes in the manufacturing chemistry and controls section of approved new animal products.

6. STERILE DRUGS BRANCH (DCGCE5).

For sterile injectable, intramammary, and ophthalmic drug products:

A. Determines raw material specifications to evaluate if the ingredients are adequate to ensure the identity, strength, quality, and purity of new animal products; reviews the product formulation for composition, characteristics, and accuracy.

B. Evaluates specifications and methods of analysis for the new animal product and its components in its dosage forms; recommends product expiration dates from stability data.

C. Evaluates the total manufacturing and control operations of a new animal product as submitted in an application to determine adherence to the Good Manufacturing Practice Regulations; ascertains the current regulatory status of a product developer prior to recommending approval of an application.

D. Recommends, and may participate in, intramural and extramural research projects to gain further information on animal product manufacturing; recommends regulatory methods and provides technical support when requested by FDA field laboratories.

E. Participates in the development and implementation of regulations, guidance, and policies pertaining to manufacturing issues for new animal products.

F. Evaluates and makes recommendations concerning changes in the manufacturing chemistry and controls section of approved new animal products.

7. AUTHORITY AND EFFECTIVE DATE.

The functional statements for the Division of Manufacturing Technologies were approved by the Secretary of Health and Human Services on July 22, 2024, and effective on August 23, 2024.