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FDA Staff Manual Guides (SMG), Volume III – General Administration

FDA Councils and Committees

Commissioner's National Priority Voucher Review Council

Effective Date: 15 January 2026

1. Purpose

As a part of the Food and Drug Administration (FDA) Commissioner's National Priority Voucher (CNPV) Pilot Program, the FDA establishes the CNPV Review Council. The CNPV Review Council (hereinafter "Council") serves as the group of individuals that performs the following functions:

A. Provides recommendations to the delegated official (e.g., Deputy Chief Medical Officer) regarding voucher selection.

B. Provides recommendations to the relevant Center Director that inform the Center Director's recommendation on approvability regarding parts of the application discussed by the Council.[1]

[1] Refers to products for human use that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 355) or under section 351 of the Public Health Service (PHS) Act (42 U.S.C. 262), when such application for marketing approval has been selected for the CNPV Pilot Program.

2. Policy

A. Council members are authorized by the FDA Commissioner to perform such delegable functions described herein. The Council ensures expedited yet rigorous review of drugs and biological products that address critical U.S. national health priorities while maintaining FDA's established safety and effectiveness standards.

B. Members of the Council will participate in two core functions, voucher selection and discussions of approvability, with input from specific individuals that may vary depending on the application-specific therapeutic area.

1. Voucher selection will involve discussion by those Council members with the greatest interest or expertise in the application being discussed. Additionally, discussion will include a broader range of relevant subject matter experts to inform questions pertaining to review complexity, operational considerations, and other factors that impact selection for the CNPV Pilot Program.

2. For discussions of approvability, all Council members are expected to participate in the discussion. The Council may invite a limited number of relevant subject matter experts nominated by the review divisions to enhance the depth of discussion.

3. Members

A. The FDA Commissioner will serve as Chair of the Council, and in that capacity will moderate discussions relating to voucher selection as well as discussion of review issues with the primary review team. The Commissioner will not vote on discussions relating to approvability.

B. Council members are:

1. Principal Deputy Commissioner
2. Chief Medical and Scientific Officer
3. Deputy Chief Medical Officer
4. Center for Drug Evaluation and Research (CDER) Director
5. CDER Deputy Director*
6. Center for Biologics Evaluation and Research (CBER) Director
7. CBER Deputy Director*
8. Principal Medical Advisor to the Commissioner
9. Senior Advisor to the Commissioner for Clinical Sciences

10. Relevant Subject Matter Expert(s) (e.g., Office or Division Director or Delegate)

Note: * indicates that this member may attend in addition to or in place of the Center Director, at the discretion of the Center Director.

C. In cases where a Council member holds multiple acting or permanent titles, the individual will represent one Council seat.

D. For voucher selection, the final decision maker will be the delegated official (e.g., Deputy Chief Medical Officer).

E. For discussions relating to approvability, each member of the Council attending the meeting with the primary review team will inform the recommendation to the Center Director using the procedures outlined below.

4. Authority and Responsibilities

The Council will convene on an as-needed basis for discussions relating to voucher selection or approvability and may meet internally or with the review team to assist with logistical questions or other issues. Meeting frequency will vary based on volume and complexity of the nominated products, with additional meetings scheduled as needed to meet accelerated review timelines. Meeting dates and times will be specified in advance and communicated to all relevant attendees. Additional details are provided below.

A. Voucher Selection

1. Potential candidates for voucher selection may be submitted via one of two pathways:

   a. Companies may apply directly to the CNPV program.

   b. Internal stakeholders (e.g., reviewers, review divisions, Center leadership) may nominate potential candidates to the CNPV program.

2. Relevant members of the Council may convene to discuss voucher candidates, together with relevant subject matter experts. Meetings may take multiple formats as appropriate to the application in question. Pertinent members of the Council and other internal stakeholders may review candidate submissions using a screening template or discussion points that consider relevant factors (outlined below in Section 5, Procedures).

3. The delegated official (e.g., Deputy Chief Medical Officer) serves as the final decision maker for voucher selection. The delegated official considers input from the relevant members of the Council, Center leadership, clinical review divisions, and other supporting disciplines.

4. The delegated official (e.g., Deputy Chief Medical Officer) will draft a selection memorandum for each product selected into the program, outlining the rationale for selection, and serving as the final signatory. This memorandum

will be retained as part of the administrative record for the program and should be finalized in advance of issuance of the voucher.

5. The delegated official (e.g., Deputy Chief Medical Officer) will sign and issue a voucher letter that will be stored in an official system of record.

B. Discussion of Approvability (i.e., CNPV Review Council Meeting)

1. The Council shall ensure review and recommendations for CNPV drug and biological product applications are consistent with FDA statutory and regulatory standards for approval.
2. Council members are expected to attend all meetings where possible. If unable to attend in-person, this should be communicated to the Deputy Chief Medical Officer, and written comments regarding the application in question should ideally be shared with the Council members in advance of the meeting.
3. Council members shall review relevant materials provided by the primary review team or delegated official in advance of all meetings and engage in thorough discussion of the application and findings presented by the review team. Council members shall review briefing materials–as applicable–examining the scientific merit, regulatory appropriateness, and potential public health implications of the application.
4. Council discussion should allow for comprehensive evaluation of complex technical issues and consideration of multiple perspectives. Members will actively participate in deliberations, and members with relevant expertise shall contribute specialized knowledge to address specific aspects of the application.
5. The Council shall make a recommendation to the relevant Center Director regarding approvability of a CNPV drug or biological product application with respect to the part(s) of the application presented to the Council for consideration.

5. Procedures

A. Voucher Selection

These procedures apply only to voucher selection and do not govern application review, labeling decisions, or approval determinations. Receipt of a voucher does not impact the likelihood of approval.

1. Purpose and Scope

    a. The selection process is designed to:

        1) Advance clearly articulated national public health priorities

        2) Ensure operational feasibility of accelerated review

        3) Ensure gold-standard scientific review

        4) Maintain flexibility appropriate to a pilot program

2. Eligibility Screening

    a. Following nomination or submission of voucher candidates as above, the delegated official (e.g., Deputy Chief Medical Officer), supported by others as needed, conducts initial screening. The delegated official, supported by Center Liaisons, compiles a *Selection Consideration Summary*, which should include:

        1) Description of alignment with national priorities

        2) Anticipated public health impact

        3) Application readiness indicators (e.g., completeness of CMC, results of key studies or pivotal trials, labeling maturity)

        4) Resource and timing considerations raised by the relevant Center(s)

        5) Known risks, uncertainties, or dependencies (e.g., potential litigation or exclusivity issues, foreign inspections or manufacturing concerns, review complexities such as unvalidated surrogate endpoints, major safety concerns)

    Note: The summary is descriptive and is intended to inform–not constrain–decision-making. This information will be used in a screening assessment to help inform selection.

3. Consultation and Input

    a. Prior to voucher selection, and to inform development of the *Selection Consideration Summary,* members of the Council, including but not limited to the Deputy Chief Medical Officer and Center Liaisons, should seek input from relevant FDA offices or review divisions on the following:

        1) Operational feasibility concerns

        2) Anticipated review complexity

3) Timing or staffing constraints

Note: Input is advisory in nature. No formal voting, ranking, or consensus determination is required or expected.

4. Selection Determination

   a. Voucher selection decisions are made by the delegated official (e.g., Deputy Chief Medical Officer), informed by:

      1) The *Selection Consideration Summary*

      2) Input from Center Leadership and relevant FDA stakeholders (e.g., Council members, subject matter experts)

      3) Overall balance of national priority alignment and feasibility

   b. The delegated official (e.g., Deputy Chief Medical Officer) may:

      1) Select a product for voucher issuance

      2) Defer a decision pending additional information

      3) Decline selection without prejudice to future consideration

5. Documentation and Administrative Record

   a. For each selection determination, the delegated official (e.g., Deputy Chief Medical Officer) maintains an administrative record, which will include:

      1) Date of selection decision

      2) National priority area(s) implicated

      3) High-level rationale for selection

      4) Consideration of council input

      5) Detailed comparative analyses or rankings are not required

      Note: Such documentation will be included in a brief, contemporaneous decisional memo to be finalized prior to the issuance of a voucher.

6. Pilot Flexibility and Iteration

   a. Because CNPV is a pilot program:

      1) Selection criteria and processes may be refined over time.

      2) Not all scenarios can be anticipated in advance.

      3) Deviations from standard process may occur when justified by programmatic needs.

      4) Any material deviations will be documented briefly to support transparency and learning.

7. Separation of Selection and Approval
    a. Voucher selection:
        1) Does not influence scientific review conclusions
        2) Does not alter approval standards

B. Discussion of Approvability (CNPV Review Council Meeting [a.k.a. “tumor board style meeting”])
    1. The length and format of the formal CNPV Review Council meeting will be determined by the delegated official (e.g., Deputy Chief Medical Officer) in consultation with the primary review division and other members of the Council to ensure adequate time is allocated for comprehensive discussion of the review issues the team chooses to present. This meeting will be scheduled to occur 1-2 weeks before the target action date.
    2. Following a presentation and preliminary recommendation by the primary review team, the Council shall make a recommendation to the relevant Center Director by vote of a simple majority of the members present at a meeting.
    3. In the event of a tie vote, the decision regarding the final Council recommendation rests with the relevant Center Director.
    4. Considering the recommendation of both the primary review team as well as the Council, and applying independent discretion, the Center Director provides a final recommendation on the parts of the application, which is presented in writing to the primary review team. The Center Director shall explain in writing his or her rationale for the recommendation whether or not the rest of the Council agrees.
    5. The recommendations of the review division, Council and Center Director will be formally documented in meeting minutes and stored in an official system of record. Following the Center Director’s recommendation, the application will proceed through normal administrative procedures (e.g., finalization of reviews, final labeling discussions, action letter preparation).
    6. During any portion of the CNPV process (presubmission, filing period, review period), review divisions may request an extension via discussion with the delegated official (e.g., Deputy Chief Medical Officer), who may grant permission to provide extensions and may consult with other members of the Council as needed.

6. Documentation

A. Voucher Selection

1. The *Selection Consideration Summary* should be populated for each candidate considered.
2. The selection memorandum should be completed by the delegated official (e.g., Deputy Chief Medical Officer), before the voucher selection decision is formally made to document the rationale for a voucher selection decision.
3. The voucher template (selection letter) should be populated by Center Liaisons and shared with sponsors following signature by the delegated official (e.g., Deputy Chief Medical Officer).

B. CNPV Review Council Meeting

1. Materials relevant to the topics to be discussed and considered by the Council prior to the Council making a recommendation to the Center Director will be maintained and stored by the Office of the Chief Medical Officer. If the application is approved by the Agency under section 505(b) of the FD&C Act or section 351 of the Public Health Services Act, such materials will be included in the action package published on the FDA's website, pursuant to 505(l)(2)(A) and (B) of the FD&C Act. For purposes of the "summary review" described in section 505(l)(2)(C)(iv) of the FD&C Act, the Council will be treated in the same manner as a reviewing discipline involved in the review of a drug application.
    a. The Deputy Chief Medical Officer will prepare and distribute an agenda.
    b. The agenda will include materials prepared by the primary review team to provide background information that can sufficiently inform the discussion of the application and key issues with the Council.
    c. The review team will share background material with the Deputy Chief Medical Officer at least 3 to 5 days before the Council meeting for subsequent distribution.
2. Meeting minutes will document and accurately reflect the Council's recommendation. The minutes will include the names of attendees, a summary of items discussed, and the voting outcome(s).
3. Meeting minutes shall be communicated to senior management and relevant FDA members, as appropriate.
4. Meeting minutes will be maintained and stored in an official system of record (e.g., DARRTS).

5. Documentation of the Center Director's recommendation shall be maintained in an official system of record.
6. Review divisions may document a brief (1- to 2-paragraph) summary of the panel meeting and relevant discussion points considered in their final reviews. Such documentation would also be included in an official system of record.
7. The Council will review and update this SMG as needed, based on internal stakeholder feedback and experience gained by the Council.

7. Effective Date

The effective date of this SMG is January 15, 2026.

8. Document History

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	12/05/2025	N/A	OC	Martin A. Makary, M.D., M.P.H. Commissioner of Food and Drugs
Version 2.0	01/15/2026	N/A	OC	Martin A. Makary, M.D., M.P.H. Commissioner of Food and Drugs